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Synopsis

Laparoscopic hysterectomy versus open abdominal hysterectomy for women with a benign gynaecological condition: the LAVA RCT

T Justin Clark[1,2*] Lina Antoun[1] Rebecca Woolley[3] Sheriden Bevan[3] Kamila Ziomek[3] William McKinnon[3] Paul Smith[1] Kevin Cooper[4,5] Ertan Saridogan[6] Bibi Zeyah Sairally[1] Jayne Fullard[7] Monique Morgan[7] Lynsay Matthews[8] Laura Jones[9] Tracy Roberts[9] and Lee Middleton[3,9]

[1]Department of Gynaecology, Birmingham Women's NHS Foundation Trust, Birmingham, UK
[2]Institute of Metabolism and Systems Research, University of Birmingham, Birmingham, UK
[3]Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK
[4]Aberdeen Royal Infirmary, Aberdeen, UK
[5]University of Aberdeen, Aberdeen, UK
[6]Elizabeth Garrett Anderson Institute for Women's Health, University College London Hospitals, London, UK
[7]Public and Patient Involvement
[8]School of Health and Life Sciences, University of the West of Scotland, South Lanarkshire, UK
[9]Institute for Applied Health Research, University of Birmingham, Birmingham, UK

[*]**Corresponding author** tjustin.clark@nhs.net

Published February 2026
DOI: 10.3310/GJTC1718
Volume 30 • Issue 14

Abstract

Background: The comparative rates of major complications and recovery times between laparoscopic hysterectomy and abdominal hysterectomy for benign gynaecological conditions remain uncertain.
Objective(s): To assess the clinical and cost-effectiveness of laparoscopic hysterectomy compared to abdominal hysterectomy in women with benign gynaecological conditions.
Design and methods: A parallel, open, non-inferiority, multicentre, randomised controlled, expertise-based surgery trial with integrated health economic evaluation and an internal pilot with an embedded qualitative process evaluation, and a post-closure survey after recruitment ended.
Setting and participants: Women in secondary care requiring hysterectomy and eligible for either surgical method.
Interventions: Laparoscopic hysterectomy versus abdominal hysterectomy.
Main outcome measures: The primary outcome was major complications (Clavien–Dindo ≥ level III) up to 6 completed weeks post surgery, and the key secondary outcome was time from surgery to resumption of usual activities using the personalised Patient-Reported Outcomes Measurement Information System Physical Function questionnaire. The principal outcome for the economic evaluation was to be cost per quality-adjusted life-year at 12 months post surgery and was feasibility and acceptability for the qualitative process evaluation.
Results: Two hundred and fifty-two patients were screened from 13 open sites over 13 months, 156 (62%) were eligible and 75 (49%) randomised. Of the 53 women not randomised, 23 (43%) preferred laparoscopic hysterectomy and 6 (11%) abdominal hysterectomy. About 32/39 (82%) and 30/36 (83%) participants randomised to laparoscopic hysterectomy and abdominal hysterectomy, respectively, had their surgery, of which 31/32 (97%) and 25/30 (83%) received their allocated route of hysterectomy. Major complications occurred in 2/32 (6%) laparoscopic hysterectomy versus 4/30 (13%) abdominal hysterectomy groups. There was no difference in time to resumption of activities [median (interquartile range, *N*) 7.5 weeks (3.6–8.2, 25) laparoscopic hysterectomy vs. 7.5 weeks (5.5–10.6, 26) abdominal hysterectomy groups] or quality of recovery [mean (standard deviation, *N*) 81.1 (13.4, 27) vs. 72.3 (17.6, 22) respectively; adjusted mean difference 7.2, 95% confidence interval −3.2 to 17.6]. The qualitative evaluation

This synopsis should be referenced as follows:
Clark TJ, Antoun L, Woolley R, Bevan S, Ziomek K, McKinnon W, *et al.* Laparoscopic hysterectomy versus open abdominal hysterectomy for women with a benign gynaecological condition: the LAVA RCT. *Health Technol Assess* 2026;**30**(14):1–28. https://doi.org/10.3310/GJTC1718

found that the trial was viewed positively by women and healthcare professionals. The reasons for failure to recruit from 21 sites open or in set-up were lack of research/clinical capacity imposed by the COVID-19 pandemic (14, 67%) and lack of clinician equipoise (11, 52%).
Limitations: The main limitation was failure to recruit, resulting in a final sample of 75 patients from a target of 3250. At the time of analysis, 13 (17%) randomised patients had not had surgery, and 6 (8%) did not adhere to the allocated route of hysterectomy. The planned health economic evaluation could not be performed.
Conclusions: The LAVA trial was acceptable for women and healthcare professionals but closed early due to the adverse impact of the COVID-19 pandemic and a lack of clinician equipoise. No significant differences in complications or recovery between laparoscopic hysterectomy and abdominal hysterectomy were observed. However, early trial cessation because of recruitment challenges limit inferences. Future large-scale trials are important, especially as laparoscopic hysterectomy and robotic techniques become standard. Success will depend on innovative trial designs and strategies that engage clinicians and research departments.
Future work: Lessons learnt from the failed LAVA trial should be used to inform the management and designs of future studies in benign gynaecological surgery.
Funding: This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128991.
A plain language summary of this synopsis is available on the NIHR Journals Library website https://doi.org/10.3310/GJTC1718.

Introduction

Rationale for research and background

Hysterectomies are increasingly performed by a laparoscopic route, as the recovery times are perceived to be faster, given the smaller incisions compared with conventional open-surgery laparoscopic hysterectomy (LH), for benign indications was found in a Cochrane review of 28 trials (3431 women) to have significantly more urinary tract injuries compared to abdominal hysterectomy (AH),[3] but the evidence was of low to moderate quality, and the trials were criticised for the relative inexperience of surgeons in novel LH.[4] No other significant differences in the costs or outcomes between LH and AH were found apart from return to normal activities. However, these recovery data were from three small trials using inconsistent and non-validated methods of measurement.

Despite the lack of clear evidence of overall benefit, the uptake of LH is increasing with greater familiarity and increased proficiency in the technique, aided by improved training and better surgical equipment.[5,6] Patient's values and preferences, especially regarding the perceived speed of recovery, may also be driving this trend.[7]

To overcome the previous limitations related to surgical expertise and validated recovery assessment methods, a large randomised controlled trial (RCT) was designed to determine the effectiveness of contemporary LH compared to AH for benign gynaecological conditions. We planned to assess major complications and time to resumption of usual activities using a relevant, personalised, validated instrument Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS-PF).[8–10]

Objectives

The LAparoscopic Versus Abdominal hysterectomy (LAVA) trial was designed to compare the clinical and cost-effectiveness of LH compared to open AH for women with a benign gynaecological condition.

The research question was: what is the clinical and cost-effectiveness of LH compared to open AH for women with a benign gynaecological condition?

The primary clinical objective was to compare LH with AH in terms of major intraoperative and postoperative surgical complications up to 6 weeks post surgery.

The principal economic objective was to compare the relative cost-effectiveness of LH with AH in terms of cost per quality-adjusted life-year (QALY). Additional cost-effectiveness analyses were to explore cost per major surgical complication avoided and cost per return to normal activities.

The key secondary objective was to measure and compare the time from surgery to resumption of usual activities. Other secondary objectives were to compare other aspects of recovery, including length of hospital stay, postoperative pain and analgesia use, minor complications,

representation/re-admission to hospital, quality of life (QoL), return to work and work productivity/activity impairment scores and satisfaction with hysterectomy.

The pilot-nested qualitative process evaluation (QPE) objectives were to explore women's views and experiences regarding the recruitment approach, randomisation, barriers and facilitators to participation, and acceptability of treatment allocations, and to explore healthcare professionals' (HCPs) views and experiences of recruitment, randomisation, including perceived barriers and facilitators, equipoise, appropriateness and acceptability of treatment allocations, and perceptions of trial processes.

Once the trial was closed due to poor recruitment, a further objective was to seek the views and experiences of clinical/research staff from active sites and those in set-up to further understand the barriers to trial participation and recruitment.

Methods for data collection and analysis

Pre-trial survey of trial viability

Prior to submitting the application for this commissioned call from National Institute for Health and Care Research (NIHR) Health Technology Assessment, a survey was undertaken of clinicians and patients.

United Kingdom healthcare provider survey

A survey of clinician members of the British Society for Gynaecological Endoscopy (BSGE), a specialist society for endoscopic surgery, showed that most respondents (100/110, 91%) regularly undertook hysterectomies, of which 91/100 (91%) regularly performed LH (mean 4.6/month) and 86/100 (86%) regularly undertook both laparoscopic and abdominal procedures. It is noteworthy that the BSGE is a specialist society for laparoscopic surgery. Across the UK, three abdominal hysterectomies for benign disease are undertaken for every one LH.[11] The LAVA trial proposed to recruit from centres with surgeons competent in both LH and AH, who were willing to approach and randomise. In addition, colleagues from the same hospital who declared competency in one of the approaches could undertake the procedure if a participant was randomised to that approach (the BSGE survey each respondent worked in a unit with an average of 10 consultant gynaecologists).

Respondents ranked composite of major intra- and immediate postoperative complications was ranked as the most important outcome 41/100 (41%) with return to usual activities and QoL completing the top three ranked most important outcomes. As these outcomes aligned with the views of patients and public (see below), they were adopted as our primary and key secondary outcomes. About 63/100 (63%) of responding clinicians in the BSGE survey agreed a RCT was needed with 56/63 (89%) willing to participate.

United Kingdom patient survey and patient focus groups

The LAVA research study was developed with involvement of members of the Royal College of Obstetricians and Gynaecologists (RCOG) Women's Voices group, the Hysterectomy Association and the Birmingham Women's Hospital Hysterectomy Focus Group. A total of 945 women responded to our patient and public involvement (PPI)[1] survey. Major complications were ranked as the most important outcome for the trial to assess, with return to usual activities considered the second most important outcome (ranked in the top three most important outcomes in the BSGE survey). The speed and quality of recovery (QoR) was also highly prioritised after major complications and improvement in QoL in the PPI survey [efaidnbmnnnibpcajpcglclefindmkaj/www.birmingham.ac.uk/documents/college-mds/trials/bctu/lava/lava-protocol-version-3.0-07-jul-2021.pdf (accessed 12 July 2025)].[1]

Almost 50% (462/945) of PPI survey respondents were willing to consider taking part in the proposed trial. However, this participation rate is likely to be misleadingly low because of how the question was interpreted; the 482 free-text responses revealed that over 90% of respondents who were 'unwilling to take part' felt this way because they had already had a hysterectomy.

Two focus groups, totalling 10 women, felt the burden placed upon women from administering outcome questionnaires at 24 hours post surgery, and the frequency of dissemination postoperatively proposed was acceptable. The consensus view was that measuring recovery against preset targets was beneficial (with tools already available on the internet). This frequency of contact was also supported by the PPI survey; 6 weeks 485/945 (51%) and 12 months 514/945 (54%) were the most popular time points.[1]

Trial design

LAVA was a parallel, open, non-inferiority, multicentre, randomised controlled, expertise-based surgery trial with integrated health economic evaluation and an internal pilot with an embedded QPE.

The detailed LAVA trial protocol has been previously published.[2] The original research pathway flow diagram can be found in *Figure 1*. The non-inferiority design

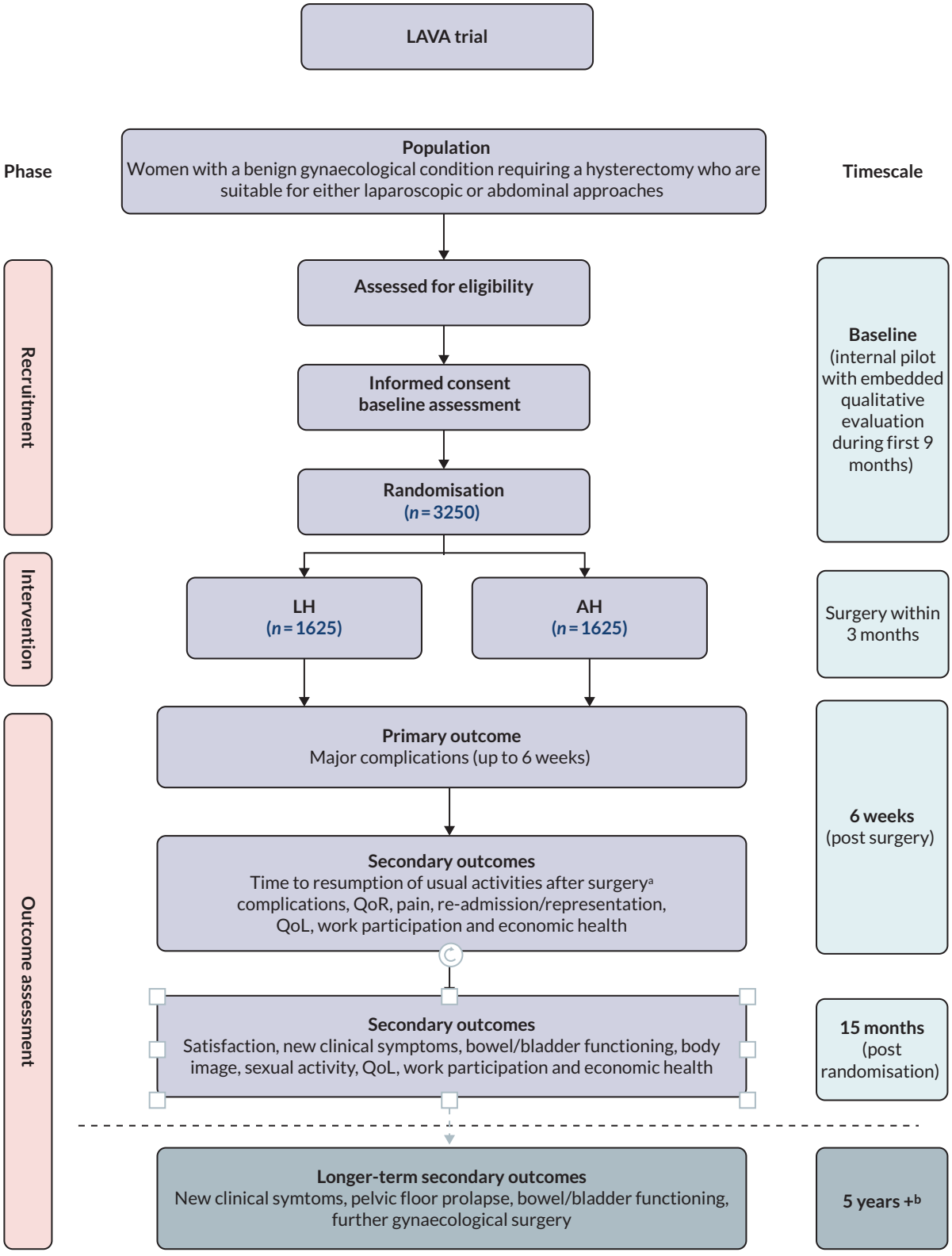

FIGURE 1 Planned research pathway (note: due to early trial closure, no 15-month follow-up questionnaires were issued). a, Time from surgery to resumption of usual activities will continue to be evaluated until all 8 selected activities have been resumed; b, Subject to further funding applications. Reproduced from Antoun *et al.*[2] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY-NC 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for non-commercial use only, provided the original work is properly cited. See: http://creativecommons.org/licenses/by-nc/4.0/ The figure includes minor additions and formatting changes to the original text.

reflected the belief that LH is not substantially worse, in terms of major complications, and has superior recovery from the patient's perspective. The trial aimed to recruit 3250 women requiring a hysterectomy for a benign gynaecological condition and who were suitable for either laparoscopic or open abdominal techniques.

Participants

Eligible women were identified by a member of the clinical team responsible for the direct care of the potential participant in outpatient gynaecology clinics and preoperative assessment clinics in each recruiting centre. The LAVA study was introduced by a member of the clinical or research team, with full counselling about the trial, including provision of information about the QPE. All participants provided fully informed written consent for the trial, with separate consent for the optional QPE interview.

Women were eligible for recruitment to the LAVA trial if they met the following inclusion criteria and did not have any of the exclusion criteria set out below.

Inclusion criteria

- Aged between 18 and 55 years of age and able to give informed consent to participate.
- Have a benign gynaecological condition that is being treated with a hysterectomy.
- Hysterectomy can be undertaken by either a laparoscopic or open abdominal routes. The feasibility and appropriateness of both routes of hysterectomy for women were to be decided pragmatically, the operating surgeon deciding where their equipoise was taking into consideration factors, such as the size of the uterus, likelihood of pelvic adhesions and anticipated surgical complexity for either approach.

Exclusion criteria

- Women with suspected malignant disease of the genital tract.
- Women who require concomitant gynaecological surgery for bladder or other pelvic support.
- Women who require concomitant gynaecological surgery for excision of deep endometriosis that requires dissection of the pararectal space.

Outcomes

No core outcome set (COS) currently exists for hysterectomy, although one under development has been registered on the Core Outcome Measures in Effectiveness Trials initiative database (www.comet-initiative.org/Studies/Details/1845). Following trial closure, outcomes were collected up until the final randomised participant, who had received surgery, reached 26 weeks post surgery to ensure collection of the personalised recovery data. However, longer-term follow-up was curtailed for the small number of participants who reached the 12-month QoL end points after the decision to close trial recruitment.

Primary outcome

The primary outcome was major complications up to 6 completed weeks post surgery assessed using the validated and widely used Clavien–Dindo classification of surgical complications.[12] They were defined as any of the following up to and including 6 full weeks post surgery: (1) all Clavien–Dindo grade III–V complications (2) Clavien–Dindo grade II complications of pulmonary embolus or blood transfusion or (3) haemorrhage ≥ 1 l or (4) major adverse anaesthetic event.

Key secondary outcome

The key secondary outcome was time from surgery to resumption of usual activities using the validated, personalised PROMIS-PF questionnaire item bank v1.2 6.[8–10] This was the first use of this recovery tool in this patient population. In brief, participants were presented with 29 items covering relevant activities for our trial population selected from the entire 121 item bank.[9] Each item contained five response categories. At baseline, participants were asked to select eight activities from this list of 29 that, in their view, would most reflect their day-to-day activities, and then select the level at which they would do this activity to consider themselves fully recovered (baseline score). In this way, participants created their personalised physical function short form. Full recovery was achieved once all eight personalised activities had returned to baseline score. Until all personalised activities returned to baseline value, participants were asked to complete this weekly for the first 12 weeks, then fortnightly from week 13 to week 26, after which follow-up was censored. The PROMIS-PF was disseminated using convenient, automated text messaging [Short Message Service (SMS)].

Other secondary outcomes

For a full list of the proposed secondary outcomes, see the published protocol.[2] The outcomes that were collected following trial closure concentrated upon minor complications and recovery-related end points:

- Inpatient assessments: postoperative pain measured using a Numerical Rating Scale (NRS); QoR score taken from the QoR-15 questionnaire[13] measured at 24 hours; time from operation to discharge in days, where the day of operation was counted as day 0 and each additional day estimates one more night in hospital.

- Up to 14 days after surgery: postoperative pain (NRS) and analgesia use.
- Up to 6 weeks post surgery: minor complications,[2] representation and re-admission to hospital; time away from normal activities.
- 6 weeks post surgery: QoL score using EuroQol-5 Dimensions, five-level version (EQ-5D-5L) index score and the visual analogue scale (VAS).[14]
- 12 weeks post surgery: EQ-5D-5L index score and the VAS; time from surgery to work in days; work productivity and activity impairment scores using Work Productivity and Activity Impairment – General Health questionnaire.[15]
- Complication data, as well as representation and re-admission information, were collected from the relevant case report forms (CRFs) completed by the local research team and participants on the day of surgery and postoperatively. Where necessary, the local principal investigators (PIs) were contacted for further details obtained from the patient's case notes.

Health economic analysis

An economic evaluation alongside the RCT was planned to explore the cost-effectiveness of LH compared to open AH based on a primary outcome of QALYs and secondary outcomes, such as major surgical complications avoided. The analysis was to adopt the perspective of the health service. All resource use data were to be collected prospectively with unit costs attached. Deterministic and probabilistic sensitivity analysis were to be performed. However, due to the early closure of the trial, the health economic evaluation was not carried out.

Randomisation and treatment allocation

Eligible and consenting patients were randomised to one of the two treatment groups using a secure online randomisation system at the Birmingham Clinical Trials Unit (BCTU). Participants were randomised online to either a LH or AH in a 1 : 1 ratio using a minimisation algorithm to ensure balance in the treatment allocation over the following variables: previous caesarean section (yes/no); body mass index (BMI) (≤ 29.9, 30–34.9, ≥ 35 kg/m^2); uterine size (≤ 12 weeks, > 12 weeks); planned retention of cervix (yes/no); recruiting centre.

Interventions and expertise-based surgery

The interventions to be compared were hysterectomy undertaken by either a laparoscopic or an open abdominal route, by a surgeon who had self-declared as having expertise in LH, AH or both approaches to hysterectomy. The decision to remove or retain cervix (total or subtotal) or remove and retain ovaries was left to the discretion of the participant in consultation with her gynaecologist. The expertise-based design process for eligible centres is depicted in *Figure 2*.[1]

To declare expertise in a surgical route of hysterectomy, surgeons were required to have performed a minimum of 30 cases[16] and to have a current caseload of at least 12 cases per year.[17,18] For surgeons to conducting both procedures, these criteria needed to be met for each route of hysterectomy. These thresholds are evidence based: in a series of over 10,000 laparoscopic hysterectomies, surgeons who had performed more than 30 laparoscopic hysterectomies had a significantly lower incidence of ureteric and bladder injuries (0.5% and 0.8%, respectively) compared with those performing 30 operations or fewer (2.2% and 2.0%, respectively).[18]

The importance of surgical experience as a predictor of successful surgical outcome has been shown in other studies.[16] Surgical volume is well recognised to correlate with safety in hysterectomy.[17] A systematic review and meta-analysis of studies including 741,760 patients reported complication rates according to surgical volume. High-volume surgeons were defined as performing at least one of a particular type of hysterectomy per month on average (i.e. a minimum of 12 per year). Low-volume surgeons performed fewer than 12 hysterectomies per year and had higher major complication rates {total complications [odds ratio (OR) 1.3, 95% confidence interval (CI) 1.2% to 1.5%], intraoperative complications (OR 1.6, 95% CI 1.2% to 2.1%) and postoperative complications (OR 1.4, 95% CI 1.3% to 1.4%)}.[19]

Sample size

To enable 90% power to test the non-inferiority hypothesis at a one-sided 2.5% significance level (two-sided 5% level) assuming a 3% margin of non-inferiority and a major surgical complication rate of 6% in the abdominal (control) group required 2634 participants. The estimate of 6% was taken from a similar previous comparative study.[20] A 3% margin was justifiable because of the trade-off of potentially swifter recovery with laparoscopic surgery; a view shared by our patient focus group and was substantially less than the 5% difference observed in the previous major trial[19] which led to the continued use of open AH.

An extra consideration was the potential for clustering by surgeon due to the expertise-based design.[21,22] Under the assumption that each of the 50 centres would use 6 surgeons (operating on approximately 9 patients on average during the study), along with an intracluster correlation coefficient (ICC) estimate of 0.02, the sample size was increased by 16% to 3055. This ICC estimate used, in the absence of precise estimates, was considered

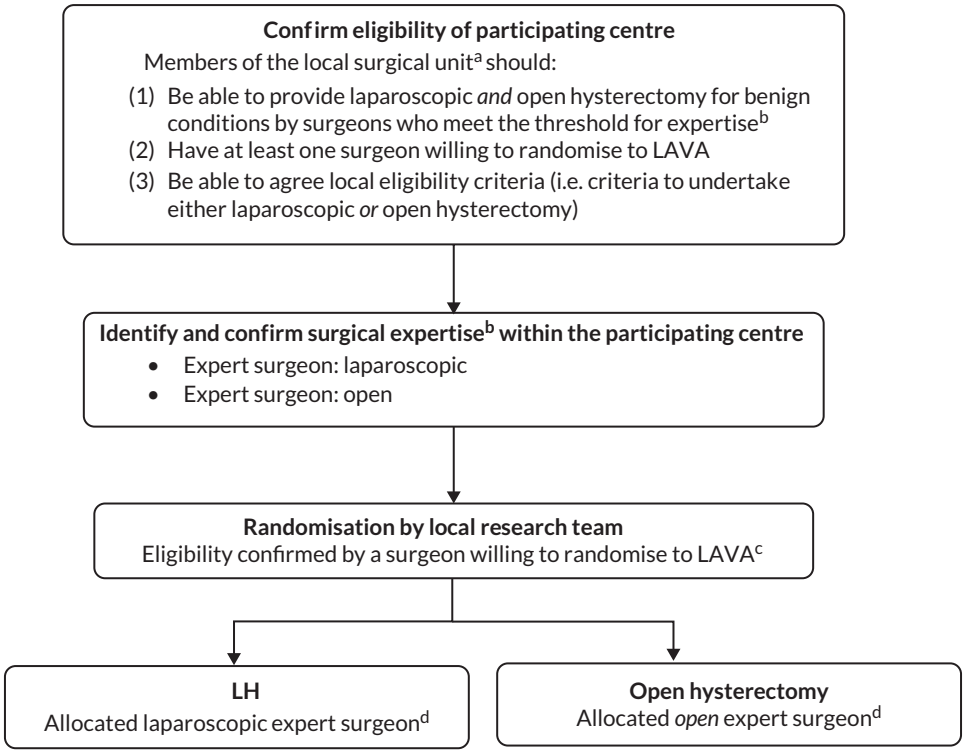

FIGURE 2 Expertise-based surgical design for the LAVA trial. a, Collective group of surgeons within a centre willing to operate on patients recruited into the LAVA trial. Not all surgeons within the LSU need to be willing to randomise but they should be prepared to perform a hysterectomy, according to their expertise, on patients following randomisation; b, Surgeons to have performed a minimum of 30 cases and to have a current caseload of at least 12 cases per year. For surgeons to conduct both procedures, these criteria will need to be met for both types of hysterectomy. In light of the unprecedented restrictions on elective operating for benign condition imposed by the COVID-19 pandemic, the required surgical caseload can be determined from the year preceding the SARS-COV2 viral outbreak in March 2020; c, The surgeon must consider the position for each individual patient. Only if they believe that either operation will be suitable for an individual patient can the patient then be recruited; d, Participants must be made aware that their surgery may be conducted by another surgeon within the LSU with the appropriate expertise.

conservative, given the outcome was clinical and of low prevalence, both of which were factors associated with low ICC.[23,24] However, even varying these factors up to an ICC of 0.07 or average cluster size of 29 shows we should have at least 80% power to establish non-inferiority in these situations. A final inflation of 6% to account for loss to follow-up brought the final sample size total to 3250 participants. This size of sample gave the ability to detect meaningful differences between groups in our key secondary outcome of time from surgery to resumption of usual activities. Assuming the median recovery time in the abdominal group was between 6 and 9 weeks,[25] we would have had high levels of power (> 90%) to detect reductions of 1 week in all cases.

Analysis

The trial was originally designed for the primary outcome to be analysed within a non-inferiority framework, but this plan was abandoned once the trial was stopped early, given the low number of events and resulting impact on statistical power. A decision was made to present summary data only (frequencies and percentages) for binary outcomes, given the low likelihood of being able to draw sensible inferences from these outcomes, but formal analysis was still planned for the time to event and continuous outcomes, which were likely to be more sensitive to detect any differences between groups.

The key secondary outcome of time from surgery to resumption of normal activities was analysed using a Cox proportional hazards model, adjusting for the minimisation variables. Observations were censored at the last response time if no final date of recovery is available (up to a maximum of 26 weeks). A hazard ratio (HR) and 95% CI was produced to assess the superiority of LH compared with open abdominal surgery. A second analysis using Restricted Mean Survival Time[26] was also undertaken. The area under the survival curve was be restricted at the point where at least one group has no one left 'at risk' of recovering. Time from operation to discharge in days was also analysed in the same way.

For continuous responses measured at a single time point, mean differences and 95% CIs were estimated using

linear regression models. For postoperative pain up to 14 days post surgery, mean differences and 95% CIs were estimated through the use of a repeated measures mixed-effects linear regression model. Parameters allowing for participant, treatment group, time and the minimisation variables were included. More details of statistical considerations and planned analyses are available in the previously published protocol.[1]

Post-closure survey of sites

After the decision to close LAVA early due to poor recruitment, we aimed to gather as much information from clinical and research staff at participating sites, regardless of whether their site was open or not. Staff were asked to provide feedback on the trial protocol and share their experiences with patient recruitment. Data were gathered through e-mail, telephone or video calls. All sites, including those who had declined participation, were contacted by e-mail at trial closure and asked to provide their views and experiences regarding the challenges encountered in recruiting patients. This inclusive approach aimed to gather valuable insights from various stakeholders to better understand the factors that led to the trial's early closure. Themes were identified and collated with data analysed descriptively (numbers and proportions). Dates at which milestones were attained at site set-up were analysed as a proxy of participating trust research and development (R&D) capacity.[27]

Embedded qualitative process evaluation

It is well documented that surgical trials face numerous challenges, particularly around informed consent and recruitment, from both the patient and surgeon perspective.[28,29] To support trial delivery, an embedded QPE, as part of the LAVA internal pilot phase, was conducted to explore the feasibility, acceptability and appropriateness of LAVA for women and HCPs.

The QPE was developed through a structured four-step approach. First, the evaluation was mapped onto the Medical Research Council (MRC)/NIHR Framework for Developing and Evaluating Complex Interventions, aligning specifically with the 'feasibility' phase. Second, the theoretical framework of acceptability was applied to explore how participants perceived the trial across seven domains, including affective attitude, burden and ethicality. Third, an initial programme theory was developed to describe hypothesised inputs and mechanisms influencing the feasibility, acceptability and appropriateness of the LAVA trial. This theory considered contextual factors, such as the clinical environment, patient characteristics and HCP equipoise, and was refined as a result of initial findings.

Fourth, a process evaluation framework was constructed following MRC guidance, enabling structured assessment of both intervention-related factors (e.g. context, fidelity, exposure, reach) and trial processes (e.g. recruitment, retention, contamination). Data were collected through semistructured interviews with women participating in the trial and with HCPs, using discussion guides informed by the frameworks and developed with input from PPI and engagement contributors. All interviews were conducted remotely (via phone or video call) by an experienced female researcher, with a participant-led approach to allow unanticipated insights to evolve.

Data from women and HCPs were analysed together using a hybrid deductive–inductive codebook thematic analysis. Deductive codes were informed by the theoretical frameworks and discussion guides, while inductive analysis allowed new, data-driven themes to be identified and interpreted. This approach ensured the evaluation captured both expected and novel insights into how the trial was understood, experienced and implemented in practice.

Health economic evaluation

The health economic evaluation has not been conducted due to early closure of the trial.

Results summary

The research papers synthesised in the LAVA study synopsis are summarised in *Box 1*.

Early closure

Recruitment to the LAVA trial started in September 2021, but the trial was closed prematurely by the funder due to our inability to recruit at the anticipated rate and considered unlikely to be able to deliver the end points in the post-pandemic environment.[2] Recruiting sites and participants were notified, and no further follow-up occurred. Over the 14 months prior to trial closure (September 2021–November 2022), 75 women were randomised from 9 of the 13 open sites. Of these, 62 (83%) patients underwent hysterectomy, and all provided data on the primary outcome; assessment of major complications, while 58 (94%) provided information on their return to usual activities.

Trial progress and recruitment

The mean time from initial site contact to opening was 253 days and 68 days to randomise their first participant. Thirteen sites opened over a period of 13 months and screened 252 patients, of whom 156 (62%) were eligible

BOX 1 Research papers synthesised in the synopsis

Manuscript	Objective
1. Antoun L, Middleton L, Smith P, Saridogan E, Cooper K, Brocklehurst P, *et al.* LAparoscopic Versus Abdominal hysterectomy (LAVA): protocol of a randomised controlled trial. *BMJ Open* 2023;**13**:e070218. https://doi.org/10.1136/bmjopen-2022-070218. PMID: 37669836; PMCID: PMC10481847.	To present the study protocol and results/inferences from the failed RCT designed to determine the clinical and cost-effectiveness of LH compared to AH for women with a benign gynaecological condition
2. Antoun L, Bevan S, Mahmud A, Jones L, Middleton L, Woolley R, *et al.* Lessons learnt from the multi-centre LAparoscopic Versus Abdominal hysterectomy (LAVA) randomised controlled trial. *Facts Views Vis Obgyn* 2024;**16**:35–45. https://doi.org/10.52054/FVVO.16.1.003.	To explore the views and experiences of clinical/research staff in order to understand how these might act as barriers to trial participation and recruitment
3. Matthews L, Clark TJ, Bevan S, Middleton L, Antoun L, Smith P, *et al.* Feasibility, acceptability and appropriateness of laparoscopic vs. abdominal hysterectomy for women and healthcare professionals: the LAVA trial qualitative process evaluation [published online ahead of print July 23 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/GJTC1325	To explore the feasibility and acceptability of LAVA for women and HCPs
4. Antoun L, Woolley R, Middleton L, Smith P, Saridogan E, Cooper K, *et al.* Comparison of complications and recovery after laparoscopic and abdominal hysterectomy for benign disease: the LAparoscopic Versus Abdominal hysterectomy (LAVA) randomised controlled trial *BMJ Open* 2025;**15**:e096265. https://doi.org/10.1136/bmjopen-2024-096265	To compare recovery after LH and AH

and 75 (49%) randomised. Of the 53 not randomised, 23 (48%) women had a preference for LH, while six (13%) had a preference for AH. The main reasons given for failure to recruit or activate set-up in the 21 sites open or in set-up were lack of research/clinical capacity imposed by the COVID-19 pandemic (14, 67%) and lack of clinician equipoise (11, 52%). Full details of the trial progress and collation of the views and experiences of clinical/research staff on key aspects of the trial are reported in the published paper.[1]

Patient characteristics and surgical details

The primary indication for surgery among participants in both groups was abnormal uterine bleeding, followed by pelvic pain. Baseline characteristics are summarised in *Table 1*. Overall, 9% of women had a uterine size > 12 weeks, 40% had a history of caesarean section, and the mean BMI was 30 kg/m^2 [standard deviation (SD) 5.2].

Only one participant underwent a subtotal hysterectomy. Moderate to severe adhesions were identified in 13 patients (41%) in the LH group and in 7 patients (23%) in the AH group. Deep endometriosis was noted in one patient assigned to the AH group. Median uterine weight was similar between groups: 131 g in the LH group and 135 g in the AH group.

Surgical duration was comparable, with a mean of 90 minutes (SD 25.5) for LH and 91 minutes (SD 57.9) for AH. Estimated blood loss (EBL) was also similar, with a median of 50 ml for LH and 100 ml for AH. One patient in the LH group experienced an EBL > 500 ml, compared to four patients in the AH group. No laparoscopic procedures required conversion to open surgery. Surgeon experience levels were similar across both surgical approaches.[1]

Participant outcomes

Of the 75 women randomised before early curtailment of the trial, 32/39 (82%) participants underwent LH and 30/36 (83%) underwent AH. The assigned route of surgery was achieved in 31 (97%) and 25 (83%) in the LH and AH groups, respectively (*Figure 3*). Of the five non-adherent patients randomised to AH, the route of surgery was changed to laparoscopic in participants at their request and one because of surgeon preference (to vaginal hysterectomy). Lack of surgical equipment was cited as the reason for the non-adherent patient randomised to LH. Major complications occurred in 2/32 (6%) of the LH group versus 4/30 (13%) of the AH group. In the LH group, the complications were an intraoperative haemorrhage > 1 l and a delayed thermal injury to a left ureter presenting 10 days later with a uretero-vaginal fistula requiring nephrostomy and eventual retrograde stenting 6 weeks later. In the AH group, there were three intraoperative haemorrhages > 1 l and one postoperative pelvic haematoma requiring radiological/surgical intervention (*Table 2*).

No difference in time to resumption of usual activities was found {median [interquartile range (IQR), *N*] 7.5 weeks (3.6–8.2, 25) LH versus 7.5 weeks (5.5–10.6, 26) for AH groups; restricted mean survival time difference (weeks) −0.49, 95% CI −2.85 to 1.87}. This extended to QoR [mean (SD, *N*) 81.1 (13.4, 27) versus 72.3 (17.6, 22), respectively; adjusted mean difference 7.2, 95% CI −3.2 to 17.6]. Likewise, no evidence of a difference in QoR at 24 hours post surgery was observed between LH and AH [mean (SD, *N*) 81.1 (13.4, 27) for LH versus 72.3 (17.6, 22)

TABLE 1 Baseline characteristics

		LH (*N* = 39)	Open AH (*N* = 36)	Overall (*N* = 75)
Minimisation variables				
Previous caesarean section	Yes	15 (38%)	15 (42%)	30 (40%)
	No	24 (62%)	21 (58%)	45 (60%)
BMI (kg/m^2)	≤ 29.9	17 (44%)	16 (44%)	33 (44%)
	30–34.9	15 (38%)	15 (42%)	30 (40%)
	≥ 35	7 (18%)	5 (14%)	12 (16%)
Uterine size (weeks)	≤ 12	35 (90%)	33 (92%)	68 (91%)
	> 12	4 (10%)	3 (8%)	7 (9%)
Planned retention of cervix	Yes	2 (5%)	2 (6%)	4 (5%)
	No	37 (95%)	34 (94%)	71 (95%)
Other baseline variables				
Age (years)	Mean (SD, *N*)	43.5 (5.5, 39)	42.7 (6.3, 36)	43.1 (5.9, 75)
	Range	32.0–55.0	29.0–54.0	29.0–55.0
Ethnicity	White	35 (90%)	32 (89%)	67 (89%)
	Black African	0 (0%)	1 (3%)	1 (1%)
	Black Caribbean	0 (0%)	1 (3%)	1 (1%)
	Asian	2 (5%)	1 (3%)	3 (4%)
	Mixed other	1 (3%)	0 (0%)	1 (1%)
	Don't know	1 (3%)	1 (3%)	2 (3%)
Parity	0	1 (3%)	1 (3%)	2 (3%)
	1	8 (21%)	6 (17%)	14 (19%)
	2	15 (38%)	14 (39%)	29 (39%)
	3	8 (21%)	8 (22%)	16 (21%)
	> 3	7 (18%)	7 (19%)	14 (19%)
Planned conservation of ovaries	Yes	18 (46%)	23 (64%)	41 (56%)
	No	21 (54%)	13 (36%)	34 (45%)
Diabetes	Yes	3 (8%)	2 (6%)	5 (7%)
	No	36 (92%)	34 (94%)	70 (93%)
If yes to diabetes				
Insulin dependent	Yes	0	1	1
	No	3	1	4
Indication for surgery according to main symptom	Abnormal vaginal bleeding	22 (56%)	24 (67%)	46 (61%)
	Pain of any type	14 (36%)	10 (28%)	24 (32%)
	Pressure-related symptoms	0 (0%)	1 (3%)	1 (1%)
	Other[a]	3 (8%)	1 (3%)	4 (5%)

a Other includes risk-reducing surgery; and fibroids, pelvic pain, heavy menstrual bleeding.

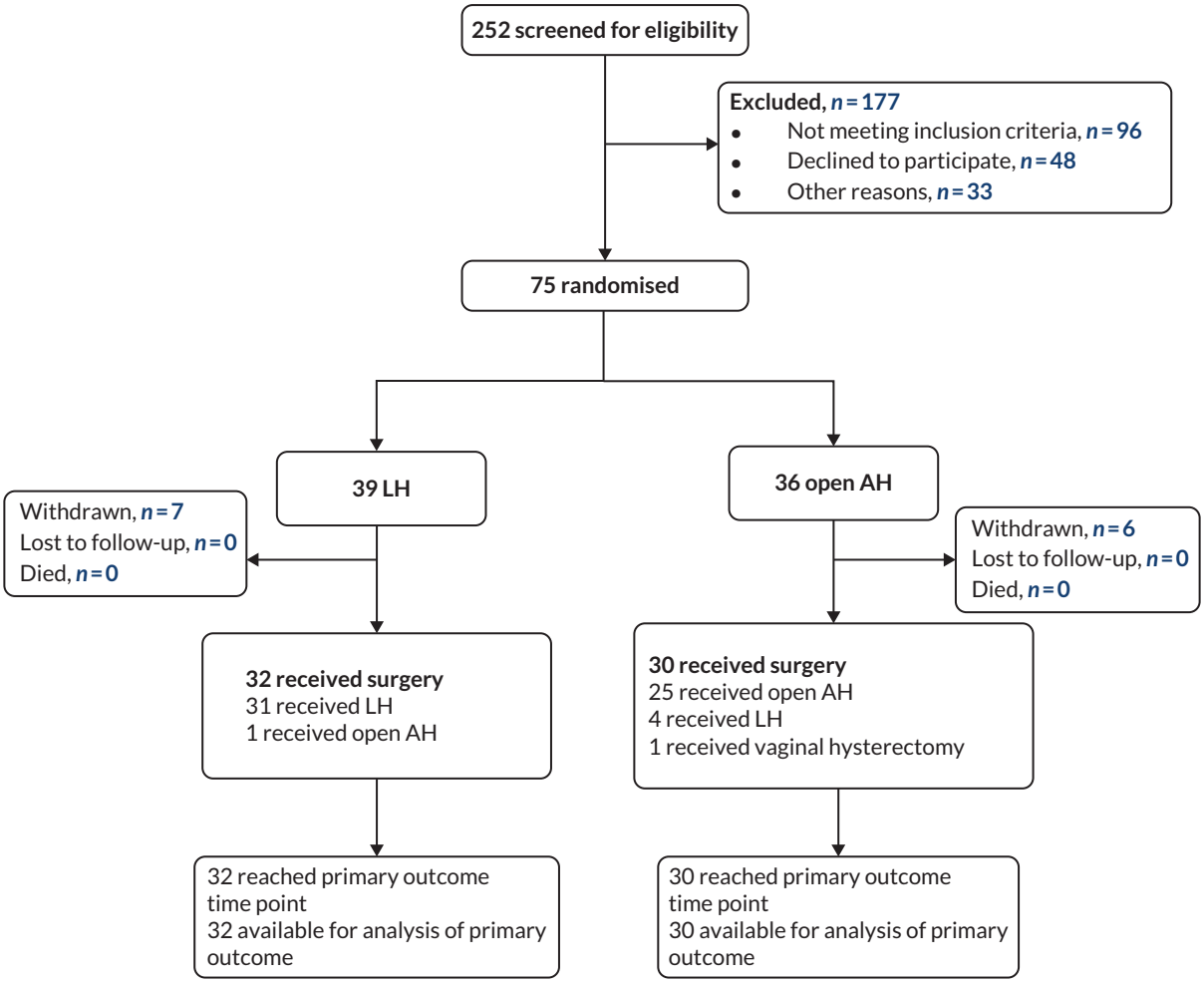

FIGURE 3 Consolidated Standards of Reporting Trials flow diagram of participants through the LAVA trial.[1] Reproduced from Antoun *et al.*[1] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY-NC 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for non-commercial use only, provided the original work is properly cited. See: http://creativecommons.org/licenses/by-nc/4.0/ The figure includes minor additions and formatting changes to the original text.

TABLE 2 Frequency of major surgical complications in the LAVA trial up to 6 weeks post surgery by group[1]

Major surgical complication[a]	LH (*N* = 32)	Open AH (*N* = 30)	Overall (*N* = 62)
Major postoperative complications			
• Haemorrhage ≥ 1 l	1 (3%)	3 (10%)[b]	4 (6%)
• Pelvic haematoma requiring radiological or surgical intervention	0 (0%)	1 (3%)	1 (2%)
• Ureteric leak (injury)	1 (3%)	0 (0%)	1 (2%)
• Ureteric fistula	1 (3%)	0 (0%)	1 (2%)
Major anaesthetic complications	0 (0%)	0 (0%)	0 (0%)
Any other complication not covered requiring surgical, endoscopic or radiological intervention[c]	1 (3%)	0 (0%)	1 (2%)
Participant had any major complication?[d]			
Yes	2 (6%)	4 (13%)	6 (10%)
No	30 (94%)	26 (87%)	56 (90%)

continued

TABLE 2 Frequency of major surgical complications in the LAVA trial up to 6 weeks post surgery by group (*continued*)

Major surgical complication[a]	LH (*N* = 32)	Open AH (*N* = 30)	Overall (*N* = 62)
Minor surgical complication[a]			
Haemorrhage 500 ml to < 1 l	0 (0%)	2 (7%)	2 (3%)
Pyrexia (presumed infection) requiring antibiotics	2 (6%)	2 (7%)	4 (6%)
Pain uncontrolled by usual analgesic management	1 (3%)	1 (3%)	2 (3%)
Urinary retention requiring recatheterisation	1 (3%)	3 (10%)	4 (6%)
Catheterisation for longer than 72 hours	0 (0%)	3 (10%)	3 (5%)
Pelvic haematoma not requiring radiological or surgical intervention	1 (3%)	0 (0%)	1 (2%)
Wound infections/complications managed at the bedside or on the ward	1 (3%)	1 (3%)	2 (3%)
Any other minor complication requiring pharmacological treatment with drugs other than antiemetics, antipyretics, analgesics, diuretics, electrolytes or physiotherapy[e]	2 (6%)	3 (10%)	5 (8%)
Participant had any minor complication?			
Yes	5 (16%)	9 (30%)	14 (23%)
No	27 (84%)	21 (70%)	48 (77%)

a Participants may experience multiple major surgical complications.
b One of these participants had vaginal hysterectomy.
c Other includes: presented to site with abdominal pain. Admitted for a pelvic ultrasound scan (USS). Two days after admission, still awaiting scan and started to complain of slight urinary incontinence. USS kidney-ureter-bladder; mild hydronephrosis at left kidney. Diagnosed with a vesicovaginal fistula and resolved with a nephrostomy and ureteric stenting for 6 weeks.
d Primary outcome measure.
e Other includes: constipation; catheter stuck and required USS guided removal; bilateral multilocular cysts on pelvic USS suggestive of haemorrhagic cysts.

for AH; adjusted mean difference 7.2 (−3.2, 17.6)]. Median time to discharge was also comparable 1.0 night (IQR 1.0–1.0) for LH versus 2.0 nights (IQR 2.0–3.0) for AH; restricted mean survival time difference −1.0 (95% CI −2.6 to 0.6); HR 2.13 (1.19 to 3.80). We found no evidence of difference in pain scores over the first 14 days following surgery [adjusted mean difference 0.28 (95% CI −0.34 to 0.89)], nor in the type of analgesia or median duration of use in the first 14 days (11 days; IQR 7–14 for LH versus 13 days; IQR 9–14 for AH). Overall, 14 (23%) participants represented to hospital within 6 completed weeks post surgery; 6 (19%), median (IQR) attendance 1 (1–1) and 8 (27%), median (IQR) attendance 2.0 (1–2) in the LH and AH groups, respectively. Three (5%) participants were re-admitted to hospital within 6 completed weeks following surgery – one (3%) in the LH group and two (7%) in the AH group.

Of patients currently employed, 19 (86%) in the LH group versus 15 (79%) in the AH group had returned to work by 12 completed weeks post surgery. The median return times to work post surgery were 50 days (IQR 42–70 days) for LH versus 40 days (IQR 28–70 days) for AH, with no significant differences in work participation between LH or AH groups. No significant differences were observed in generic health-related QoL post hysterectomy between LH and AH [EQ-5D-5L VAS 0–100 (SD) at 6 weeks post surgery 70.6 (20.5) vs. 70.5 (15.9), adjusted mean difference 0.7, 95% CI −10.3 to 11.7]. At 12 months after surgery, 17/17 (100%) of patients in the LH group were very satisfied or satisfied with their hysterectomy compared to 11/13 (84%) of patients in the AH group.

Full details of the primary and secondary outcomes (major surgical complications – Clavien–Dindo ≥ level III – up to 6 completed weeks post surgery), key secondary outcome (time to resumption of normal activities measured by the PROMIS-PF tool) and other secondary recovery and QoL outcomes are reported in the published paper.[1]

Qualitative process evaluation

Eleven women (four randomised to the abdominal group, six randomised to the laparoscopic group and one who declined trial entry) and seven HCPs (five research nurses, one research midwife and one consultant gynaecologist) were interviewed as part of the QPE. Four themes were interpreted. Theme 1 identified decision-making processes for LAVA participation. Conditional altruism motivated women to participate, alongside the 'relief' of being offered a hysterectomy. The decision to decline participation was influenced by surgical preference and beliefs of laparoscopy having a faster recovery rate. Theme 2 highlighted surgical preferences, with women's preferences being influenced by their previous experiences of surgery or perceived recovery times, and their family/friends. All HCPs demonstrated community equipoise (where there was genuine uncertainty about the effectiveness of the two surgeries) but did observe that 'younger surgeons' may prefer laparoscopic surgery based on their contemporary training. Theme 3 identified attitudes towards the LAVA trial, with women and HCPs reporting positively about LAVA's feasibility, acceptability and appropriateness in terms of burden, information and understanding of the study. Theme 4 identified facilitators and barriers for LAVA participation. Facilitators included the key role of the research nurses, and women having personal social support during their recovery. Telephone consultations may be a barrier, with face-to-face discussion being preferred by both women and HCPs. These findings informed the refinement of the LAVA programme theory, identifying the interplay of factors related to the environment, patients and HCPs (see *Figure 4* for the initial programme theory and *Figure 5* for the refined programme theory).

Post-closure survey

The main reasons given for failure to recruit or activate set-up in the 21 sites open or in set-up were lack of research/clinical capacity (14, 67%) imposed by the COVID-19 pandemic and lack of clinician equipoise (11, 52%).[29]

Discussion/interpretation

Principal findings and achievements

The LAVA RCT was halted by the funding body after the pilot phase due to poor recruitment from participating centres and of eligible women. Thus, with the failure of the LAVA trial, it appears that the current trend to fewer abdominal hysterectomies will continue without robustly answering important clinical questions around patient safety, recovery and cost-effectiveness. Seventy-five participants were randomised into the LAVA trial. Six major complications occurred, equating to a major complication rate of 6% for LH and 13% for AH, but the numbers were too small to test the non-inferiority hypothesis for LH compared with AH. The four major complications in the AH group were all related to bleeding; intraoperative > 1 l or postoperative pelvic haematoma. In the LH group, there

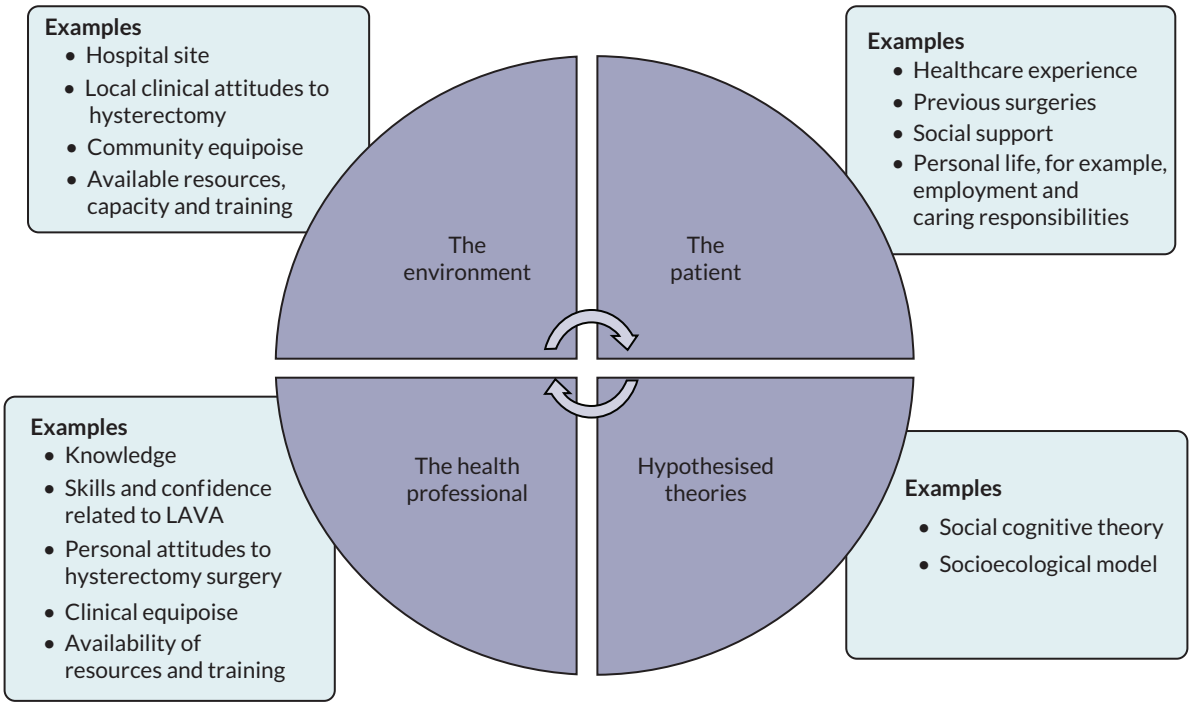

FIGURE 4 Initial programme theory for feasibility, acceptability and appropriateness of the LAVA trial.

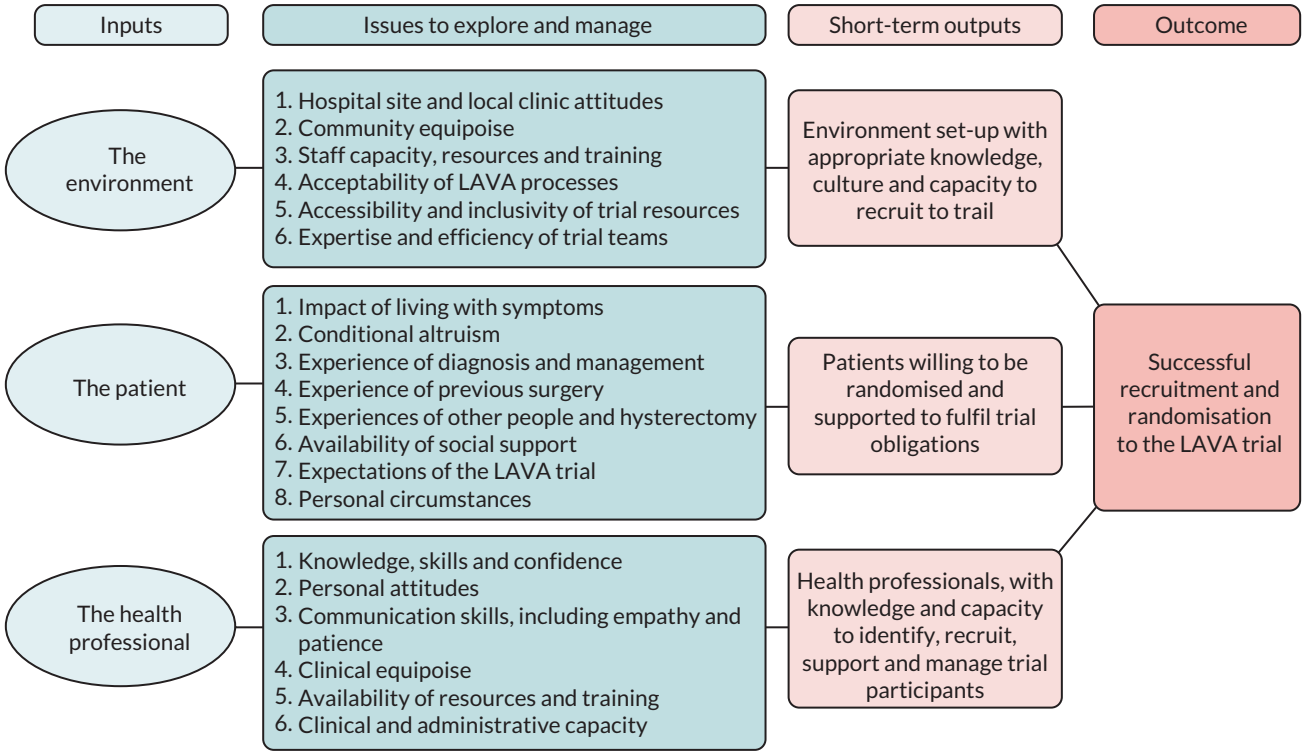

FIGURE 5 The refined LAVA programme theory.

was one intraoperative haemorrhage and one visceral injury; thermal damage of a ureter resulting in a fistula into the vagina. Only one patient (3%) in the LH group and two patients (7%) in the AH group were re-admitted to hospital within 6 completed weeks of surgery.[1]

No clear differences in recovery between LH and AH were observed, but the small sample precludes any meaningful inferences. Recovery quality in hospital as well as pain scores and use of analgesia during the first 14 days were comparable. No differences in generic QoL were observed for LH and AH at 6 and 12 weeks after surgery. Median times to resumption of preoperatively selected activities of importance to individual patients were between 49 and 53 days, and the median time for returning to work was between 40 and 50 days, with no significant differences between LH or AH. Ninety per cent of participants were satisfied with the outcome of their hysterectomy at 1 year.[1]

Feedback from women and HCPs involved in the trial generally indicated positive perceptions of the recruitment and randomisation processes. The qualitative findings, when viewed alongside lessons learnt by premature closure of the LAVA trial, highlight the challenges of patient and HCP equipoise and the complexity of undertaking clinical research in a post-COVID environment.

The pre-trial survey and focus groups of patient representatives that helped design the LAVA trial and supported its viability held true, with most eligible women agreeing to be randomised. It is worth noting that when a surgical preference was expressed that precluded participation, nearly a quarter of women preferred open abdominal surgery. In contrast, the results of a pre-trial survey of clinicians which established support for the trial were not upheld once the trial was funded and opened. Of the 90 sites responding to our initial expression of interest, only one-third agreed to take part, falling short of our target of 50, albeit this was only the first wave of site recruitment. It is telling that the majority of sites declining to participate in LAVA cited a lack of surgeon equipoise, with most expressing a preference for LH, and 50% of sites that were open or in set-up stated this as the reason for poor recruitment in the post-trial survey. However, this certainty was not shared by the very women whose treatment the trial was aiming to inform. Surgeons, by the nature of their job, need to be decisive, but they should reflect upon their duty to patients where the evidence base is lacking and the Hippocratic Oath of 'first doing no harm'. Randomisation, if 1 : 1, protects 50% of participants from unwanted outcomes, both known and unknown.

Contribution to existing knowledge

The failure of the LAVA trial to recruit resulted in little new clinical and no new economic information pertaining to the relative merits of LH compared to AH for benign conditions.

Systematic reviews and meta-analyses of previous RCTs have shown no overall benefit of a LH over AH for benign indications.[3] Indeed, the largest RCT to date showed a higher major complication rate, driven by urinary tract injuries, with LH.[19] In our curtailed trial, one urinary tract injury occurred with LH; this visceral damage necessitates further invasive intervention, often takes months to resolve and may lead to issues with chronic pain or renal damage. In contrast, while bleeding complications were seen more commonly with AH, intraoperative bleeding can be resolved with blood and/or fluid replacement and postoperative pelvic haematoma with drainage and antibiotics, generally without prolonged morbidity or long-term symptoms.[1]

Using a novel, personalised and validated recovery tool (PROMIS PF) administered regularly by SMS, our trial found the time to full resumption of usual activities to be comparable between LH and AH. While lacking power, this finding is in contrast to earlier trials[3] (6 trials, 618 patients) that suggested a quicker return to normal activities on average for women undergoing LH (22–25 days) compared to AH (37 days). In our trial, it took 52.5 days (7.5 weeks) on average for full recovery regardless of the route of hysterectomy.[1] Our recovery data are more valid than previous trials, because we used a personalised recovery tool (i.e. recovery end points that are important to individual women).[8–10] These data might be useful in counselling women about their recovery, regardless of the type of hysterectomy, about their recovery.

This is important because laparoscopic surgery is increasingly forming an integral part of modern care packages of nursing, anaesthetic and surgical care designed to enhance recovery and allow day-case or 24-hour hospital discharge.[30] Enhanced recovery has the potential to be economically advantageous to the NHS through resource efficiencies and wider society via increased productivity. Despite this move to same-day discharge with LH,[31,32] there are a lack of data to support the use of laparoscopic approaches over others, and our trial did not show a difference in time to discharge from hospital between LH and AH.

Large-scale, multicentre surgical RCTs that can answer clinically important questions are rare, because they are difficult to successfully complete.[33–36] Surgical trials appear to face greater challenges than non-surgical trials because of patient preferences and clinician lack of equipoise.[37,38] Furthermore, prolonged surgical waiting times add further barriers, because they can reduce patients' willingness to join trials.[21] It is estimated that fewer than one-third of surgical trials successfully recruit their target sample size within the planned time frame,[39] and more than 20% of surgical trials are discontinued earlier than anticipated, with poor recruitment being the main reason. The LAVA trial reinforces these previous observations, highlighting lessons that can be learnt for future trials to succeed and to avoid research waste.

Strengths and weakness

The LAVA trial was a robustly designed, multicentre RCT using validated outcome measures and an embedded QPE, addressing an important and relevant clinical question. Unfortunately, due to early trial closure, the planned economic cost-effectiveness analysis could not be undertaken. This study design and viability was informed by large, pre-trial surveys and small focus groups of both clinicians and patient representatives. The LAVA trial planned to be as large as all the previous 28 RCTs evaluating LH and AH for benign conditions (3250 vs. 3431) and of higher quality, addressing the methodological deficiencies of previous trials – namely, their lack of power to show a meaningful difference, the validity of outcomes assessment, especially the key outcome of recovery, and a failure to account for surgical expertise. In the LAVA trial, we used a novel, validated, personalised recovery tool (PROMIS-PF)[8,9] disseminated at regular intervals via SMS to gain meaningful, accurate information about recovery milestones and time to resumption of self-selected activities. Furthermore, we employed an expertise-based design to mitigate against confounding arising from variation in surgeon proficiency,[21] acquiring information regarding experience and caseload for individual surgeons. Third-party randomisation was performed balancing important prognostic variables, and rates of follow-up for trial outcomes were high. In addition, these findings are generalisable in light of the trial's multicentre nature.[27]

We conducted a formal QPE using semistructured interviews and thematic analysis to gain insight from women who agree to be randomised and one woman who declined to take part. Throughout the lifetime of the trial, we recorded, collated and analysed additional quantitative and qualitative data from interactions with clinicians and researchers obtained from several sources, including telephone, e-mail, teleconferences, site visits and consultant/research meetings. As the QPE was downstream of the main trial, recruitment depended on trial enrolment and was constrained by slow site uptake. A limitation of the QPE was the delay in insights being actionable because patients and HCPs could not be approached until the trial had become embedded in collaborating sites. In light of slow recruitment, the interviews were delayed, and due to time constraints and early trial closure, it was not possible to use these findings during the pilot phase to inform any

This synopsis should be referenced as follows:
Clark TJ, Antoun L, Woolley R, Bevan S, Ziomek K, McKinnon W, *et al.* Laparoscopic hysterectomy versus open abdominal hysterectomy for women with a benign gynaecological condition: the LAVA RCT. *Health Technol Assess* 2026;**30**(14):1–28. https://doi.org/10.3310/GJTC1718

changes to the recruitment process. These data provided useful perspectives from clinical and research staff at participating or declining sites. The lessons learnt from these views and experiences will help future research teams hoping to execute large, surgical RCTs.[27]

The over-riding limitation of the LAVA trial is the relatively small sample of 75 patients. At the time of trial analysis, 17% of randomised patients had not had surgery due to prolonged waiting lists following the COVID-19 pandemic, medical contraindications or patients no longer wanting surgery. Non-adherence to the allocated route of hysterectomy was noted in 10% of participants undergoing hysterectomy. Given the nature of the intervention, it was not possible to blind either the care providers, investigators or participants to their allocated group. The QPE only included interviews with 11 women from 3 different sites, and the majority of these interviews and hence insight was from the lead site, which was the first to open and, by far, the best recruiting site. Of the seven HCPs, most were nurses, with insight being obtained from only one consultant gynaecologist. The QPE would have benefited from great numbers of interviewees, from across more recruiting sites as well as insight from sites who declined to participate.

Take-home messages

The trial question 'What is the clinical and cost-effectiveness of LH compared to open AH for women with a benign gynaecological condition?' remains important and relevant in contemporary women's health care, and has not yet been answered. The Cochrane systematic review on the 'Surgical approach to hysterectomy for benign gynaecological disease'[3] identifies that research is needed from 'large study populations, with surgeons well beyond their learning curve'. The LAVA trial was designed to meet these demands and was planned to be, by far, the largest to date and employed an expertise-based design so would have satisfied these demands. Moreover, the review highlighted an absence of data for long-term outcomes, including urinary, bowel and sexual function, along with occurrence of fistulae, in RCTs comparing surgical approaches to hysterectomy and also the importance of costs of the different routes, including environmental perspectives. The LAVA trial was designed to evaluate all such outcomes.

Clinicians need to be advocates for their patients by being prepared to participate in crucial surgical trials where there are evidence gaps and, as a result, uncertainty regarding the appropriateness of surgery compared to other surgical or non-surgical interventions or, as in the LAVA trial, evaluating the optimal surgical method. The LAVA trial revealed that clinicians' assumptions about patient preferences are not always accurate. While many gynaecologists interacting with the LAVA trial team (whether participating or declining to participate) had a preference for LH, presumably believing that it was superior, the data we collected during LAVA suggest that there is no advantage of LH in reducing major complications or speeding recovery compared to AH, albeit inferences are restricted greatly by the small sample.[27]

The failure of the LAVA trial is, therefore, very disappointing, because it could have guided clinical practice and improve the outcomes for the many women undergoing hysterectomy for a benign reason optimising the utilisation of scarce health resources. The LAVA trial experience highlights obstacles to the successful completion of robust trials in benign gynaecological surgery. These observations can inform the design and execution of future research studies in this field, whether RCTs or alternative, more feasible study designs.

Reflections on the project and what could have been done differently

The original LAVA trial protocol was amended, but these were generally minor procedural issues and clarifications rather than any major issue with trial design (e.g. eligibility, intervention, outcome measures, etc.) (*Table 3*).

TABLE 3 Protocol amendments

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
AM02	7 July 2021	3.0	Non-substantial	Minor changes to ensure consistent language throughout the protocol and with the CRFs/independent verification of classification of surgical complications is no longer required/clarification of haemorrhage ≥ 1 l as a major surgical complication, ensuring consistency with CRFs/change to scheduled window for completion of follow-up forms/clarification of withdrawal types

The LAVA trial was funded prior to the unforeseen COVID-19 pandemic. The clinical and research infrastructure was put under great stress. Non-essential clinical services were shut down and surgical waiting times rose exponentially, especially those in women's health many of which were designated as 'non-urgent'.[31] Consequently, the absence of paid or protected time for clinical PIs made trial engagement difficult while restoration and recovery of clinical services took priority. Moreover, R&D departments had to reallocate research priorities and deal with staff shortages because of redeployment of staff to clinical areas and long-term sickness. At least 10% of sites willing to take part in LAVA were lost due to this lack of capacity not to mention those sites that had not responded to the initial invitations of expressions of interest. Our post-trial closure clinician survey identified a lack of R&D support and lack of clinician time as factors impairing recruitment.

The primary outcome of major complications was measured 6 weeks post surgery, the key secondary outcome of personalised recovery was to be censored at 6 months and the longest outcomes relating to satisfaction and conditions specific QoL was to me measured at 12 months. The prolongation in surgical waiting list times following the pandemic, in general 12–24 months, created a number of challenges: (1) the timing of consent– delays from agreeing to take part impacting on recruitment; (2) validity of baseline data if completed at the time of recruitment; (3) retaining participants who may change their mind about participation, seek non-surgical alternative treatments or develop medical conditions contra-indicating participation and (4) completeness of follow-up, especially the longer-term 12 month data.

The decision to open the LAVA trial during the slow restoration of clinical services was a risk; there was a balance between the responsibility to deliver a well-funded trial to answer an important question of relevance to the NHS in a timely fashion against uncertain feasibility in a volatile, unprecedented, post pandemic environment. All trials need to gain a critical mass of collaborating centres actively recruiting. The trial encountered difficulties gaining momentum, especially during the second wave of a COVID-19 variant, which led to a redeployment of clinical and research staff that affected recruitment efforts.[28] Thus, once the clinical impact of this second wave had peaked, the need to re-engage with open centres and those in set-up had to begin again. Thus, with hindsight, we were too optimistic as regards restoration of clinical and research infrastructure within the NHS and should have delayed commencement of trial recruitment for at least 18 months.

Challenges faced and limitations

The trial COVID-19 pandemic, which had a major impact on global health services, and the far-reaching challenges on the clinical and research infrastructure imposed by this, have been described in the preceding section.

Clinician equipoise emerged as a significant challenge. Although the pre-trial clinician survey had indicated support for the feasibility of the LAVA trial, this was not reflected in actual recruitment once the trial commenced. The trial was pragmatically designed, with broad eligibility criteria to allow surgeons the discretion to decide which cases they were comfortable randomising. Additionally, an 'expertise-based' design was incorporated to reduce bias related to surgical skill, with the expectation that surgeons unwilling to randomise would still contribute as 'expert surgeons' for participants enrolled by colleagues in equipoise. In practice, however, most participating surgeons reported expertise in both surgical approaches. Further barriers to implementing the expertise-based model and engaging surgeons included the use of pooled surgical waiting lists, a younger generation of gynaecological surgeons with limited experience in abdominal surgery due to reduced training opportunities, and the increasing feasibility of same-day discharge following laparoscopic procedures.[32] These challenges were further compounded by the pressures on hospital resources during the COVID-19 pandemic, which intensified the focus on minimising hospital stays.

Clinicians who declined participation in the LAVA trial, as well as some within participating units, expressed concerns about the feasibility of recruitment, presuming that patients would have a strong preference for LH as a 'modern technique'.[28] This perception assumed that patients would prioritise smaller abdominal scars and anticipate quicker recovery with the laparoscopic technique. However, our recruitment data challenged this belief, presenting a more balanced picture. Nearly 60% of eligible women agreed to be randomised, indicating a willingness to consider different types of hysterectomy. It is worth noting that when a preference was expressed that precluded participation, nearly a quarter of women preferred open abdominal surgery.

The final challenge related to delays in site set-up and lack of R&D efficiency. Only 13 (40%) of the initial 31 sites agreeing to participate in LAVA were open for recruitment when the study was closed. This fell way short of our target of 28 sites by the end of pilot phase. The trial team maintained regular contact with sites supported, where necessary, in both a proactive and reactive way by the

chief investigator through phone and e-mail contact and attendance remotely at departmental meetings to present the LAVA trial and address questions and queries.[28] At many sites, the local PIs were keen to move the set-up process along but had little influence. The delays were due to local clinical management decisions, R&D department priorities, capacity and efficiency. Sites in the set-up phase would frequently ask for more time or to be recontacted after a few months to facilitate the evaluation of the changing clinical and research situation. Thus, while many clinicians were keen to get involved with the LAVA trial, they were unable to do so in a timely way.[28]

Engagement with partners and stakeholders

Patient and public views were integral throughout the design, conduct, reporting and dissemination of the study. Collaboration with groups like the RCOG Women's Voices group, the Hysterectomy Association, and the Birmingham Women's Hospital Hysterectomy Focus Group ensured the inclusion of patient perspectives. A total of 945 women responded to our PPI survey. These groups were of key importance when choosing our most important outcome measures and how and when to assess them. Our multidisciplinary trial team included all necessary expertise, including clinical, research, PPI and trial management capability.

Individual training and capacity-strengthening activities

There were no identified clinical or research training issues. Site initiation training was conducted at each site opened to recruitment, and the chief investigators and LAVA Clinical Trial Team based at BCTU and the University of Birmingham were accessible and responsive, be it in person or remotely, with many queries being addressed promptly by e-mail.

Institutional capacity strengthening

See *Challenges faced and limitations* and *Impact and learning*.

Patient and public involvement

The research team included PPI partners who contributed throughout the study informing trial design and helping the development of patient-facing study materials and QPE discussion guides. The Trial Management Group (TMG) and independent Trial Steering Committee included PPI members who were actively involved in discussions at meetings, reviewing and commenting on patient-facing materials and contributing to the review of the plain language summary as well as the close-out letter to consented participants. The study outcomes have been disseminated to PPI partners and participants.

Equality, diversity and inclusion

Benign gynaecological conditions, such as abnormal bleeding and pelvic pain, necessitating hysterectomy affect biological women, of all races/ethnicities, sexual orientation and social status.[40] Thus, in the LAVA trial, we approached all patients listed for a hysterectomy for a benign condition and who satisfied the eligibility criteria to optimise the validity and generalisability of our findings. At the time of trial closure, 6 of the 73 patients (8%) recruited who completed their ethnicity data were from an ethnic minority, but the numbers were too small to make any reliable inference regarding the equality, diversion and inclusion within the study processes and recruitment.

Of the 16 members of the research team (8 grant holders), none were from an ethnic minority and 6 (38%) were women (2 being a PPI representatives). Of the 10 members of the Trial Oversight Committees (Trial Steering Committee and Data Monitoring Committee), 5 (50%) were women (1 being a PPI representative) and 2 (20%) from an ethnic minority.

Impact and learning

The main learning from the LAVA trial relates to the reasons for its failure to complete, and these are expounded in the published papers.[1,27] The initial clinician and patient representative surveys we conducted prior to trial funding and final protocol design supported the feasibility of the LAVA trial, with clinicians at many centres stating their willingness to participate, recruit and randomise. However, this initial enthusiasm did not materialise, such that by the time of trial closure, we had only accrued 13 centres out of a projected 25 by the end of the pilot phase (and 50 by the end of the trial). The slow accrual of sites was caused by research and clinical capacity issues. The COVID-19 pandemic further reduced this lack of human and material resource, and restoration of these services was slow. With hindsight, we opened the trial to recruitment too early, as the restoration of clinical and research services was slower than anticipated, with clinical and research staff diverted to alternative duties and long-term sickness of staff affecting several R&D departments. The PI and local R&D departments need to confirm site capacity (clinical and research infrastructure) and, importantly, that clinical colleagues are prepared to take part. There also

appeared to be a lack of capacity and urgency within local R&D departments to interact with the BCTU in a timely fashion. R&D departments need to be incentivised and become more accountable as regards meeting time frames and opening trials.

The enormity of the clinical burden post COVID may have also impacted upon the time, resource and enthusiasm of clinicians to commit to the LAVA trial. Clinicians reported within our post-trial closure surveys, time pressures and most PIs did not have protected paid time for this research. Consequently, trial engagement was compromised against a background of prioritising restoration and recovery of clinical services.

Members of the TMG communicated regularly with R&D departments in open sites, those in set-up or considering participation. The chief investigator was responsive, attended in-person or virtual local hospital meetings, and we had a weekly online 'surgery' for research nurses and PIs from participating centres to troubleshoot problems, answer queries and encourage recruitment, as well as raising awareness of the trial through conference presentations and editorials in specialist journals. Despite these efforts, the lack of clinician equipoise and the post-pandemic environment made it unlikely that more interaction with trial sites and PIs would have influenced the trial's fate. In the absence of funding restrictions, it is likely that the LAVA trial could have been successfully delivered, but the uncertainty of the time frames for the restoration of clinical and research infrastructure made this less tenable. The chief investigator and trial team have successfully delivered other multicentre surgical trials, primarily in a pre-COVID environment.[41–44] Our post-trial closure clinician surveys indicated that there was a lack of surgeon equipoise.

Implications for decision-makers

The LAVA trial closed early due to poor recruitment, limiting any implications for decision-makers about the relative effectiveness and cost-effectiveness, on minimising complications and enhancing recovery and QoL, of women undergoing LH compared to AH for common, benign gynaecological conditions. However, there are implications for decision-makers arising from the failure of this well-designed, multicentre surgical RCT. The trial's clinical question remains important to thousands of women across the UK, and far more on an international perspective, suffering with common gynaecological symptoms necessitating hysterectomy. In addition, the economic and environmental consequences of this highly prevalent operation on the NHS and wider society are clear. The LAVA trial's design and support by an experienced Clinical Trials Unit incorporating a multidisciplinary team of clinicians, patients and researchers makes its failure disappointing.

The findings of the pre-trial survey of patients and focus groups supporting the trial were valid, but the clinician survey proved unreliable. Despite their assurances, the reality on the ground was that fewer centres than anticipated to participate. Clinicians appeared to lack enthusiasm either through lack of clinical equipoise (generally preferring LH) or limited time (and generally no protected time) and resources. The slow recovery of the research infrastructure post pandemic along with substantial delays in some R&D departments, further hampered the trial.

Important clinical questions remain unanswered when trials fail and leads to considerable research and resource waste.[45–47] This has financial and ethical implications.[32,48,49] Patients will continue to be offered a type of hysterectomy based on opinion and preference rather than clear scientific evidence. Moreover, unbiased and balanced information available to patients to inform their decision-making remains deficient.

The lack of clinical and research capacity needs to be addressed if meaningful surgical trials answering clinically important questions for patients, the NHS and wider society are to be successfully completed. Research is needed to find innovative interventions and other solutions that can increase recruitment and targeted investment in research support. Adequately resourcing R&D departments is important as well as more accountability for their performance. During the LAVA trial, there appeared to be a lack of urgency in some R&D departments and among the PIs, particularly in timely responses to the trial unit, leading to delays in site opening and lag time between opening and randomising their first patient.

From a clinician perspective, a greater emphasis is needed on the importance of contributing to research during undergraduate and postgraduate training and understanding equipoise and uncertainty. There should be more formal evaluation of new surgical procedures or those of uncertain benefit, taking into account safety and effectiveness, should be required before they are introduced into routine practice. Medical schools, the Royal Colleges and specialist bodies should include research training as part of their curricula if we want to promote the importance of engaging with research as part of day-to-day clinical responsibilities.

This synopsis should be referenced as follows:
Clark TJ, Antoun L, Woolley R, Bevan S, Ziomek K, McKinnon W, *et al.* Laparoscopic hysterectomy versus open abdominal hysterectomy for women with a benign gynaecological condition: the LAVA RCT. *Health Technol Assess* 2026;**30**(14):1–28. https://doi.org/10.3310/GJTC1718

Research recommendations

The LAVA trial was closed due to an inability to recruit at an acceptable rate despite a UK NHS Clinical Research Network and a highly prevalent operation (~ > 30,000/year in the England for benign indications excluding urogynaecological indications). It is unlikely that such a multicentre trial will be feasible elsewhere in the world. Thus, there is a need for alternative study designs, incorporating innovative approaches to attract participants and generate enthusiasm among clinicians and other HCPs, while minimising bias. Moreover, research is needed to identify how to incentivise and support NHS and research staff and enable NHS services to participate in research post COVID, where clinical and research capacity remains a significant challenge to the conduct of research.

The Cochrane review evaluating hysterectomy for benign gynaecological disease[3] discussed implications for research and concluded that larger trials with expert surgeons, longer term follow-up and economic/environmental evaluations were needed. We agree with these conclusions because these recommendations were fulfilled entirely by the LAVA trial design. Thus, the LAVA trial design and outcomes are still relevant, but any future attempts should perhaps include robotic laparoscopic surgery alongside environmental end points assessed.[50] Sustainability and the carbon footprint of using disposable equipment in modern laparoscopic surgery, compared to more conventional abdominal and vaginal surgery that does not rely on such throwaway resources, needs formal evaluation. The cost-effectiveness, including consideration of health service and societal/environmental costs, of the different routes and techniques of hysterectomy needs examination.

Future research in this field should also consider the development of a COS with standard patient-reported outcome measures that would help standardise data collection and interpretation. Long-term outcomes, such as urinary, bowel, sexual and body image, from trials comparing the routes if hysterectomy should be conducted. Less ambitious, but still relevant RCTs evaluating components of the surgical technique (e.g. suturing, energy, anti-adhesive and haemostatic technologies) or procedural modifications should be undertaken. Trials should also be designed and conducted to assess the acceptability, effectiveness and cost-effectiveness of day-case hysterectomy. Such evaluations should consider scrutinising the components (e.g. education, preoperative work up/support, perioperative surgical/anaesthetic measures and short and long-term postoperative interventions) to enhance recovery and successful day-case discharge from hospital.

Conclusions

Hysterectomies are increasingly performed by a laparoscopic route as the technique is perceived to be less invasive and as a consequence the recovery times are thought to be faster compared with conventional open abdominal surgery. However, the available trial data from RCTs albeit of low to moderate quality, do not clearly support these contentions. Moreover, LH appears to be associated with significantly more urinary tract injuries compared to AH.[3] Despite the lack of clear evidence of overall benefit, the uptake of LH is increasing with greater familiarity and increased proficiency in the technique, aided by improved training and better surgical equipment.[5,6] Patient's values and preferences, especially around the perceived speed of recovery, may also be driving this trend.[7] Thus, we designed a large RCT to determine the effectiveness of contemporary LH compared to AH for a benign gynaecological condition overcoming previous RCT limitations relating to expertise and validated recovery assessment. We assessed major complications and time to resumption of usual activities using a relevant, personalised, validated instrument (PROMIS-PF).[8–10]

The LAVA trial failed to recruit for two main reasons. Firstly, the unfortunate timing, because funding was secured, and the trial due to open just as the unforeseen COVID-19 pandemic arrived. This virus had a devastating impact, and indeed continues to have, on the clinical and research infrastructure. The prolongation of surgical waiting lists had a particular impact on the LAVA trial, as a large surgical trial, compounded by the uncertainty caused by the pandemic and new waves of infection affecting the restoration of services. Secondly, we had not anticipated the lack of clinician engagement. Some of this related to the additional pressures of restoring clinical services during and after COVID-19 pandemic and a lack of paid or protected clinician time for acting as PIs. There was a lack of enthusiasm to become involved in the LAVA trial mostly related to a belief among many gynaecologists that LH was superior to AH. It became apparent that many gynaecological surgeons, particularly the younger generation, were more familiar and proficient in LH and less confident with AH as a result of less exposure in more recent training programmes to the approach.[27]

It is possible that the clinical members of our research team could have foreseen the issue of clinician equipoise in favour of LH. Publications from the Department of Health Hospital Episode Statistics data had shown the proportion of all hysterectomies performed by LH or AH, done by LH, to have increased over a just few years from 30% to 50% over just a few years.[6] This speed of change in practice,

driven by surgical technologies and clinician enthusiasm, is highlighted further when considering the rapid increase in uptake of robotics.[51,52] When conceptualising the LAVA trial, robotically assisted LH was in its infancy within the NHS, so we did not include it within the LH group, but now it is estimated that up to 43%[53] of LHs are performed robotically, and this is set to rise further, despite any formal clinical or economic comparative evaluations. In our defence, the pre-trial clinician surveys had shown initial enthusiasm for participation that was not ultimately borne out.

We have analysed and reported the key outcomes acquired until the trial was discontinued following implementation the Department of Health and Social Care 'Research Reset programme'.[54] No differences were found in complications or recovery between LH and AH. However, the early cessation of the trial due to recruitment challenges limit clinical inferences. The results of the LAVA trial suggest that women can be counselled that while there is a small but significant risk of major complications, a problematic or protracted recovery is unusual, following a hysterectomy for a benign condition being undertaken by either a laparoscopic or open route. Women can be informed that most patients resume their normal activities at levels commensurate with their preoperative abilities within 8 weeks of their procedure and are satisfied with the result of surgery.

It is disappointing that we were unable to recruit to the LAVA trial, and it seems unlikely that such an ambitious, large-scale, pragmatic, multicentre trial evaluating surgical techniques and approaches in hysterectomy, one of the commonest operations in gynaecological practice, will ever be deliverable in the future. Large, multicentre surgical trials that can answer relevant clinical questions are scarce, because they are difficult to accomplish.[33,37] It remains important, however, that rigorous, comparative clinical studies are conducted now that LH, including robotics, is becoming adopted as standard practice. The safety and recovery benefits need to be evaluated as well as the economic consequences important to the NHS and wider society. It is important to justify the increasing equipment costs, including robotic technologies and concerns over environmental sustainability from greater use of disposable equipment in LH.[55]

Such studies may need to adopt novel designs and innovations to educate, enthuse and incentivise both patients and clinicians, surmounting the challenges posed by surgical trials especially around the lack of surgeon equipoise. From the bureaucratic point of view, simplification of study processes to expedite study site set-up, along with increased accountability and funding to motivate local R&D departments and PIs, is necessary. Hopefully, the LAVA trial has illuminated some of the obstacles to successfully conducting robust trials in major gynaecological surgery for benign conditions. This knowledge will hopefully allow the design and successful delivery of future research studies in this field.

Additional information

CRediT contribution statement

T Justin Clark (https://orcid.org/0000-0002-5943-1062): Conceptualisation (lead), Data curation (supporting), Formal analysis (supporting), Funding acquisition (lead), Investigation (equal), Methodology (equal), Project administration (supporting), Supervision (equal), Visualisation (equal), Writing – original draft (lead), Writing – reviewing and editing (equal).

Lina Antoun (https://orcid.org/0000-0003-4893-0576): Investigation (supporting), Visualisation (supporting), Writing – reviewing and editing (equal).

Rebecca Woolley (https://orcid.org/0000-0001-5119-1431): Data curation (equal), Investigation (equal), Methodology (equal), Software, Validation (equal), Writing – original draft (supporting), Writing – reviewing and editing (supporting).

Sheriden Bevan (https://orcid.org/0000-0002-0389-4412): Investigation (equal), Project administration (equal), Resources (equal), Writing – reviewing and editing (supporting).

Kamila Ziomek (https://orcid.org/0009-0001-9432-8378): Investigation (equal), Project administration (supporting), Resources (equal), Writing – reviewing and editing (supporting).

William McKinnon (https://orcid.org/0000-0001-8734-2932): Investigation (equal), Project administration (equal), Resources (equal), Writing – reviewing and editing (supporting).

Paul Smith (https://orcid.org/0000-0002-1430-5732): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

Kevin Cooper (https://orcid.org/0000-0003-1486-0071): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

Ertan Saridogan (https://orcid.org/0000-0001-9736-4107): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

This synopsis should be referenced as follows:
Clark TJ, Antoun L, Woolley R, Bevan S, Ziomek K, McKinnon W, *et al.* Laparoscopic hysterectomy versus open abdominal hysterectomy for women with a benign gynaecological condition: the LAVA RCT. *Health Technol Assess* 2026;**30**(14):1–28. https://doi.org/10.3310/GJTC1718

Bibi Zeyah Sairally (https://orcid.org/0000-0001-5704-6489): Investigation (equal), Visualisation, Writing – reviewing and editing (supporting).

Jayne Fullard (https://orcid.org/0000-0002-9437-7356): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

Monique Morgan (https://orcid.org/0009-0008-7172-9604): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

Lynsay Matthews (https://orcid.org/0000-0002-5760-1080): Investigation (equal), Methodology, Writing – reviewing and editing (supporting).

Laura Jones (https://orcid.org/0000-0002-4018-3855): Data curation, Funding acquisition (supporting), Investigation (equal), Methodology (equal), Supervision (equal), Writing – reviewing and editing (supporting).

Tracy Roberts (https://orcid.org/0000-0002-0624-0537): Funding acquisition (supporting), Investigation (equal), Writing – reviewing and editing (supporting).

Lee Middleton (https://orcid.org/0000-0003-4621-1922): Data curation (equal), Funding acquisition (supporting), Investigation (equal), Methodology, Software (equal), Supervision (equal), Validation (equal), Writing – original draft (supporting), Writing – reviewing and editing (supporting).

Acknowledgements

The authors wish to thank:

- Independent members of the (1) Trial Steering Group and (2) Data Monitoring Committee who oversaw this study:

(1) Patrick Chien (Gynaecologist) (Chair), Elizabeth Ball (Gynaecologist), Gilly McDonald (Gynaecology nurse), Lazaros Andronis (Health Economist), Soo as cae (Qualitative researcher), Nicki Burnett (PPI), Louise Linsell (Statistican).

(2) Simon Skene (Clinical Trialist/statistician), Peter O'Donovan (Gynaecologist), Tyrone Carpenter (Gynaecologist).

Members of the Trial Management Group: T Justin Clark (Chief Investigator), Lee Middleton (Statistics Lead), Jayne Fullard (PPI), Monique Morgan (PPI), Kevin Cooper (Gynaecologist), Ertan Saridogan (Gynaecologist), Laura Jones (Qualitative and Mixed-Methods Health Research Lead), Paul Smith (Gynaecologist), Lina Antoun, Bibi Zeyah Sairally, Tracy Roberts (Health Economics Lead), William McKinnon (BCTU Team Leader).

Peter Brocklehurst (previous Director of the University of Birmingham Clinical Trials Unit and LAVA trial co-applicant) for his contribution to the research design, support, initial oversight, advice and guidance.

LAVA recruiting sites:

Opened site	Staff
Aberdeen Royal Infirmary	Kevin Cooper (PI), Danielle Pirie
Aneurin Bevan University Health Board	Miroslava Slavska (PI), Tracey James, Hayley Forbes, Jamie Morris, Jo Kitt
Basildon University Hospital	Yatin Thakur (PI), Princess Gabiana Miranda Forsey, Joanne Riches, Raiji Koothoor
Birmingham Women's and Children's NHS Foundation Trust	T Justin Clark (PI), Faye Andrews, Lina Antoun, Fiona Beale, Parminder Chana, Clare Hannon, Kirsty Parkes, Zeyah Sairally, Paul Smith
Bradford Royal Infirmary	Carmel Ramage (PI), Tom Pettinger, Kari Swettenham, Kate Pittendreigh, Jenny Butler, Jennifer Syson, Hannah Brookes, Anne Bowyer Georgina Goodaire
Macclesfield District General Hospital	Jyotsna Acharya (PI), Joanne Bradley-Potts, Katherine Rose, Natalie Keenan, Emma Jones
Manor Hospital, Walsall	Archana Hatti (PI), Betty Ojong, Danielle Pyatt, Robert Chadwick, Tasmin Akhtar
Queen Alexandra Hospital, Portsmouth	Janet Berry (PI), Deirdre Rodgers, Emma Helyer
Royal Bolton Hospital	Prasanta Chattopadhyay (PI), Kat Rhead, Shirley Cocks, Scott Latham, Emma Tanton, Rebecca Flanagan
Southend University Hospital	Munawar Hussain (PI), Lester De Silva, Ali Shokou Amiri, Beena Saji, Raiji Koothoor, Bernard Hadebe
St Thomas' Hospital. London	Tom Holland (PI), Leanna Brace, Kawai Chan,
University Hospital Lewisham, London	Javaid Muglu (PI), Richa Kalia, Olatanwa Ogbara, Lara Robles Gutierrez, Chidera Onyeagor
University Hospital of North Durham	Partha Sengupta (PI), Sachinta Wijesiri, Michelle Wood, Jamie Greenwood

• LAVA sites in set-up: Thanks to the eight additional sites in set-up.

• Participants: The authors also gratefully acknowledge the support of the participants who consented and were randomised into LAVA, as well as those who were approached and considered participation in LAVA.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

LAVA was reviewed by the West Midlands-Edgbaston Research Ethics Committee. REC approval for the protocol was issued on 18 February 2021. IRAS ID: 287988.

All participants gave written informed consent before participation. The trial was being conducted in accordance with the Research Governance Framework for Health and Social Care, the applicable UK Statutory Instruments (which include the Data Protection Act 1998) and the Principles of GCP.

Information governance statement

All personal information was processed in accordance with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Birmingham and NHS West Midlands is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for the University of Birmingham Data Protection Officer here legalservices@contacts.bham.ac.uk

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJTC1718.

Primary conflicts of interest: T Justin Clark declares receiving fees for running educational courses from Medtronic who manufacture energy modalities for laparoscopic surgery, Baxter Medical who make anti-adhesives and haemostats for use in surgery and Arthrex who manufacture endoscopic operating monitors/stacks. He was a member of HTA prioritisation Committees 2017–22.

Ertan Saridogan declares receiving fees from running educational courses for the following surgical technology companies: Arthrex, Hologic, Intuitive, Karl Storz, Medtronic and Olympus.

Monique Morgan and Tracy Roberts are Trustees of FABRIC and Independent Directors of Queen Alexandra College.

None of the other authors declare a conflict of interest.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Antoun L, Middleton L, Smith P, Saridogan E, Cooper K, Brocklehurst P, *et al*. LAparoscopic versus Abdominal hysterectomy (LAVA): protocol of a randomised controlled trial. *BMJ Open* 2023;**13**:e070218. https://doi.org/10.1136/bmjopen-2022-070218

Antoun L, Bevan S, Mahmud A, Jones L, Middleton L, Woolley R, *et al*. Lessons learnt from the multi-centre LAparoscopic versus Abdominal hysterectomy (LAVA) randomised controlled trial. *Facts Views Vis Obgyn* 2024;**16**:35–45. https://doi.org/10.52054/FVVO.16.1.003

Matthews L, Clark TJ, Bevan S, Middleton L, Antoun L, Smith P, *et al*. Feasibility, acceptability and appropriateness of LAparoscopic Versus Abdominal hysterectomy for women and healthcare professionals: the LAVA trial qualitative process evaluation [published online ahead of print July 23 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/GJTC1325

Antoun L, Woolley R, Middleton L, Smith P, Saridogan E, Cooper K, *et al*. Comparison of complications and recovery after laparoscopic and abdominal hysterectomy for benign disease: the LAparoscopic versus Abdominal hysterectomy (LAVA) randomised controlled trial. *BMJ Open* 2025;**15**:e096265. https://doi.org/10.1136/bmjopen-2024-096265

Trial registration

This trial is registered as ISRCTN14566195.

Funding

This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number NIHR128991.

This synopsis provided an overview of the research award *LAparoscopic Versus Abdominal hysterectomy (LAVA) trial*. For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR128991).

About this synopsis

The contractual start date for this research was in July 2020. This synopsis began editorial review in July 2024 and was accepted for publication in July 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' synopsis and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this synopsis.

List of abbreviations

AH	abdominal hysterectomy
BCTU	Birmingham Clinical Trials Unit
BMI	body mass index
BSGE	British Society for Gynaecological Endoscopy
COS	core outcome set
CRF	case report form
EBL	estimated blood loss
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
HCP	healthcare professional
ICC	intracluster correlation coefficient
LAVA	LAparoscopic Versus Abdominal hysterectomy
LH	laparoscopic hysterectomy
MRC	Medical Research Council
NIHR	National Institute for Health and Care Research
NRS	Numerical Rating Scale
PI	principal investigator
PPI	patient and public involvement
PROMIS-PF	Patient-Reported Outcomes Measurement Information System Physical Function
QALY	quality-adjusted life-year
QoL	quality of life
QoR	quality of recovery
QPE	qualitative process evaluation
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
R&D	research and development
SMS	Short Message Service
TMG	Trial Management Group
VAS	visual analogue scale

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