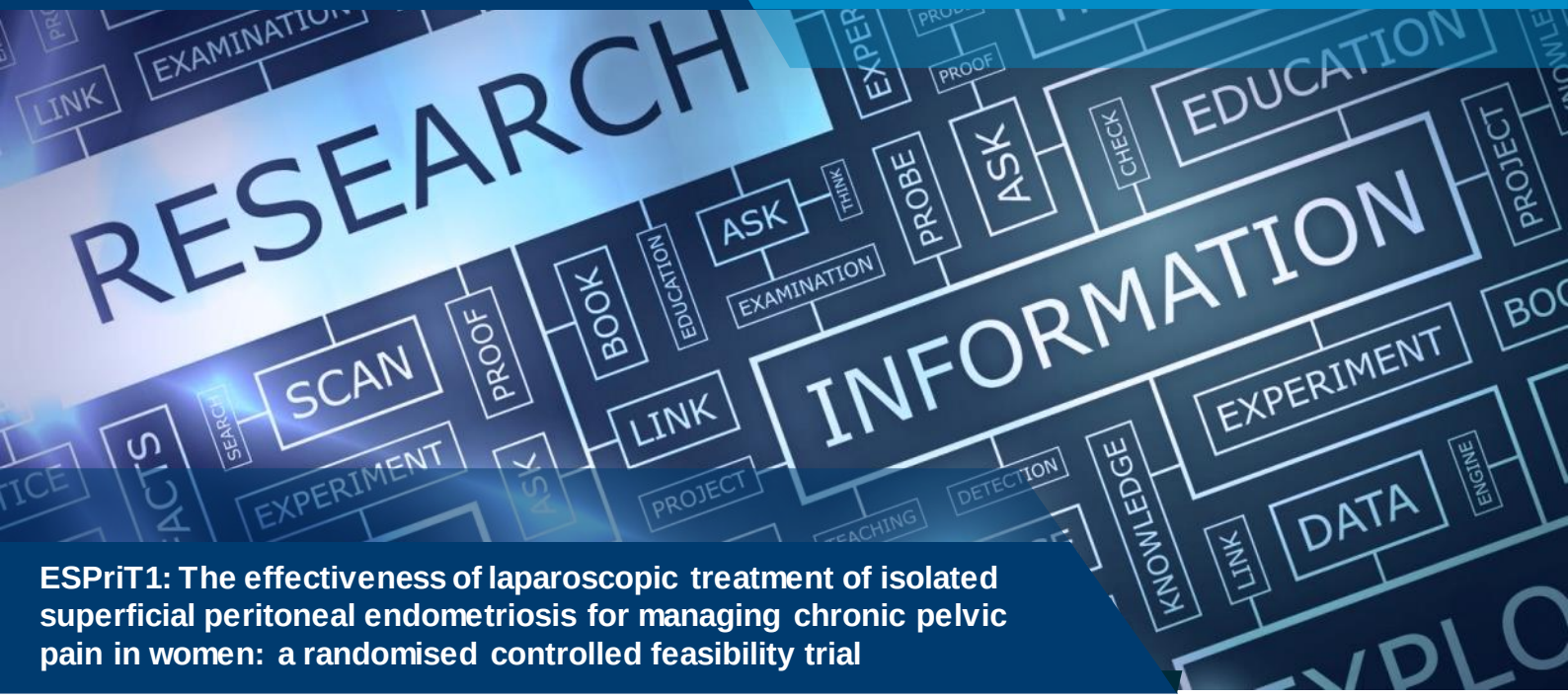
CHIEF SCIENTIST OFFICE

CODE: TCS/18/43

RESEARCH PROJECT BRIEFING



ESPriT1: The effectiveness of laparoscopic treatment of isolated superficial peritoneal endometriosis for managing chronic pelvic pain in women: a randomised controlled feasibility trial

AIMS

The aim of this feasibility trial, called ESPriT1, was to inform a future large trial across the UK where women who have only 'superficial peritoneal' endometriosis (endometriosis lesions on the pelvic lining) found at laparoscopy (keyhole surgery) are randomly allocated to have surgical removal of disease or to not have it treated surgically straightaway. Ultimately, we want to determine whether surgical management improves overall pain symptoms and quality of life, or whether surgery is of no benefit or exacerbates symptoms. In ESPriT1, we aimed to determine what proportion of women with chronic pelvic pain undergoing laparoscopic investigation for suspected endometriosis would be willing to take part and how best to design the future trial.

KEY FINDINGS

- Between October 2019 and February 2021, in three Scottish centres, 46% of eligible women (26/57) consented to randomisation.
- Seven women have undergone surgery and been randomised to date.
- 19 participants did not have superficial peritoneal endometriosis found at laparoscopy so they were not eligible for randomisation.
- Six of the randomised participants have completed six months follow-up and remain in the study, and three participants have completed 12 months follow up.
- The majority of participants described their trial experience favourably supporting a similar design for our future definitive randomised controlled trial.

WHAT DID THE STUDY INVOLVE?

- We recruited women with suspected superficial peritoneal endometriosis undergoing diagnostic laparoscopy over a 16-month recruitment period in three Scottish centres (Dundee, Aberdeen and Edinburgh) and randomised them 1:1 to either diagnostic laparoscopy alone or surgical removal of endometriosis. Our planned fourth Scottish centre was unable to open due to the impact of COVID.
- Participants were followed up by online questionnaires assessing pain, physical and emotional function at baseline, 3 months, 6 months and 12 months.
- We calculated the proportion of eligible women who agreed to take part and consented to the trial, recorded the number of participants who underwent surgery and were randomised, and of randomised participants who were followed up to 12 months.
- An acceptability questionnaire was used to assess participants' experiences of the trial.
- We involved patient representatives and members of the relevant professional surgical societies throughout the study to help increase buy-in of the trial by highlighting the importance of the research question and the worthiness of the placebo design.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

- **The COVID pandemic impacted considerably on the progress of our trial because all elective gynaecological surgery was paused for six months during the recruitment phase.**
- **Nonetheless, from 57 eligible women, we consented 26 women (46%) and seven participants have undergone surgery and been randomised to date. 19 participants did not have superficial peritoneal endometriosis found at laparoscopy so they were not eligible for randomisation. The commonest example of reasons recorded for 'not wanting to participate' was 'prefers to have endometriosis treated at time of surgery'.**
- **The majority of participants described their overall trial experience favourably, and rated it 1 or 2 on a 5-point scale from positive to negative. Positive responses were recorded for the recruitment approach used, paperwork burden for participants and the experience of randomization of participants.**

WHAT IMPACT COULD THE FINDINGS HAVE?

- This study with embedded evaluation of trial processes and collection of outcome data, allowed us to undertake detailed feasibility work to inform a future large-scale trial in the important but challenging area of surgery for endometriosis-associated pain.
- As a result of the trial, we have secured substantive NIHR/HTA funding to support "ESPriT2: a multi-centre randomised controlled trial to determine the effectiveness of laparoscopic removal of isolated superficial peritoneal endometriosis for the management of chronic pelvic pain in women" (see www.ed.ac.uk/centre-reproductive-health/esprit2).

HOW WILL THE OUTCOMES BE DISSEMINATED?

The results of ESPriT1 will be published in peer-reviewed journals and presented at international conferences.

The clinical study report will be used for publication and presentation at scientific meetings. We will make the information obtained from the study available to the public through national and international bodies, e.g. Endometriosis UK and Endometriosis.org.

CONCLUSION

Recruitment to a randomised controlled trial to assess the effectiveness of surgery for endometriosis can be challenging because of preconceived ideas about treatment success amongst patients. However, this study showed feasibility of recruitment and has helped to inform the design of (including sample size), and secure funding for, a future definitive multicentre trial.

RESEARCH TEAM & CONTACT

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Additional Information

Recruitment to ESPriT1 was completed on 31 March 2021 (data analysis is ongoing and will contribute to ESPriT2). The CSO provided £162,561 to support the trial.