Gynecologic Oncology 198 (2025) 96–103

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

Integration of self-hypnosis in an enhanced recovery after surgery program in gynecologic oncology – A prospective randomized trial

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HIGHLIGHTS

- Self-hypnosis before open gynecologic oncology surgery significantly decreased anxiety levels but not postoperative pain.
- Self-hypnosis with an audiofile was not associated with improved quality of life, or opioid use during hospital admission.
- Incorporating self-hypnosis to an enhanced recovery pathway was feasible with high levels of satisfaction.

ARTICLE INFO

Article history:
Received 4 February 2025
Received in revised form 16 May 2025
Accepted 20 May 2025
Available online 3 June 2025

Keywords:
Self-hypnosis
ERAS
Open gynecologic surgery
Postoperative pain
Anxiety

ABSTRACT

Objective. To evaluate whether adding self-hypnosis (SH) to our enhanced recovery after surgery (ERAS) pathway was feasible and could improve patient-reported pain.

Methods. Patients undergoing exploratory laparotomy were randomized to ERAS or ERAS+SH. Patients in the ERAS+SH arm were asked to listen a SH audio file in the preoperative holding area. Feasibility endpoint was defined as 60 % of patients listening to the audio in the preoperative holding area. Primary effectiveness outcome was patient-reported worst pain on postoperative day 1. Secondary outcomes included patient-reported anxiety, quality of life, symptom burden, time to first opioid, morphine equivalent daily dose after surgery, and satisfaction with the SH experience.

Results. 152 patients were randomized and 138 underwent open gynecologic surgery and were evaluable: 67 (48.6 %) to ERAS and 71 (51.4 %) to ERAS+SH. Incorporation of SH was considered feasible with 77.5 % of patients listening to the entire audio file in the holding area. The study was closed prematurely before achieving the $N = 224$ sample size due to futility in achieving the primary effectiveness outcome. There were no significant group differences in patient-reported worst pain on postoperative day 1, median morphine equivalents during admission or time to first opioid after surgery. In the ERAS+SH arm, there was a 2-point decrease (median score of 2; IQR 1–3; $p < 0.001$) in anxiety scores after the SH intervention. Median scores on satisfaction questions were 8/10 or above.

Conclusions. Incorporating SH to an ERAS pathway was feasible with high levels of satisfaction. While the SH intervention statistically and clinically significantly decreased self-reported anxiety, there was no improvement in self-reported pain, quality of life, time to first opioid, or opioid consumption during admission.
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1. Introduction

Enhanced recovery after surgery (ERAS) programs significantly decrease intraoperative and post-operative opioid use, length of stay and

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https://doi.org/10.1016/j.ygyno.2025.05.018
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complications [1–3]. Although ERAS programs are successful, continued efforts to reduce opioid use nationwide are warranted [4,5]. Implementation of an ERAS care pathway in our center for women undergoing open gynecologic surgery decreased opioid intake postoperatively during admission by 72 % with 16 % of patients remaining opioid-free in the first three postoperative days [6]. These outcomes were obtained without an increase in patient-reported pain scores.

Studies have suggested an association between preoperative anxiety and postoperative pain [7–9]. Psychological distress has been correlated with both postoperative pain as well as consumption of postoperative analgesics [7]. Additionally, preoperative emotional distress has been associated with impaired recovery after surgery [10]. Stengrevics et al. reported a significant association of preoperative anxiety on postoperative complications after cardiac surgery [11]. Other studies reported that increased state anxiety resulted in impaired wound healing after inguinal hernia repair and after a standardized wound in volunteers [12,13]. Therefore, we hypothesized that interventions addressing perioperative anxiety or distress could diminish patients' experience of pain perioperatively and improve ERAS programs.

Self-hypnosis (SH) has been investigated as a method for improving outcomes when undergoing surgical procedures [14–16]. SH involves inducing patients into a hypnotic state through deep breathing, guided imagery, and a focus on a floating sensation to help with dissociation [17]. In a variety of surgical populations using prospective randomized clinical trial designs, patients induced into self-hypnotic relaxation during their procedure reported significantly less anxiety and pain and requested less analgesic medication than controls [14–16]. These studies also demonstrated decreased heart rate, lower blood pressure, and reduced cortisol [18,19]. Montgomery [20] found in a mixed population of women either undergoing hypnosis during biopsy or before lumpectomy surgery with general anesthesia that SH lead to less: pain intensity, use of propofol and lidocaine, fatigue, discomfort, nausea, and pain unpleasantness, and were less emotionally upset than the control group after the surgery was completed. Meta-analyses by Schnur [16] and Tefikow [21] suggest that SH results in medium to large effect sizes in subjective outcomes and smaller effects for analgesic use and physiological outcomes. Schnur examined studies that measured the effect of SH in reducing distress (anxiety) or emotional well-being (relaxation) and found an effect size of 0.88 in favor of hypnosis [16]. They also noted that the effects were larger when SH was delivered before and during the medical procedures. Tefikow [21] reported a medium effect size for emotional distress (0.53), pain unpleasantness (0.56), pain intensity (0.36) and medication consumption (0.38), and smaller but significant effect sizes for recovery, procedure time, and physiological parameters, with enhanced effects when the SH was done before and during the procedures. Yet for most of these studies, the SH was delivered by a trained health care professional. Given potential challenges of needing a live person regarding more widespread implementation, we aimed to determine if the use of a pre-recorded audio-delivered SH in the preoperative setting was feasible. Additionally, we aimed to assess if SH was effective by comparing postoperative self-reported pain and anxiety scores in patients undergoing open gynecological surgery under the ERAS pathway versus patients who received ERAS+SH.

2. Methods

2.1. Study design and population

This was a single center, prospective randomized study of preoperative SH in patients undergoing open gynecologic surgery on an ERAS pathway, following published guidelines [22–24]. All patients received preoperative counselling and education about surgical and anesthetic procedures, as well as the care plan for pain management in the postoperative setting. This protocol was approved by the institutional review board (Protocol 2018–0413). There were dual primary outcomes to assess feasibility and effectiveness. Feasibility was defined as 60 % of patients listening to the entire SH audio file in the preoperative holding area. Partial listening was not considered feasible. The self-hypnosis script was developed in collaboration with MD Anderson's Integrative Medicine Program following prior research by Lang in patients undergoing invasive procedures [18,25]. It was a 20-min pre-recorded audio file inducing patients into a hypnotic state through deep breathing, guided imagery, and a focus on a floating sensation to help with dissociation. The primary effectiveness outcome was worst pain on postoperative day (POD)1 on a 0–10 scale assessed with the MD Anderson Symptom Inventory PeriOPGyn instrument (MDASI) [26]. Patients were asked to complete MDASI-PeriOPGyn at baseline, daily while admitted, day 3 and 7 after discharge and weekly to complete 6 weeks from the date of discharge. Secondary outcomes measured included anxiety on a 0–10 numeric rating scale (NRS) [14], symptom burden (MDASI-PeriOPGyn), time to first opioid, and morphine equivalent daily dose (MEDD). Verbally self-reported anxiety was assessed on a 0 to 10 scale, with 0 being no anxiety and 10 being worst anxiety. NRS is frequently used to assess anxiety trajectory throughout a medical procedure [14] and is considered a reliable descriptor of the anxiety experience from numerous other studies [27–29]. Satisfaction with the SH procedure was assessed 14 days after surgery for participants in the ERAS+SH arm. Participants were asked to rate on a scale 0–10 how useful they found the SH audio intervention, how easy it was to follow the instructions, whether they would participate in the program again, and whether they would recommend it to a friend. Hypnotic suggestibility was assessed at baseline with the Tellegen Absorption Scale [30]. Expectations and manageability of post-surgery symptoms (anxiety, pain, nausea, vomiting, and fatigue) were assessed at baseline using an adapted version of the Side-Effect Expectancy Questionnaire (SEEQ) [31].

Participants had to be 18 years or older and undergo exploratory laparotomy for a suspected or known cancer on our ERAS pathway. Full inclusion and exclusion criteria are outlined in Supplemental Table 1. After signing informed consent patients were randomized using REDCap [32] in a 1:1 fashion (ERAS pathway (Arm 1), ERAS pathway +SH (Arm 2)). Patients on both arms were provided with an MP3 player which was empty for those on Arm 1 and preloaded with the SH audio file for those on Arm 2. Patients randomized to the intervention arm were instructed to listen the SH audio file one time in the hospital at the time of their preoperative clearance visit and while not required, encouraged to use it at least once a day leading up to surgery. Baseline anxiety was obtained at time of consenting, during the preoperative visit for patients in both arms. On the day of surgery, a research data coordinator met with the patient in the preoperative holding room to assess reported anxiety. Self-reported anxiety was assessed once for patients on Arm 1 (as they did not have any intervention performed) and for those on Arm 2 both before and after they listened to the SH audio file at baseline and day of surgery. Participants verbally conveyed their anxiety scores to the research team. A change of 1 or greater on a 0–10 numeric rating scale is considered clinically significant.

2.2. Data collection

Study data were collected and managed using REDCap [32]. Demographic and clinical data were extracted from medical records including patient age, body mass index (BMI), ethnicity and race, tumor type and primary site. American Society of Anesthesiologists (ASA) classification and Charlson Comorbidity Index (CCI) [33] assessed comorbidities. Intraoperative data collected included procedure type, duration of surgery, and intraoperative MEDD. Postoperative data collected included incidence and severity of pain, medication use, MEDD, and length of stay. Complications, readmissions, and reoperations were recorded for 30 days after surgery. The Clavien-Dindo grading system [34] was used to characterize complications. Adverse events were assessed at baseline and during preoperative holding, after listening to the SH audio file.

2.3. Statistical analysis

A sample size of 106 per arm was estimated to yield at least 80 % power to detect a 2 points difference in the median pain scores between the treatment arms using a two-sided Wilcoxon rank sum test with $\alpha = 0.05$. To account for 5 % attrition, we increased the target accrual to 112 patients per arm (224 patients total). A planned interim analysis for feasibility was conducted after 30 patients were randomized to the intervention arm. Feasibility was defined as 60 % of patients on the SH arm listening to the complete audio file on the day of surgery in the preoperative holding area. If the SH intervention was found to be not feasible the trial would have been suspended.

Descriptive statistics for patients' clinical/demographic characteristics and questionnaires were reported as median and inter-quartile range (IQR) for continuous variables, and percent for categorical variables. Differences in symptom severity between arms were tested by the Wilcoxon rank-sum test at POD1 and discharge timepoints. Severity of MDASI symptoms was defined as moderate (5–6) and severe (≥7). Treatment arm differences in percentage of moderate-to-severe symptom scores was tested by Pearson's chi-square test at POD1 and discharge time points.

Longitudinal mixed-effect models were used to determine if symptom reduction over time differed between treatment arms. In these models, the outcome measure was the score of a selected MDASI item as a continuous variable; the predictor variables were POD as a continuous variable and treatment arm as a categorical variable. Postoperative functional recovery was defined as the patient reporting two consecutive postoperative interference ratings below a score of 4. Recovery days since surgery by treatment arm were estimated for each selected MDASI item using Kaplan-Meier analysis, and log-rank tests were used to compare time to postoperative functional recovery by treatment arm.

All statistical procedures were performed using SAS statistical software, version 9.4 (SAS Institute, Cary, NC). All *p*-values are 2-tailed. Statistical significance was set at $P < 0.05$.

3. Results

A total of 152 patients consented and were randomized from October 2018 to October 2020. There were 4 patients who withdrew consent from study before surgery and 10 patients whose surgery got cancelled or surgical approach changed to minimally invasive surgery, so 138 underwent open gynecologic surgery and were evaluable: 67 (48.6 %) to ERAS and 71(51.4 %) to ERAS+SH (Fig. 1). Patient demographic and clinical characteristics are shown in Table 1.

The SH intervention was feasible (co-primary feasibility endpoint) as of the first 30 eligible patients randomized to the SH arm, 25 (83.3 %) patients listened to the entire audio file on the day of surgery while in the preoperative holding area. During active accrual, the Data Safety Monitoring Board at MD Anderson requested an interim analysis on the co-primary effectiveness outcome of self-reported pain on POD1 as measured by the MDASI-PeriOpGYN. The study was closed prematurely before achieving the $N = 224$ sample size due to futility in achieving the primary effectiveness outcome. The DSMB determined that even with full accrual, the data indicated that no significant differences in pain scores on POD1 would be observed.

Patients in both arms exhibited similar levels of hypnotic suggestibility when assessed with the Tellegen Absorption Scale at time of randomization (ERAS = 16 (IQR 8–20), ERAS+SH = 17 (IQR 9–22) $p = 0.31$). More patients in the ERAS+SH arm expected to have pain after surgery, with no differences for the other symptoms (anxiety, nausea, vomiting, fatigue). Regarding the perceived ability to manage postoperative symptoms, both arms reported similar scores. (Table 5).

Intraoperatively, there were no differences in terms of anesthesia technique, surgical time, surgical complexity, estimated blood loss or MEDD administered during surgery. Postoperatively, there were no significant differences in the median length of stay, complications, readmissions, and reoperations between both arms (Supplemental Table 2).

There were no differences in median anxiety scores comparing both groups during the preoperative visit (ERAS = 3 (IQR 1–6) vs ERAS +SH = 3 (IQR 1–5) $p = 0.65$) or in the holding area (ERAS = 4 (IQR

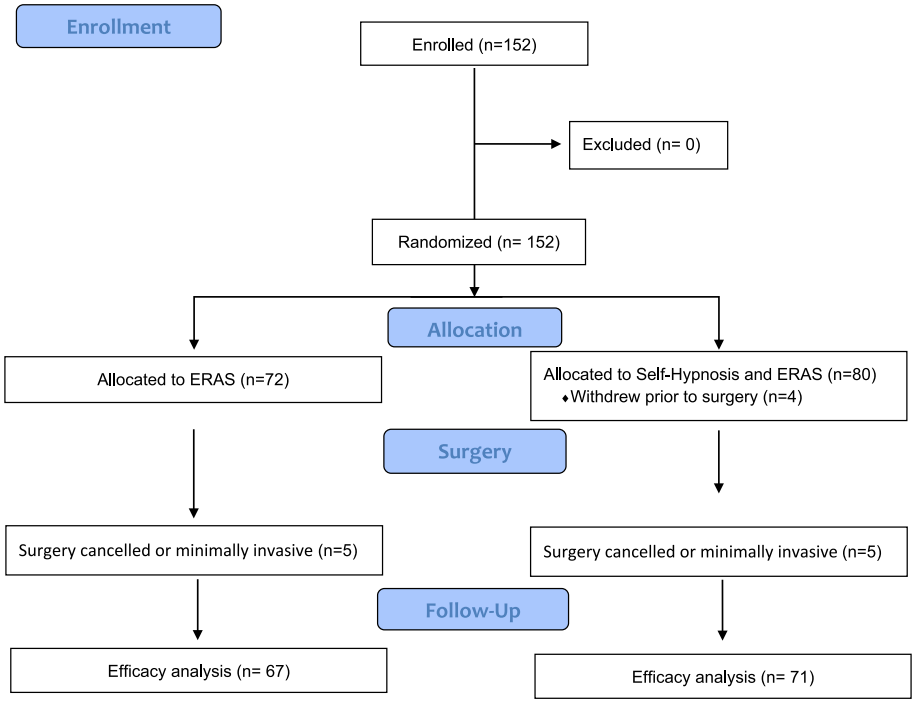

Fig. 1. CONSORT diagram.

Table 1
Demographic and clinical characteristics.

	ERAS ($N = 67$)	ERAS +SH ($N = 71$)	Total ($N = 138$)
Age at Surgery			
Median (IQR)	61 (46, 69)	54 (40, 64)	57 (44, 67)
Race, n (%)			
White or Caucasian	57 (85 %)	54 (76 %)	111 (80 %)
Black or African American	3 (4 %)	6 (8 %)	9 (7 %)
Asian	4 (6 %)	3 (4 %)	7 (5 %)
American Indian or Alaskan Native	1 (1 %)	0 (0 %)	1 (1 %)
Other	2 (3 %)	8 (11 %)	10 (7 %)
Ethnicity, n (%)			
Hispanic or Latino	8 (12 %)	13 (18 %)	21 (15 %)
Not Hispanic or Latino	59 (88 %)	58 (82 %)	117 (85 %)
Marital Status, n (%)			
Married	47 (70 %)	46 (65 %)	93 (67 %)
Single	7 (10 %)	12 (17 %)	19 (14 %)
Divorced	6 (9 %)	7 (10 %)	13 (9 %)
Widowed	7 (10 %)	4 (6 %)	11 (8 %)
Significant Other	0 (0 %)	2 (3 %)	2 (1 %)
Employment Status, n (%)			
Unemployed	26 (39 %)	28 (39 %)	54 (39 %)
Employed Part-Time	4 (6 %)	1 (1 %)	5 (4 %)
Employed Full-Time	37 (55 %)	41 (58 %)	78 (57 %)
Student	0 (0 %)	1 (1 %)	1 (1 %)
Highest Level of Education, n (%)			
Grade School	1 (1 %)	1 (1 %)	2 (1 %)
Not High School Graduate	2 (3 %)	2 (3 %)	4 (3 %)
High School Graduate	9 (13 %)	14 (20 %)	23 (17 %)
Some College of Associate Degree	21 (31 %)	19 (27 %)	40 (29 %)
Bachelor's Degree	15 (22 %)	21 (30 %)	36 (26 %)
Master's Degree	15 (22 %)	7 (10 %)	22 (16 %)
Doctoral Degree or Professional Degree	4 (6 %)	7 (10 %)	11 (8 %)
BMI (kg/m^2) (Preop)			
Median (IQR)	27.0 (23.0, 33.1)	29.1 (23.3, 34.7)	28.2 (23.2, 33.5)
ASA Physical Status Class, n (%)			
I	1 (1 %)	0 (0 %)	1 (1 %)
II	7 (10 %)	6 (8 %)	13 (9 %)
III	59 (88 %)	65 (92 %)	124 (90 %)
ECOG Score, n (%)			
0	53 (79 %)	60 (85 %)	113 (82 %)
1	10 (15 %)	9 (13 %)	19 (14 %)
2	2 (3 %)	1 (1 %)	3 (2 %)
Unknown	2 (3 %)	1 (1 %)	3 (2 %)
Current Tumor, n (%)			
Malignant - Primary	53 (79 %)	54 (76 %)	107 (78 %)
Malignant - Recurrent	6 (9 %)	6 (8 %)	12 (9 %)
Benign	3 (4 %)	6 (8 %)	9 (7 %)
Neoplasm of Uncertain Malignant Potential - Primary	2 (3 %)	2 (3 %)	4 (3 %)
Malignant - Dual Primary	3 (4 %)	3 (4 %)	6 (4 %)
Charlson Comorbidity Index, n (%)			
0–1	16 (24 %)	30 (42 %)	46 (33 %)
2–4	47 (70 %)	35 (49 %)	82 (59 %)
≥ 5	4 (6 %)	6 (8 %)	10 (7 %)
History of Tobacco Use (Smoking), n (%)			
No	42 (63 %)	49 (69 %)	91 (66 %)
Current	8 (12 %)	4 (6 %)	12 (9 %)
Former	17 (25 %)	18 (25 %)	35 (25 %)
History of Alcohol Use, n (%)			
No	32 (48 %)	32 (45 %)	64 (47 %)
Yes	34 (52 %)	39 (55 %)	73 (53 %)
Missing	1	0	1
History of Chronic Pain, n (%)			
No	61 (91 %)	59 (84 %)	120 (88 %)
Yes	6 (9 %)	11 (16 %)	17 (12 %)
Missing	0	1	1
Chronic Opioid Use, n (%)			
No	67 (100 %)	71 (100 %)	138 (100 %)

IQR, interquartile range

Table 2
Anxiety and self-hypnosis.

		ER ERAS ($N = 67$)	ERAS + SH ($N = 71$)	P-value
Baseline (Pre-Op)	**How would you rate your anxiety on a scale from 0 to 10?**[§]			
	Before SH intervention, Median (IQR)	3 (1–6)	3 (1–5)	0.65[1]
	After SH Intervention, Median (IQR)	–	1 (0–3)	
	Decrease in Anxiety	–	2 (1–3)	<0.001[1]
Holding	**How would you rate your anxiety on a scale from 0 to 10?**[§]			
	Before SH Intervention, Median (IQR)	4 (1–6)	4 (3–7)*	0.09[1]
	After SH Intervention, Median (IQR)	–	2 (1–5)	
	Decrease in Anxiety	–	2 (1–3)	<0.001[1]

IQR, interquartile range; SH, self-hypnosis.
[1] Wilcoxon rank sum *p*-value.
* $n = 70$.
[§] (0 being No Anxiety and 10 being the Worst Anxiety).

1–6) vs ERAS+SH = 4 (IQR 3–7) $p = 0.09$) (Table 2). In the ERAS+SH arm, there was both a statistically and clinically significant reduction in anxiety scores reported before and after the SH intervention when they first listened to the SH recording during the preoperative appointment and in also the holding area before surgery, median reduction of 2 points (IQR1–3) $p < 0.001$ (Table 2).

There were no significant differences in the worst pain experienced on POD1 between the two arms (ERAS = 6 (IQR 5–8), ERAS+SH = 7 (IQR 5–8), p = 0.31), as assessed using the MDASI- PeriOPGyn. Furthermore, the analysis of opioids administered measured by MEDD on POD1–3 did not reveal significant arm differences (Table 3). The daily MEDD ranged from 0 to 35, indicating consistency in opioid use across the arms. Median time to first opioid administration on the floor after surgery was 10.4 h for both arms.

The longitudinal mixed models analysis selected MDASI items (pain, fatigue, drowsiness, sleep disturbance, general activity, walking, mood, and distress) to model symptom reduction over time and between treatment arms. There were no significant arm differences in symptom reduction over time (Supplemental Table 3). The median time to return to mild pain on Kaplan-Meier analysis was not significantly different between the 2 arms (Supplemental Fig. 1).

Satisfaction with the self-hypnosis audio intervention was assessed 14 days after surgery. Patients reported high levels of satisfaction, with most responses falling within the higher end of the satisfaction scale. The median scores for these questions were 8 out of 10 or above (Table 4).

There were no grade 2 or higher adverse events related to the self-hypnosis intervention reported in either arm. However, one patient in the ERAS+SH arm reported grade 1 anxiety after listening to the audio file that required stopping the intervention.

Table 3
Pain assessment and management.

		ERAS (N = 67)	ERAS+SH (N = 71)	P-value
POD1	N	63	70	
	Pain at its Worst, Median(IQR)*	6 (5–8)	7 (5–8)	0.31[1]
POD2	N	66	70	
	MEDD, Median (IQR)	11 (0−30)	15 (0–35)	0.22[1]
	N	62	68	
	Pain at its Worst, Median (IQR)*	5 (4–7)	6 (4–7)	0.53[1]
POD3	N	64	68	
	MEDD, Median (IQR)	0 (0–15)	13 (0–30)	0.09[1]
	N	44	45	
	Pain at its Worst, Median (IQR)*	5 (3–7)	6 (4–7)	0.06[1]
	N	46	44	
	MEDD, Median (IQR)	8 (0–15)	15 (0−23)	0.21[1]

POD, postoperative day; SH, self-hypnosis MEDD, morphine equivalent daily dose; IQR, interquartile range.
[1] Wilcoxon rank sum p-value.
* Assessed with MDASI-PeriOP-GYN, pain item.

4. Discussion

Within an ERAS pathway, the addition of self-hypnosis in the perioperative setting did not improve worst pain reported in POD1. Importantly, we were able to detect a statistically and clinically significant reduction in anxiety scores after the self-hypnosis intervention at both the preoperative visit and in holding area before surgery. A change of 1 or greater on a 0–10 numeric rating scale is considered clinically significant as previously reported by Hui et al. [35] The absence of significant differences in the worst pain levels suggests that, while self-hypnosis may have impacted anxiety, it did not translate into a notable effect on early postoperative pain outcomes. Pain levels were generally low to moderate, and the total MEDD in the postoperative period was similar in the two arms. This similarity raises the question of whether there is a "ceiling effect" to improving postoperative pain or that perhaps the ERAS pathway was already effective enough to control pain for these patients.

To our knowledge, this is the first study using self-hypnosis within an ERAS program for gynecologic oncology patients. There have been previous studies evaluating the use of self-hypnosis in different surgical settings. In a randomized clinical trial in patients undergoing laparoscopic colorectal cancer surgery, patients in the experimental group were given progressive relaxation exercises for 15 min preoperatively and on POD1–3 after breathing exercise training. The authors concluded that patients in the experimental group had lower postoperative pain and anxiety levels and a lower rate of using opioid analgesic on POD0 compared to the control group [36]. Montgomery conducted a randomized clinical trial in patients undergoing excisional breast biopsy or lumpectomy, patients in the intervention group received a 15-min pre-surgery hypnosis session conducted by a psychologist or nondirective empathic listening [20]. Patients in the hypnosis group required less

Table 4
Satisfaction survey- self-hypnosis+ERAS arm.

	Median (IQR)*
How SATISFIED were you with the self-hypnosis experience?	8 (7–10)
How USEFUL did you find the intervention?	8 (5.5–9)
How EASILY were you able to follow the instructions?	10 (9–10)
How likely would you be to RECOMMEND self-hypnosis prior to surgery to your friends and family?	9 (7–10)
If you had to undergo a future surgical procedure, how likely would you be able to USE self-hypnosis AGAIN prior to surgery?	9 (7–10)

IQR, interquartile range.
* $n = 65$.

Table 5
Side effect expectancy questionnaire.

	ERAS (N = 67)	ERAS+SH (N = 71)	P-value
Please rate whether you think you will EXPERIENCE the following symptoms at SOMETIME after your surgery			
1. Anxiety, n (%)			0.46[1]
I am certain I will NOT have	8 (12 %)	12 (17 %)	
Unsure	38 (57 %)	32 (46 %)	
I am certain I WILL have	21 (31 %)	25 (36 %)	
Missing	0	2	
2. Pain, n (%)			<0.001[1]
I am certain I will NOT have	1 (1 %)	2 (3 %)	
Unsure	22 (33 %)	5 (7 %)	
I am certain I WILL have	44 (66 %)	62 (90 %)	
Missing	0	2	
3. Nausea, n (%)			0.20[1]
I am certain I will NOT have	11 (16 %)	6 (9 %)	
Unsure	52 (78 %)	54 (78 %)	
I am certain I WILL have	4 (6 %)	9 (13 %)	
Missing	0	2	
4. Vomiting, n (%)			0.54[1]
I am certain I will NOT have	13 (19 %)	13 (19 %)	
Unsure	53 (79 %)	52 (75 %)	
I am certain I WILL have	1 (1 %)	4 (6 %)	
Missing	0	2	
5. Fatigue, n (%)			0.46[1]
I am certain I will NOT have	4 (6 %)	2 (3 %)	
Unsure	31 (46 %)	28 (41 %)	
I am certain I WILL have	32 (48 %)	39 (57 %)	
Missing	0	2	
Please rate the extent to which you think you will be able to MANAGE the following symptoms after your surgery			
1. Anxiety, n (%)			0.37[1]
I am certain I will NOT manage well	1 (1 %)	0 (0 %)	
Unsure	18 (27 %)	14 (21 %)	
I am certain I WILL manage well	48 (72 %)	54 (79 %)	
Missing	0	3	
2. Pain, n (%)			0.58[1]
I am certain I will NOT manage well	1 (1 %)	0 (0 %)	
Unsure	18 (27 %)	22 (32 %)	
I am certain I WILL manage well	48 (72 %)	47 (68 %)	
Missing	0	2	
3. Nausea, n (%)			0.43[1]
I am certain I will NOT manage well	2 (3 %)	1 (1 %)	
Unsure	20 (30 %)	28 (41 %)	
I am certain I WILL manage well	45 (67 %)	40 (58 %)	
Missing	0	2	
4. Vomiting, n (%)			0.49[1]
I am certain I will NOT manage well	2 (3 %)	1 (1 %)	
Unsure	21 (31 %)	28 (41 %)	
I am certain I WILL manage well	44 (66 %)	40 (58 %)	
Missing	0	2	
5. Fatigue, n (%)			0.12[1]
I am certain I will NOT manage well	3 (4 %)	0 (0 %)	
Unsure	26 (39 %)	22 (32 %)	
I am certain I WILL manage well	38 (57 %)	47 (68 %)	
Missing	0	2	

[1] Fisher Exact p-value.

propofol and lidocaine than patients in the control group and reported less pain intensity and pain unpleasantness. Another study on patients undergoing total hip or knee replacement determined that relaxation techniques and back massage had a significant effect in lowering pain, anxiety, and vital signs in the 3-day postoperative rest period. Additionally, experimental patients in the study reported that the intervention helped them to "forget about their pain for a while and improved their anxiety state" [37]. Our trial used an audio recording for the SH and most prior research used a health care professional to guide the session. The presence of the healthcare professional could explain the larger effect of prior studies relative to the current study findings. Alternatively, these studies might not have been performed within the context of an ERAS pathway that has already achieved significant reductions in perioperative opioid use. While many studies typically measure average pain levels, this study specifically assessed worst pain experienced by patients. This distinction could explain differences in findings between this study and others, as assessing worst pain captures the peak intensity of pain experienced by patients and could represent breakthrough pain versus assessing just the average pain.

By integrating self-hypnosis into ERAS protocols, healthcare providers can offer patients additional tools for managing anxiety and promoting relaxation during the perioperative period. This supportive approach added to ERAS programs addresses physical aspects and attends to patients' psychological well-being, potentially leading to improved overall satisfaction with their surgical experience. Moreover, the affordability and ease of implementing relaxation techniques via audio files make them accessible options for managing anxiety and pain, aligning with the goals of ERAS pathways to optimize patient outcomes while minimizing costs and resources utilization. This underscores the importance of adopting a multidimensional approach to patient care that addresses both physical and psychological needs throughout the surgical journey.

Incorporating methods for personalization of self-hypnosis interventions in future studies or clinical implementations could significantly enhance their effectiveness and relevance to individual patients. This could involve modifying the content, duration, or frequency of hypnosis sessions to better suit each patient's unique circumstances and preferences and/or having the sessions delivered by a health care professional.

The main strength of the study is the randomized design and the fact that it was conducted in a tertiary care center enhancing the generalizability of the findings to similar settings and populations, as it reflects real-world clinical practice in specialized medical centers. However, because of the nature of the self-hypnosis intervention, neither patients nor investigators were blinded to the treatment assignment. This lack of blinding introduces the potential for bias in reporting outcomes, as patients in the self-hypnosis group may have had different expectations for symptom management compared to those in the control group. This could influence their perceptions of pain, anxiety, and overall satisfaction with the intervention. One limitation could be the fact that participants verbally conveyed their anxiety scores to the research team instead of entering their scores in an electronic device, what could potentially generate a bias on the patient reporting lower anxiety scores. In addition, anxiety was assessed once in the control group and twice in the intervention, what could introduce a detection bias as patients could expect that the intervention was supposed to decrease their anxiety. Patients were advised to listen to the SH audio file ad libitum from the time of consent to surgery however this information was not collected. Another limitation is the standardization of the self-hypnosis procedure, particularly the use of an audio file. This standardized approach may not have allowed for adaptation to individual patient situations, potentially limiting the effectiveness of the intervention. Hypnosis is often personalized and tailored to individual needs and preferences, and a one-size-fits-all approach may not have adequately addressed the diverse experiences and responses of participants.

In conclusion, the integration of self-hypnosis into an ERAS pathway was found to be feasible, and participants expressed high levels of satisfaction with the intervention. The self-hypnosis intervention demonstrated statistically and clinically significant reductions in self-reported anxiety among participants who listened to the audio file in the preoperative period. Despite the positive impact on anxiety, there were no discernible group differences in self-reported pain, time to first opioid use or MEDD during admission. The ease of accessibility and the simple nature of listening to an audio file during the perioperative period suggests that self-hypnosis intervention could be seamlessly integrated into routine care to effectively mitigate preoperative anxiety. These findings highlight the potential of self-hypnosis as a valuable adjunct in perioperative care, emphasizing its ability to address specific aspects of patient well-being, particularly in reducing preoperative anxiety, and warrant further exploration in larger-scale studies within

gynecologic surgery that explore how to enhance the effects of self-hypnosis.

Conflict of competing interest

LAM reports research funding from AstraZeneca for unrelated work, consulting for Glaxo-Smith-Kline, and stocks in Crispr, Denali, Johnson & Johnson, and Bristol-Myers Squibb. The remaining authors report no conflicts of interest related to the subject matter of this manuscript.

CRediT authorship contribution statement

Maria D. Iniesta: Writing – review & editing, Writing – original draft, Supervision, Project administration, Investigation, Data curation. **Pedro T. Ramirez:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization. **Mark F. Munsell:** Writing – review & editing, Visualization, Software, Methodology, Formal analysis, Data curation. **Sol Basabe:** Writing – review & editing, Data curation. **Shu-En Shen:** Writing – review & editing, Visualization, Software, Methodology, Formal analysis, Data curation. **Katherine E. Cain:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Aaron Shafer:** Writing – review & editing, Data curation. **Javier Lasala:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Gabriel Mena:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Xin S. Wang:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Lorenzo Cohen:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Larissa Meyer:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Funding

This work was supported in part by the MD Anderson Cancer Center Support Grant from the National Cancer Institute of the National Institutes of Health (NIH/NCI P30 CA016672) and used the Biostatistics Resource Group, and Foundation for Women's Cancer grant. LAM is supported by a NIH/NCI K07-CA201013 grant. LC is supported by the Richard E. Haynes Distinguished Professorship for Clinical Cancer Prevention at The University of Texas MD Anderson Cancer Center (LC). XSW and SES are partially supported by NCI/NIH grant funding R01CA205146. The NIH/NCI Cancer Core Support Grant (CA016672) supports the Biostatistics Resource Group at MD Anderson Cancer Center. None of the funding sources were involved in the study design; collection, analysis, and interpretation of data; writing of the report; or decision to submit the article for publication.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ygyno.2025.05.018.

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