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Impact of an educational physiotherapy-yoga intervention on perceived stress in women treated with brachytherapy for cervical cancer: a randomised controlled mixed study protocol (KYOCOL)

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ABSTRACT

Introduction Cervical cancer is a major global health issue. The standard treatment for locally advanced disease involves radiochemotherapy followed by uterovaginal brachytherapy (UBT). UBT requires several days of hospitalisation and strict bed rest. UBT often induces pain, anxiety, stress, distress and a decline in physical capacity during and after treatment. Previous research suggests that non-pharmacological interventions, such as yoga, may help alleviate these issues. However, few studies have specifically evaluated their effectiveness in reducing stress during UBT. Furthermore, patient education has been shown to facilitate autonomous practice and to improve patient empowerment. This study aims to evaluate the impact of the KYOCOL protocol, which integrates both a physiotherapy-yoga intervention and an educational programme, on perceived stress and its correlates in patients undergoing UBT.

Methods and analysis KYOCOL is an ongoing randomised, prospective trial carried out in three French comprehensive cancer centres, using a quantitative approach complemented by a qualitative component. Eighty patients are planned to be randomised (1:1) into a control arm (standard care) or an intervention arm. In the intervention arm, patients will be educated and supervised by a trained physiotherapist in a physiotherapy-yoga programme and will then perform daily autonomous sessions during UBT and for up to 15 days post-treatment. The primary objective is to assess the impact of the KYOCOL intervention compared with standard care during UBT, on perceived stress 15 days post-UBT, using the 10-item Perceived Stress Scale. Secondary objectives include evaluating the safety of the intervention, its effects on stress, pain and fatigue during UBT, and patient adherence to the programme. Qualitative analyses based on semistructured interview surveys will be conducted to gather valuable information and analyse in depth patients' experiences with the intervention and UBT.

Ethics and dissemination This study was approved by the French ethics committee (Comité de Protection des Personnes Ouest V, reference number 2023-A01491-44) on 22 February 2024 and will be carried out in accordance with the good clinical practice guidelines and the Declaration of Helsinki. The results will be shared with patients and healthcare professionals and published in a peer-reviewed journal.

Trial registration number NCT06263283.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The KYOCOL study will innovatively assess the safety and benefits of a physiotherapy-yoga-patient education (PE) programme on perceived stress during the stressful immobilisation required for brachytherapy.
⇒ The KYOCOL intervention aims to reduce stress and physical discomfort in the context of pathology and treatment, using breathing exercises, education and adapted yoga postures to mobilise the upper part of the body.
⇒ The KYOCOL intervention will enable patients undergoing brachytherapy, a highly stressful treatment, to independently practice stress-reducing techniques, even when healthcare professionals cannot access the treatment room.
⇒ The qualitative component of the study will enable us to gather in-depth information on patients' experiences of brachytherapy and the physiotherapy-yoga-PE intervention.
⇒ It may be challenging to isolate the specific effects of the KYOCOL intervention on perceived stress due to the use of concomitant medication and/or other psycho-oncological interventions.

INTRODUCTION

In France, approximately 3000 women are diagnosed with cervical cancer annually, with a median age at diagnosis of 51 years.[1] Cervical cancer represents a significant proportion of the global cancer burden among women, and it was the fourth most common cancer in terms of both incidence

and mortality in 2020.[2] The standard treatment for locally advanced cancer involves radiochemotherapy followed by uterovaginal brachytherapy (UBT).[3 4] This technique delivers radiation directly to the tumour site via an applicator inserted under anaesthesia. Treatment usually requires 3 to 5 days of hospitalisation, during which patients must remain on strict bed rest, avoiding any pelvic movement until the applicator is removed. Prolonged immobilisation combined with the psychological distress due to the disease and the sensitivity of the treated area is a well-documented source of anxiety.[5] Kirchheiner *et al* reported that 30% of patients treated with UBT experienced symptoms of acute stress disorders (ASD) 1-week post-treatment, with 41% developing post-traumatic stress disorders (PTSD) within 3 months.[6] These stress reactions include intrusive recollections of the UBT experience, avoidance of related stimuli, negative mood, dissociative symptoms (eg, derealisation and amnesia), avoidance of reminders and increased arousal. PTSD is diagnosed when significant symptoms persist beyond 1 month.[7] Holt and colleagues also observed a significant decline in physical capacity during and after treatment for gynaecological cancers.[8] A recent literature review confirmed that UBT leads to different levels of pain, anxiety and emotional distress.[9] Most studies reported investigations of pain medication during UBT.[9] Moreover, Christiansen *et al*'s qualitative study emphasised the importance of patient self-management of symptoms during cervical cancer treatment.[10] As PTSD results from unresolved ASD, addressing or alleviating stress during UBT may be critical in preventing long-term effects. This is particularly important in oncology, as increased stress levels correlate with higher pain perception.[11] Taken together, these findings underscore the potential value of non-pharmacological interventions (NPIs) in reducing the long-term impacts of UBT. Limited research has evaluated the efficacy of NPIs in reducing anxiety and stress during UBT, although existing studies indicate that manual therapies (eg, foot reflexology) and art therapies (eg, music therapy) may provide benefits.[12–14] To our knowledge, no study has combined physical and psychological approaches in this context, despite the bidirectional nature of stress effects (ie, stress is the body's reaction to a threat, and anxiety is the body's reaction to stress[7]).

Yoga, a mind-body NPI, has demonstrated efficacy in reducing perceived stress and stress-related biological markers in adults with[15] or without[16] depressive and anxiety symptoms. It has also shown benefits in patients undergoing cancer treatment.[17] Previous results have highlighted the relevance of integrating yoga into cancer care, underscoring the need for ongoing assessment of the benefits of breathing and meditation exercises. Breathing exercises, central to yoga practice, have garnered significant interest.[18 19] Dhruva and colleagues demonstrated the feasibility of breathing interventions in patients receiving chemotherapy, reporting improvements in mental health.[20] Similarly, yoga interventions have been associated with reduced perceived stress in women undergoing radiotherapy for breast cancer.[21] Furthermore, the American Society of Clinical Oncology (ASCO) has endorsed evidence-based guidelines supporting integrative therapies, including yoga, for managing stress and anxiety during and after breast cancer treatment.[22 23] Despite these promising results, no standardised yoga protocol has been established across different cancer care settings, particularly in patients undergoing treatment for cervical cancer.

This study aims to evaluate the impact of an adapted yoga programme, supervised by a physiotherapist, on perceived stress in patients undergoing UBT. Integrating patient education (PE) into the yoga programme may empower patients to practice independently post-treatment, addressing their high educational needs and improving quality of life, pain and stress management.[24] Providing patients with self-management tools may help alleviate stress and immobility-related pain.

Therefore, the objective of this study will be twofold: (1) managing physical discomfort associated with prolonged bed rest using adapted upper body yoga-based postures and (2) reducing stress through breathing and relaxation exercises. Both the scientific literature and our clinical experience in a comprehensive cancer centre[25 26] highlight the need to improve the patient experience during UBT. Moreover, the study aims to enhance understanding of patients' experiences with UBT and the integrated physiotherapy-yoga-PE intervention. The qualitative approach will enable us to adapt the multidisciplinary care strategies. This initiative is part of our ongoing commitment to improving the care pathway by integrating personalised supportive care, tailored to individual patient needs.

METHODS AND ANALYSIS

Study design and settings

KYOCOL is an ongoing randomised, prospective, multicentre, comparative trial performed in three French comprehensive cancer centres with extensive experience in UBT: the Montpellier Cancer Institute, the Eugène Marquis centre (Rennes) and the IUCT-Oncopôle (Toulouse). The study is open for recruitment since April 2024 and expected to be completed in February 2026. Physiotherapists and other paramedical professionals involved in the study underwent a 1-day training session on the principles of yoga and PE before the beginning of the study. All interventions will be provided in French. The study protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines.

Patient and public involvement

A female patient representative contributed to the design of the research project, and her valuable reflections and constructive insights have been integrated throughout the development of the project.

Eligibility criteria

A total of 80 patients with cervical cancer meeting the following criteria will be included:

1. Patients older than 18 years of age
2. Patient treated for histologically proven cervical cancer with UBT
3. Patient with a stress level scored ≥3 on a visual analogue scale (VAS) ranging from 0 to 10[27]
4. Patient who signed the informed consent form
5. Patient covered by the French social security system.

Non-inclusion criteria are:

1. Physical impairment preventing the practice of upper body yoga postures
2. Patient unable to understand or speak French
3. Patient for whom regular follow-up is deemed impossible due to psychological, familial, social or geographical reasons
4. Patient under legal protection (eg, guardianship, curatorship)

Study objectives

The primary objective of the study is to evaluate the impact of the KYOCOL physiotherapy-yoga-PE intervention compared with standard care during UBT on perceived stress, evaluated 15 days after the initiation of the treatment.

Secondary objectives include:

1. Evaluating the safety of the physiotherapy-yoga-PE intervention (experimental arm).
2. Assessing patient adherence to both supervised and independent components of the KYOCOL programme.
3. Assessing the immediate effect of the KYOCOL intervention on patient-reported stress, fatigue and pain (general pain and immobility-related pain) and their evolution during UBT.
4. Evaluating psychological distress at baseline and 15 days after the initiation of UBT.
5. Describing the use of anxiolytics by treatment arm.
6. Qualitative description of the KYOCOL intervention during UBT in the experimental arm.

Outcome measures

Primary outcome measures

The primary endpoint will be the perceived stress score, evaluated 15 days after the initiation of UBT, using the 10-item Perceived Stress Scale (PSS) self-questionnaire, ranging from 0 to 40.[28 29]

Secondary outcome measures

1. Safety outcomes will be determined by the number of treatment interruptions due to probe displacement and/or source friction following the KYOCOL intervention.
2. Patient adherence to autonomous sessions will be recorded in the logbooks completed by the patients. Supervised sessions will be documented by physiotherapists.
3. Stress, fatigue and pain will be evaluated using a VAS, with scores ranging from 0 to 10 (0=no stress, fatigue or pain and 10=the highest imaginable).[27 30 31]
4. The Hospital Anxiety and Depression Scale (HADS) will be used to assess patient anxiety and depression.[32 33]
5. The use of anxiolytic treatments will be recorded in the logbooks completed by the patients.
6. To gather patients' experiences and perceptions of the KYOCOL programme, as well as their experience of cervical cancer and treatment, a semistructured interview lasting about 40 min will be conducted during the week following applicator removal. An anthropologist will lead the interviews, capturing verbatim responses and semantic insights. An interview guide (online supplemental file 1) will ensure consistency across interviews while allowing new themes to emerge during the course of the exchange.

Table 1 provides details of the data collection process.

Sample size

We hypothesise that the KYOCOL programme will reduce perceived stress compared with standard care. To detect a difference of at least four units in the mean perceived stress level on the PSS between the experimental arm and the control arm with 90% power (β=0.10), a bilateral risk (α) of 5%, and assuming a standard deviation (σ) of 5, 34 patients per arm are required for 1:1 randomisation. Accounting for an anticipated 15% of patients may be unevaluable, 40 patients per arm are needed. In total, 80 patients will be included.

Patient timeline and study flow diagram

Details of the study flow diagram and patient participation are presented in figures 1 and 2. The investigator, either a physician, a physiotherapist or a radiology technologist, will recruit patients during the UBT consultation. The investigator will inform the patients about the study and obtain their informed consent (online supplemental file 2).

Randomisation

On signing the informed consent form and confirming that the patient meets eligibility criteria, the investigator will register and randomise the patient using an electronic case report form (eCRF). Randomisation (1:1 ratio) will be conducted via an online portal ('CSOnline'). On randomisation, the investigator will receive an email notification indicating the patient's assigned treatment arm. Randomisation will be stratified by study centre, patient stress level as measured by the VAS score (≤4, 4–6, >6) and the use of anxiolytics within the 3 days preceding randomisation (yes vs no). The study is open-label, as blinding is not feasible due to the nature of the intervention. Neither the patients nor the physiotherapists will be blinded.

Table 1 Study assessments and outcome evaluations

	Inclusion	UBT						Post-UBT	
	D-30 to D0	D0	D1	D2	D3	D4	D5	D5 to D12	D15
Patients' baseline characteristics*	✓								
Physiotherapy check-up	✓								
Educational check-up†	✓								
HADS	✓								✓
PSS		✓							✓
Recording of adverse events and concomitant treatments				✓	✓	✓			✓
VAS (stress, fatigue and pain)	✓			✓‡	✓‡	✓‡	✓§		✓
Qualitative interview †								✓	
Physiotherapy-yoga-PE session†				✓	✓	✓		✓¶	✓¶

*Includes demographic (age, sex) and clinical data (medical history, concomitant treatments).
†Performed only for the experimental arm.
‡Performed before and after the physiotherapy-yoga session in the experimental arm, and two times a day in the control arm.
§Recorded before and after the removal of the applicator.
¶At-home yoga session performed one or more times a day.
HADS, Hospital Anxiety and Depression Scale; PSS, Perceived Stress Scale; UBT, uterovaginal brachytherapy; VAS, visual analogue scale.

Treatments

Uterovaginal brachytherapy (UBT)

UBT is a form of internal radiotherapy of gynaecological cancer. This technique begins on day 1 with the placement of an applicator within the uterus, serving as a vector to allow the precise delivery of high-dose radiation directly to or near the tumour site while minimising exposure to surrounding organs at risk. In this study, two UBT modalities are used according to the centre's practice:

- High-dose rate UBT, where radiation is administered in sessions (1 to 2 per day), each lasting a few minutes.
- Pulsed-dose rate UBT, where radiation is delivered in timed pulses, typically once per hour, within a shielded room.

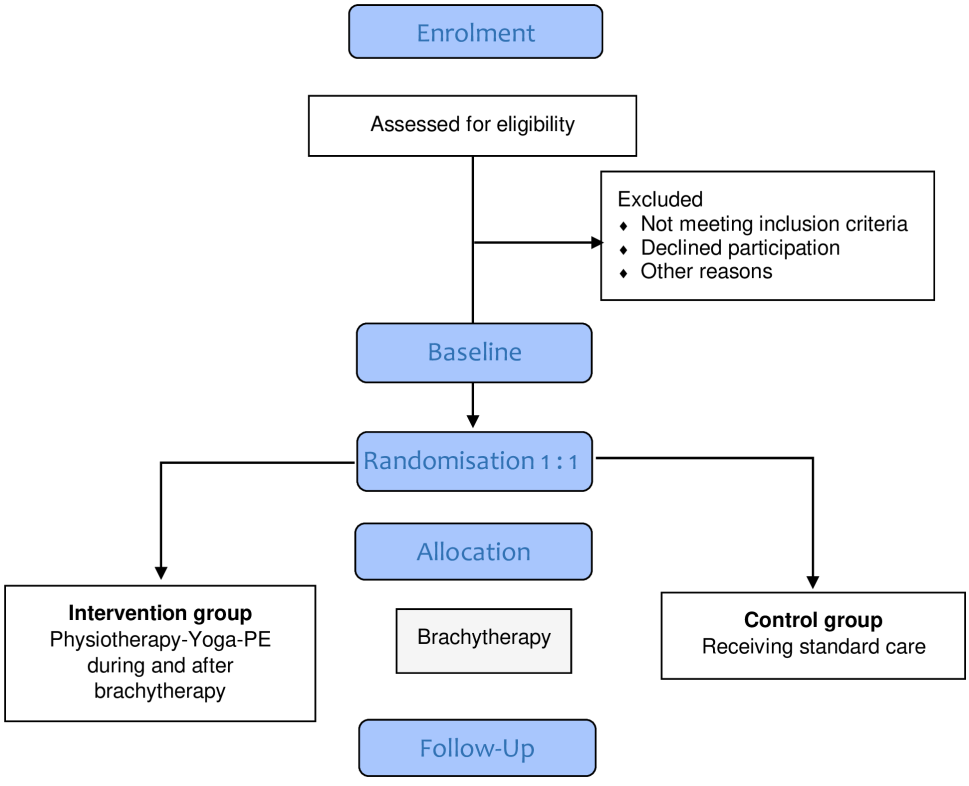

Figure 1 KYOCOL study flow diagram.

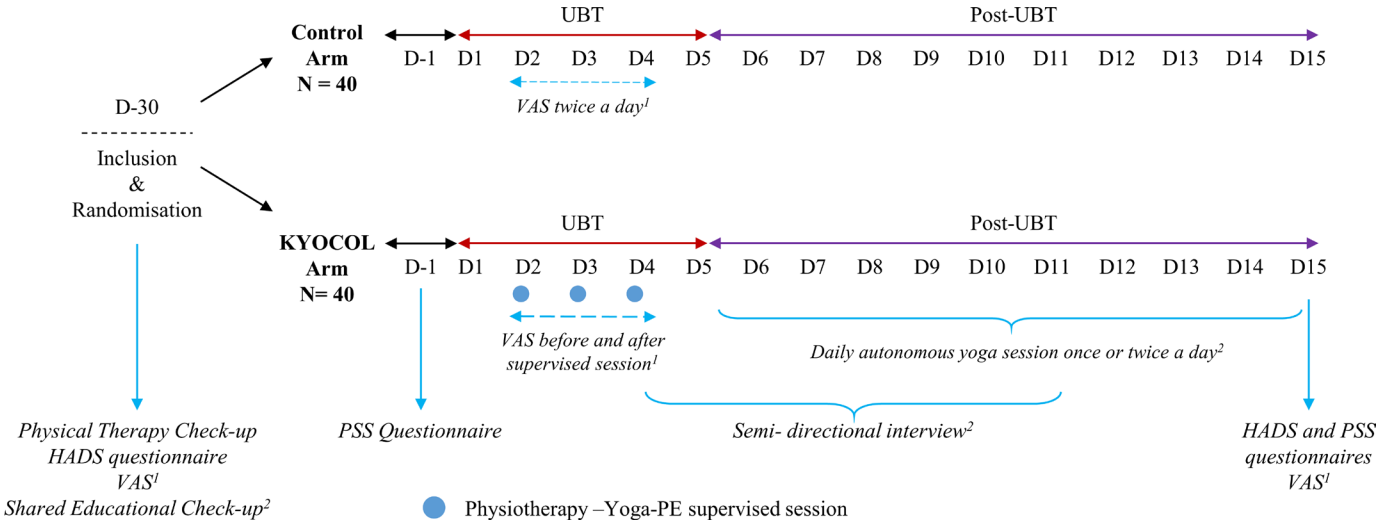

Figure 2 Participant timeline. [1]Evaluation of pain, stress and fatigue, [2]Experimental arm only. HADS, Hospital Anxiety and Depression Scale; PSS, Perceived Stress Scale; UBT, uterovaginal brachytherapy; VAS, visual analogue scale.

All patients receive the first UBT session a few hours after applicator placement, with following sessions occurring between day 1 and day 3 or 5. Bed rest is required throughout the treatment period, and the applicator is removed after the final session.

Physiotherapy-yoga-patient education (PE) intervention

This intervention was developed in collaboration with radiotherapists, taking into account the constraints of the treatment. During the shared educational check-up at inclusion, the investigator will present the physiotherapy-yoga-PE intervention and conduct one session with the patient. All patients in the experimental arm will receive paper and audio guides, a logbook and an ergonomic pillow to support their practice. Autonomy goals will be established for each patient.

The intervention, developed by a physiotherapist trained in yoga through the 'Institut Français de Yoga', includes 12 yoga postures. These sessions are tailored to the patients' physical limitations and are compatible with UBT. Details of the breathing exercises and adapted postures are presented in table 2. The session is designed to assist the patient in:

1. Stress management through breathing exercises (eg, awareness of abdominal breathing, box breathing).
2. Managing immobilisation with self-mobilisation exercises for the neck and upper body, combined with arm and eye movements. The postures are synchronised with the breathing rhythm.

Each session will last 15–20 min and will conclude with a brief relaxation period.

The educational intervention aims to empower patient to practise autonomously, allowing them to practise the breathing exercises and postures when needed, even when the room is not accessible to others, such as during UBT sessions. Behaviour change strategies will help identify optimal conditions for practice. Discussions will address:

- Challenges: factors that may hinder programme adherence such as lack of self-confidence or fear of making mistakes.
- Resources: supportive factors, including good body awareness, regular physical activity, and self-confidence.
- Motivations: motivating factors for programme engagement, including reducing pain, improving tolerance to immobilisation, or managing stress.
- Educational objectives: goals defined by the patient and healthcare professional, such as practising yoga exercises autonomously, respecting body sensations and enhancing competence in managing pain or discomfort related to immobilisation.

A trained paramedical professional will conduct supervised sessions on days 2, 3 and 4. Independent practice is also recommended one or two times per day for up to 15 days post-UBT, based on the patient's needs and preferences. Patients will record independent sessions in a logbook. Practice reminders will be sent two to three times per week to patients via the e-health application.

Control arm

During UBT, all patients will be immobilised and will receive standard care according to their centre's practice. Patients in the control arm will not participate in physiotherapy-yoga-PE sessions during UBT or for 15 days post-treatment. However, standard physical therapy sessions may be provided on request as part of routine care.

Concomitant care

All concomitant treatments are permitted. The use of analgesics, anti-inflammatory medications, hypnotics, antidepressants and anxiolytics will be documented in the eCRF. Modifications to the UBT dose are allowed but must be recorded in the eCRF. Additional supportive care may include psychological support, physiotherapy

Table 2 Detailed description of breathing exercises, upper-body yoga postures and relaxation

Physiotherapy-yoga-patient education intervention		
Starting position	Body awareness in supine position	The patient is invited to take a few moments to become aware of the sensations throughout the body while lying on their back.
Breathing exercises	Abdominal breathing (diaphragmatic breathing)	Abdominal breathing involves engaging the diaphragm to take deep, full breaths. The patient places one hand on the abdomen and focuses on the rise and fall of the hand with each breath. This ensures that the breath is drawn from the abdomen rather than the chest.
	Box breathing (square breathing)	Box breathing consists of four equal steps: inhale, breath retention, exhale and breath retention. Each phase lasts the same duration, creating a rhythmic 'box' pattern.
	Resistance breathing (Ujjayi breathing or ocean breath)	This technique involves slow, subtle inhalations and exhalations through the nose, with a slight constriction at the back of the throat. This constriction produces a soft, soothing sound, similar to ocean waves.
Upper-body yoga postures	Shoulders elevation	The patient inhales while raising the shoulders towards the ears, and exhales as they gently lower the shoulders back down.
	Raise the shoulders towards the ceiling	The patient inhales and, as she exhales, lifts one shoulder forward towards the ceiling. She inhales as she returns to the starting position, then exhales as she lifts the opposite shoulder towards the ceiling.
	Arm opening to the side	Starting with both hands resting on the abdomen, the patient inhales while opening one arm to the side, maintaining eye contact with the hand. She then exhales as she returns the hand to the abdomen. This movement is repeated on the opposite side.
	Opening both arms to the sides	Starting with both hands resting on the abdomen, the patient inhales and opens both arms out to the sides, focusing on bringing the shoulder blades closer to each other. Patient comes back to the initial position while exhaling.
	Upper body rotation (shoulder girdle mobility)	The patient inhales and opens both arms to the sides. On the exhale, the patient brings one hand to the opposite shoulder. The patient then inhales back to the previous position and alternates sides.
	Raising one arm up	Starting with both hands resting on the abdomen, the patients inhales and raises one arm up towards the wall behind her, keeping eye contact with the hand. The patient exhales and returns to the starting position. This movement is repeated with the opposite arm.
	Raising both arms up	The patient starts with both hands on the abdomen. During inhalation, she rises both arms up, towards the wall behind her, while keeping eye contact with her hands. She exhales as she returns to the starting position.
Relaxation	Relaxation	With the hands resting on the abdomen and the eyes closed (if comfortable), the patient is encouraged to focus on her breathing and enable her body to relax.

and dietary consultations or services provided by social workers, addiction specialists or pain management teams. Massages may also be provided during hospitalisation as part of routine care.

Discontinuation or modification of allocated interventions

Missing physiotherapy-yoga-PE sessions will not be rescheduled; attendance will be documented. Premature study withdrawal may occur for personal reasons, investigator recommendation, protocol deviations or loss to follow-up.

Patients will be monitored until the planned end date or until recovery or stabilisation from adverse events. Treatment interruptions will be recorded in the eCRF. Patients can withdraw consent at any time without consequences. Withdrawal must be documented and data collected before withdrawal will be analysed, but no further data will be gathered. Investigators will make all efforts to contact patients missing visits and document all attempts. Patients will be deemed lost to follow-up if contact attempts are unsuccessful.

Data collection

Details of data collection are provided in table 1. At inclusion, the investigator will record the patient's medical history and concurrent treatments (pharmacological and NPIs). This will be followed by a 20-min physiotherapy assessment to evaluate levels of pain, stress and fatigue using the VAS, as well as mobility and any physical limitations requiring intervention adaptations. In the experimental arm, a 20-min shared educational check-up will also be conducted to prepare and support the patient in learning yoga practice during and after UBT.

The HADS questionnaire will be completed at inclusion and 15 days post-UBT and the PSS 1 day before UBT initiation and 15 days post-UBT. Pain, stress and fatigue will be

assessed using the VAS at multiple time points: before and after applicator placement and removal on the first and final UBT days and 15 days post-UBT. In the experiment, arm, pain, stress and fatigue levels will also be recorded before and after each physiotherapy-yoga-PE session from day 2 through the final UBT day. In the control arm, these measures will be recorded twice daily from day 2 to the final UBT day, with at least a 20-min interval between assessments. Adverse events and concomitant treatments will be recorded 15 days post-UBT.

Patients may complete the VAS, HADS and PSS using the *My Patient Trial* application provided by Exolis (HOPPEN, 14 rue Henri Fiocca, 13001, Marseille). Patients will receive notifications (via SMS or email) to complete the assessments. Paper versions of the VAS and questionnaires will be available for patients preferring not to use the digital application.

Approximately 20 patients in the experimental arm will participate in an individual semistructured interview 7 days after post-UBT. These interviews will follow COnsolidated criteria for REporting Qualitative Research guidelines and will be conducted by an anthropologist trained in qualitative research.[34 35] Each interview will last approximately 1 hour and will follow a predeveloped and pretested interview guide (online supplemental file 1).

Safety

All adverse events will be reported to the relevant health vigilance systems in compliance with current regulations. Investigators must immediately notify the sponsor of any patient safety concerns related to the research.

Data management, quality and monitoring

The sponsor will oversee database management, with data securely stored at the Biometrics Unit of the Montpellier Cancer Institute. The Ennov Clinical software will be used to design the eCRF and handle clinical data management. Access to trail data and documents will be granted on reasonable request, contingent on signing a data access agreement.

In adherence to the General Data Protection Regulation, each patient will be assigned a unique registration number. Associated data will be encrypted and securely stored to ensure anonymisation. To ensure data anonymisation, special precautions will be applied throughout the study.

Data monitoring will be performed across all participating centres according to a sponsor-defined monitoring plan. The data to be monitored will be determined accordingly, with verification of all signed informed consents as a minimum requirement. Data will be stored in accordance with current regulations, and the sponsor competent authorities may conduct audits for at least 15 years following the trial.

Statistical methods

A detailed statistical analysis plan will be drafted for quantitative data before the data lock. No interim analysis is planned. The analyses will be performed on the intention-to-treat population, with efficacy analyses also conducted on the per-protocol population. Baseline characteristics and stratification criteria will be described for each arm. Missing data will be reported but not imputed unless explicitly specified.

Categorical variables will be reported as frequencies and percentage (%) for each category. Quantitative variables will be presented as counts (N), median, range, mean and SD.

The primary endpoint, the mean perceived stress score, based on the PSS questionnaire at day 15 post-UBT, will be calculated for both arms and will be compared using a Student's t-test. To compare categorical variables between arms, a $\chi 2$ test or a Fisher's exact test will be applied. For the quantitative variables, such as VAS scores, a Student's t-test or a Kruskal-Wallis test will be used. In the experimental arm, a Wilcoxon signed-rank test will be used to compare pre- versus post-intervention data. All statistical analysis will be two-sided and p values <0.005 will be considered statistically significant.

The qualitative analysis will be validated progressively, through a triangulation carried out during the inclusions. This triangulation will be based on full transcriptions of the interviews and will involve regular discussions between the investigative team and the anthropologist. These steps will enable the harmonisation of data interpretation and minimise subjective biases linked to individual perspectives. The qualitative sample will be constructed to explore a maximum diversity of experiences. Interviews will be conducted until theoretical saturation is reached (an estimated 20 participants). Additional interviews may be conducted to refine and confirm the themes identified. The qualitative analysis will focus on themes emerging from the discourse, cross-referenced with those previously identified in the interview guide, and will include significant verbatim extracts to illustrate the findings.

Responsibilities

The study sponsor, Montpellier Cancer Institute (ICM), is responsible for study design, management and compliance with ethical standards. The sponsor will obtain all authorisations, ensure study insurance, notify relevant authorities of the study inclusion period and results, produce the final study report and retain all study-related documents for at least 15 years. Additionally, ICM will oversee data quality, analysis, confidentiality and storage.

ETHICS AND DISSEMINATION

This study will be conducted in compliance with the French Public Health Code, Good Clinical Practice guidelines and the principles outlined in the Declaration of Helsinki. This trial has been registered on ClinicalTrials.gov (NCT06263283) and approved by an ethics committee (Comité de Protection des Personnes Ouest V, reference number 2023-A01491-44, accepted on 22 February 2024). The 'Agence Nationale de Sécurité du

Médicament et des produits de santé' (French National Agency Authority for the Safety of Health Products) was notified on 26 February 2024. Before enrolment, investigators will inform all participants about the study's objectives and procedures. Informed consent form will be obtained from all patients prior to study initiation. Patients are free to withdraw from the study at any time, for any reason, without any consequences or negative impact on their ongoing treatment.

Any substantial protocol amendments will require formal approval from the ethics committee. Once approved, the revised protocol will be communicated to all investigators.

On study completion, participants will be able to request access to the study results. The findings will be published in peer-reviewed journals and presented at national and international conferences.

DISCUSSION

To the best of our knowledge, this is the first study evaluating the impact of tailored yoga postures for the upper body, combined with breathing exercises, on perceived stress levels and their correlates in patients undergoing treatment for cervical cancer during and after UBT.

UBT is inherently stressful, involving strict bed rest for 3 to 5 days, isolation in a protected room during treatment and the presence of an applicator. These conditions contribute to increased anxiety, stress and discomfort. The cumulative psychological distress experienced by patients, from diagnosis through treatments, can contribute to the overall psychological vulnerability, which may result in a higher probability of developing ASD and PTSD symptoms. This highlights the importance of interventions aimed at enhancing well-being during this challenging period. Reducing perceived stress and its correlates may lower the risk of long-term psychopathological syndromes, thereby improving overall quality of life.

This interventional study integrates three sources of stress associated with UBT:

1. Immobility with the applicator in place between fractions:[10 36] the yoga-based programme is designed to address this with tailored self-mobilisations.
2. Accumulation of previous adverse events and potential current pain:[15 20] breathing and relaxation exercises are included to help patients manage discomfort.
3. Loss of control and uncertainty about the treatment:[9 24] PE aims to empower patients by providing them with knowledge and practical skills.

The qualitative analysis will further enrich the understanding by exploring how patients perceive the physiotherapy-yoga-PE intervention. This feedback will provide critical insights into the effectiveness of the intervention and the broader context of UBT. Patients' feedback will be crucial for refining and adapting the intervention to better meet their needs.

We expect both immediate and medium- to long-term effects on stress as a result of this intervention. While immediate stress relief is a primary goal, determining whether these benefits will persist over time is equally important. Questions to address include whether patients remain motivated to continue these practices independently at home, and how best to support sustained engagement. Additionally, we aim to disentangle the specific effects of the intervention from potential influences such as the supportive presence of staff and a compassionate care environment.

This study has several limitations. The lack of blinding could introduce bias in patient responses and outcomes. Additionally, individual variability in stress levels and receptivity to the intervention may affect outcomes. Factors such as personal background, psychological state and previous experiences with stress management techniques could influence responses to the intervention. Patients experiencing distress or pain during UBT can receive medication in addition to the intervention, and the type and intensity of pharmacological intervention (as well as NPIs) may vary across patients. The interpretation of our results should be interpreted with caution, considering the influence of these parameters. Finally, standard supportive care may vary according to the centre's practice, leading to heterogeneity in the control arm. While this reflects 'real-life' conditions, it may induce variability that needs to be considered in the analysis.

In conclusion, evidence supports the use of yoga and patient education for improving psychological and physical symptoms in patients undergoing cancer treatment, in particular stress-related outcomes. This study proposes a novel NPI specifically designed to alleviate stress and its correlates during UBT. The insights gained would contribute to a deeper understanding of therapeutic approaches for enhancing the overall patient experience in this highly stressful treatment setting.

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for methodological and statistical design and defined the planned analysis. EL oversaw the qualitative analysis and its reporting and is currently conducting the individual semistructured interviews. LM handled the legal, ethical and administrative aspects. All authors reviewed and approved the final protocol. KF is the guarantor. Chat GPT was used for translation and formulation of sentences.

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