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Importance of Patient Education for At-home Yoga Practice in Women With Hormonal Therapy-induced Pain During Adjuvant Breast Cancer Treatment: A Feasibility Study

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Abstract

Background: Osteo-articular pain (OAP) is experienced by approximately 50% of women under hormonal therapy (HT) for breast cancer (BC), which increases the risk for therapy discontinuation. This study was aimed to assess benefits of yoga practice combined with patient education (PE) for at-home practice by evaluating feasibility among BC patients under HT and measuring OAP, flexibility and satisfaction. **Methods:** Feasibility was evaluated by patient adherence as accomplishment of at least 4 out of 6 supervised yoga-PE sessions along with 70% or more at-home yoga sessions. Intervention (12 weeks) included two 6-weeks periods: P1 comprising one 90-minutes supervised yoga-PE session/week and 15-minutes daily at-home yoga and P2, daily autonomous at-home yoga sessions. Evaluations (at inclusion and by the end of each period) consisted in assessment of OAP on Visual Analog Scale (VAS), forward flexibility (cm) and patient satisfaction on Likert (0-10 points) scale. **Results:** Between September 2018 and May 2019 we included 24 patients of median 53 years (range 36-72). Feasibility was validated by 83% successful adherence rate. Pain was significantly reduced from median VAS of 6 [range 4-10] to 4 [range 0-7] at the end of both P1 and P2 ($p < 0.01$), albeit with no difference between P1 and P2. Forward flexibility improved by a median gain of 8 cm (end of P2) and median satisfaction score of 10/10 [range 8-10]. **Conclusion:** Combined physiotherapy-yoga-PE intervention is a feasible strategy to increase at-home yoga practice with potential benefit on pain, flexibility, and satisfaction, thus prompting further evaluations in larger randomized multicenter trials.
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Keywords

patient education, physiotherapy, breast cancer, hormonal therapy, pain, yoga

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Background

Breast cancer (BC) positive for estrogen receptors represents 65% to 75% of cases and requires hormonal therapy (HT) after initial treatment.[1] HT is usually administered over a long period of time (5 years) and for some patients it is recommended to extend the treatment up to 10 years.[2] Managing associated side-effects is a major concern regarding patients' quality of life (QOL) and treatment adherence,[3-5] given that dose reduction and treatment interruption negatively impact therapeutic effectiveness and patient survival.[6,7] Non-adherence to hormonal treatment is not always easily recognized by physicians but when identified, solutions could be proposed to increase disease-free survival.[8] According to a recent online survey, 31.5% of patients felt their side-effects as being underestimated by the medical team and approximately

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one-third of patients interrupted their treatment prematurely.[9] Among side-effects of HT the osteo-articular pain (OAP) also known in the literature as "joint pain", was reported in 45% to 60% of patients under either *aromatase inhibitors* (AI) or *tamoxifen* (TM) treatment.[10,11] Moreover, a recent meta-analysis showed that treatment with AI would be associated with 51% increased risk for therapy discontinuation due to side effects, including OAP.[12]

Patient demand for complementary therapies in symptom management has considerably increased in recent years. In North America for instance, such therapies are used by 48% to 80% of BC patients.[13] The *American Society of Clinical Oncology* recently endorsed evidence-based guidelines for the use of complementary therapies during and after BC treatment.[14] Mechanistically, the link between HT to OAP remains poorly understood, but seems to involve estrogen deprivation and/or increased levels of inflammatory markers.[15] A study comparing different strategies for OAP management during HT concluded that anti-inflammatory medications, paracetamol and yoga were the most effective.[16] Furthermore, numerous studies showed beneficial short-term effects of yoga for BC patients at various moments on anxiety, stress, QOL, fatigue, and pain[17-22] and a few during HT .[23-26]

Along this line, several previous studies suggested that the combination of supervised sessions and at-home yoga practice could increase long-term at-home yoga practice.[18,19,22,23] However, to the best of our knowledge, there are no studies that integrate patient education (PE) in order to increase autonomous at-home practice. Since PE may improve yoga learning by including personal objectives to be met, it appears crucial to understand how integrated PE may improve at-home practice and what would be the level of adherence.[27-29]

As a first step of the SKYPE (*Suivi en Kinésitherapie et Yoga - Projet Educatif*) study, this investigation was aimed to assess the feasibility of intervention combining yoga with PE supervised by a physiotherapist for women with HT-induced pain following BC. Secondarily, we intended to assess potential beneficial effects of the intervention on OAP, flexibility gain and degree of patient satisfaction.

Methods

Patients

Patients were recruited among women receiving early BC treatment at the *Institut du Cancer de Montpellier* (ICM), France and included by the following criteria: age ≥ 18 years, non-metastatic BC, ongoing adjuvant HT and with no treatment modification over the past 30 days, OAP ≥ 4 on the pain visual analog scale (VAS), any oncologic treatment other than HT terminated at least 2 months before inclusion, written informed consent and French social security insurance cover. Exclusion criteria were: chronic rheumatologic pain with specific care management, yoga practice in 3 months prior to inclusion or contraindication to practice physical exercise. A written informed consent was obtained from all patients before inclusion. The study was approved by the French ethics committee "*Comité de Protection des Personnes* (CPP) Ouest VI" (May 2018) and was conducted in accordance with the Helsinki declaration and good clinical practice guidelines. The SKYPE study was registered at ClinicalTrials.gov (NCT04001751).

Intervention: Physiotherapy, Yoga, and PE

The intervention was carried out over 12 weeks, separated into 2 periods: P1 including supervised and at-home practice and P2 comprising only at-home yoga practice (Figure 1). Since OAP was generally experienced mostly in distal joints, the yoga postures were chosen to avoid putting body-weight on the wrists. As it is common for yoga practice, patients were encouraged to adapt postures to their limitations and capacities. A detailed description of the yoga sessions is provided in Table 1. PE was an important part of the study and theory-based on the implementation intentions model and the concept of perceived behavioral control.[30-32] Thus, at the inclusion, patients were invited to define their objectives of personal yoga practice and to specify the timing, location, frequency and duration of their at-home practice (Figure 1). A minimum of 15 minutes daily yoga practice was recommended.

The first period (P1) of the study for 6 weeks aimed to initiate the learning process for at-home yoga practice benefitting from supervised sessions by a physiotherapist trained in postural yoga and PE. A minimum required training period for physiotherapists in postural yoga is 9 days, ending with a certification. One 90-minutes yoga session/week was delivered in the physiotherapy unit at the Institut du Cancer de Montpellier, for groups of maximum 5 women. Each patient received a learning kit containing a booklet on yoga practice ("*My yoga guide*") and benefit from audio sessions sent by email or copied on USB stick. A logbook was also provided in order to report daily information on the regularity and duration of at-home yoga practice. The different steps of sessions were planned and detailed in accordance with "*The Physiotherapist's Guide book*," which also ensured the reproducibility of the intervention.

The second period (P2) of 6 weeks was aimed to extend the daily at-home yoga sessions learnt during previous P1 period. To reinforce motivation, the physiotherapist sent collective e-mails during weeks 2 and 4 and, on patient's request, personal support was provided by phone.

Outcomes

For this feasibility study, the primary endpoint was to evaluate patient's adherence defined as participation at 4 or more out of the 6 supervised sessions as well as the completion of 70% or more home-sessions. For the P1 supervised sessions, the physiotherapist recorded participation. Adherence to home sessions during the 12 weeks of P1 and P2 was evaluated from data registered in the patient's-completed logbooks. The initial

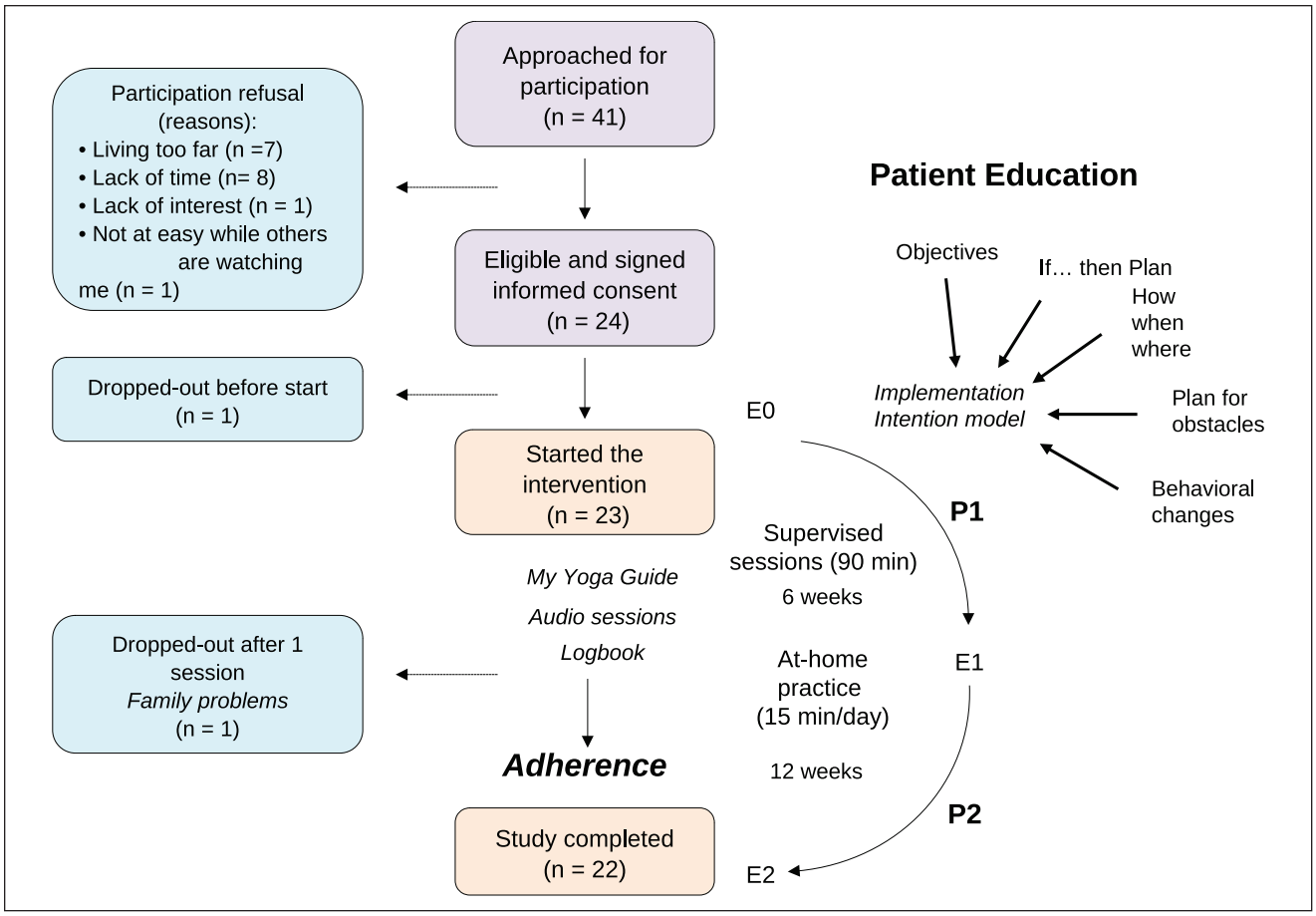

Figure 1. Flow diagram of participant recruitment and main steps in the intervention.

evaluation (E0) was performed at inclusion; the intermediate evaluation (E1) was defined at the end of P1 and the final evaluation (E2) at the end of P2. At inclusion (E0), socio-demographic and clinical characteristics of patients were also collected: age, weight, body mass index (BMI), TNM stage of BC, previous and current oncologic treatments as well as the geographic distance between their home and the hospital.

For secondary endpoints, the physiotherapist used VAS (from 0 to 10) to measure the maximum intensity of HT-associated OAP during the previous week. Flexibility was evaluated by measurement of the distance between fingertip and the floor while the patient was bending forward, keeping knees straight and feet together and placed on a step. Values were expressed as median and range (in cm). Negative values (under the floor level) indicated more flexibility. Satisfaction of patients for the intervention was evaluated at E1 and E2 using Likert scale ranging from 0 to 10 points.

Adverse effects were recorded at all assessments or supervised sessions according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v4.03. Other possible limitations for yoga practice were noted by the physiotherapist such as lymphedema, scar tightness and movement limitations.

Statistical Considerations

Sample size was calculated using a single-stage Fleming design. With α set at 0.05, the 82% power and p0 and p1 values of 50% and 75%, respectively, a sample size of 24 patients was required for this study. The feasibility was considered when at least 16 of the 24 patients adhered to the intervention.[33] The adherence rate was expressed with 95% confidence interval (95% CI). Categorical variables were described using frequencies and percentages and continuous variables using median and range. A non-parametric Wilcoxon paired test was used to compare OAP between evaluations at E0, E1, and E2. The statistical significance level was set at $p < .05$. Data were analyzed using Stata version 16 (StataCorp LP, College Station, TX).

Results

Patients

Of the 41 eligible women who were approached between September 2018 and May 2019, a proportion of 58.5% agreed to participate (Figure 1). The main reasons for refusing were: not available/too busy (19.5%), lived too far away

Table 1. Detailed Description of Yoga Sessions.

	Yoga sessions	
	Supervised by physiotherapist	Home practice
Period	Only during P1	During P1 and P2
Number of sessions	6	78
Duration of session	1 h 30 min	≥15 min
Total duration	9 h	9 h (P1) and 10 h 30 (P2)
Content	Welcome, handing-in of the previous week logbooks (5') Introduction (5') Sharing/exchanging of experiences (10') Philosophical perspective (10') Postural yoga (Asanas) + relaxation (30') - Session 1-2 learning of "*My Yoga guide*" - Session 3-6 introduction to other postures • *Ardha uttanasana* • *Parsva uttanasana* • *Utkatasana* • *Urdhva prasrta padasana* • *Pascimatanasana* • *Virabhadrasana* • *Prasarita pada uttanasana* • *Upavista konasana* Breathing exercises: Pranayama (10') • *Ujjayi* • *Nadi sodhana* Sharing personal experience about session (10') Definition of personal educational objectives (5') Conclusion (5')	**10 numbered postures** 6 lying down and 4 standing up, with movements of flexion, extension, stretching, rotation and balance. No pressure on wrists. *1. Savasana* and body scan *2. Savasana* and hand rotation etc. *3.* Half side stretch *4. Jathara parivritti* knees bent *5. Dvipada pitham* *6. Apanasana* *7. Utthita trikonasana* 2 *8. Uttanasana* *9. Utthita trikonasana* 1 *10. Tadasana* **Option 1:** Recommended as aid for waking-up: sequence of postures **from 1 to 10** (lying down first, then standing postures). **Option 2:** Recommended for evening relaxation: sequence of postures **from 10 to 1** (standing first, then lying down postures)

(17%), bothered by others looking at me (2.5%) and not interested (2.5%). After acceptance, 24 women were included in the study displaying a median age of 53 years [range 36-72]. Regarding previous treatments, all women undergone breast surgery combined with sequential anthracyclines-taxanes chemotherapy (71%) and/or radiotherapy (92%) (Table 2).

Feasibility and Adhesion

Of the 24 women, 20 patients have met the criteria for adherence to the intervention, including those who completed 70% (55 out of the expected 78) at-home sessions, which represents 83% adherence rate, 95% CI [62.6%-95.3%]. Among the remaining 4 patients, 2 dropped-out, 1 before and 1 after the first supervised session, and another 2, although they completed supervised sessions, did not fulfill required number for at-home sessions. Eighteen patients among all 24 women (75%) attended 6 supervised sessions, 3 attended 5 sessions, and 1 attended 4 sessions. The number of performed at-home sessions was in median 74 [range: 43-83] with a median duration of 15 minutes [range 8-105]. Seven of 24 women (29%) completed all and sometimes even more than required number of at-home sessions, 13 patients (54%) completed 70-99% of at-home sessions and 2 patients (8.3%) did not complete the required numbers of at-home sessions and another 2 (8.3%) did not participate in the supervised sessions.

Osteo-articular Pain, Flexibility, Patient's Satisfaction, and Adverse Effects

A significant reduction in OAP was reported between E0 and E1 with median value of 6 [range 4-10] for E0 and 4 [range: 0-7] for E1 ($p < .01$) as well as between E0 and E2: median 6 [range: 4-10] and 4 [range: 0-7] ($p < .01$), respectively (Figure 2). However, there was no significant difference in pain reduction between E1 and E2 ($p = .09$). For 14 patients (58.3%) the reduction between E0 and E2 in pain intensity was at least 2 points on VAS.

Significant increase in forward flexibility was reported between the start and the end of each period. Between E0 and E1 (P1 period) the median value dropped from 4 cm (range 18 to −7) to −2.5 cm (range 13 to −11), respectively. Between E1 and E2 the median value dropped further from −2.5 to −4 cm (rage 10 to −14). Thus, the overall median gain between E0 and E2 at the end of the study was 8 cm (Figure 2).

Table 2. Patients' Characteristics at Baseline.

	Patients (n = 24)
Age (years), median [range]	53 [36-72]
BMI (kg/m^2), n (%)[a]	
Underweight (<18.5)	1 (4)
Normal (18.5-25)	12 (50)
Overweight (25-30)	9 (38)
Obese (≥30)	2 (8)
Physical activity, n (%)	
None	2 (8)
Occasional[b]	10 (42)
Frequent[c]	12 (50)
TNM stage[d] (T), n (%)	
T1	16 (67)
T2	8 (33)
TNM stage (N), n (%)	
N0	14 (59)
N1	8 (33)
N2	2 (8)
Previous treatments, n (%)	
Surgery	24 (100)
Radiotherapy	22 (92)
Chemotherapy	17 (71)
Current hormone therapy, n (%)	
Tamoxifen (TM)	9 (37)
Letrozole (AI)	10 (42)
Exemestane (AI)	4 (17)
Anastrozole (AI)	1 (4)

[a]Body Mass Index.
[b]Activity equivalent to a 30-minute walk : 1 to 3 times a week.
[c]Activity equivalent to a 30-minute walk 4 times/week and more.
[d]TNM, Classification of Malignant Tumors.

The median satisfaction score about patient's participation evaluated at E1 and E2 was 10/10 [range 8-10]. No adverse events related directly to the yoga practice were reported during the study. There were no significant differences ($p > .4$) for all parameters already indicated (pain, flexibility, and satisfaction) between the group of patients under treatment with AI (n = 15) or TM (n = 9).

Discussion

Our study reported 83% adherence rate to physiotherapy-yoga-PE for BC patients under HT and displaying OAP whatever the HT used. In addition, we reported a significant reduction in HT-induced OAP by the end of study and amelioration of flexibility and degree of satisfaction. These data taken together highlight the feasibility of the intervention and beneficial effects while the absence of adverse events and high level of satisfaction indicate that the intervention met patients' expectations and needs. This study represents a crucial step in further randomized interventional programs such as the SKYPE2 protocol initiated by our institution (NCT04457895). In face of quite low adherence of yoga practice at-home, our results reinforce the concept that PE combined with supervised sessions might increase the autonomy for at-home yoga practice. Thus, using the concept of implementation intentions and distance learning, the adherence of such programs is expected to increase among BC patients, particularly in the context of Covid-19 outbreak sanitary crisis.

The good adherence rate highlights the feasibility of an intervention combining physiotherapy, yoga, and PE. Moreover, the absence of severe adverse events suggests a safety strategy concordant to previous reports.[22,34,35] The 58.5% high participation rate among patients initially approached for the study confirmed the growing interest and demand for non-pharmacological interventions in BC patients.[13] It should be indicated that participation rates for similar studies in the literature ranged from 23.3% to 56%.[18,21,22] The main reasons for refusal are in general the geographical distance or transportation difficulties. Offering supervised video sessions could increase participation and the ongoing Covid-19 sanitary crisis has accelerated the development of such distance learning in order to ensure continuity of care.

Among patients included in the study, the high adherence to our protocol (83%) and the high satisfaction level (10/10 at both E1 and E2) suggested that intervention met patients' expectations and needs. Indeed, some BC patients expressed the feeling of being abandoned by the health care system in the management of their symptoms during adjuvant HT period. Similar feedback of patients has been reported for instance, by French National Cancer Institute in the VICAN survey (*Life 5 years after a cancer diagnosis*).[36] This explains why support, listening and follow-up offered by our protocol appeared particularly relevant at this point of the care pathway.

We aimed to increase the adherence to our program by integrating PE into the protocol in order to optimize the learning process and autonomy in practicing at-home yoga. In this goal, we used the concept of implementation intentions[37] and helped each patient to identify early their personal resources and perceived potential obstacles. Patients were also encouraged to anticipate the time-window, place and equipment necessary for at-home sessions taking into account various constraints and symptom management. We believe that this self-management may have reinforced patient's feeling of self-efficacy and security.

Previous similar studies in this field used slightly different designs and content. Thus, some studies offered 2 weekly sessions of similar length than ours, but did not include at-home practice.[17,20,24] Others included at-home practice, but without PE programs.[19,22] Two studies offered a 4:1 ratio of supervised over home-practice cumulated duration.[18,23] However, these above cited studies evaluated

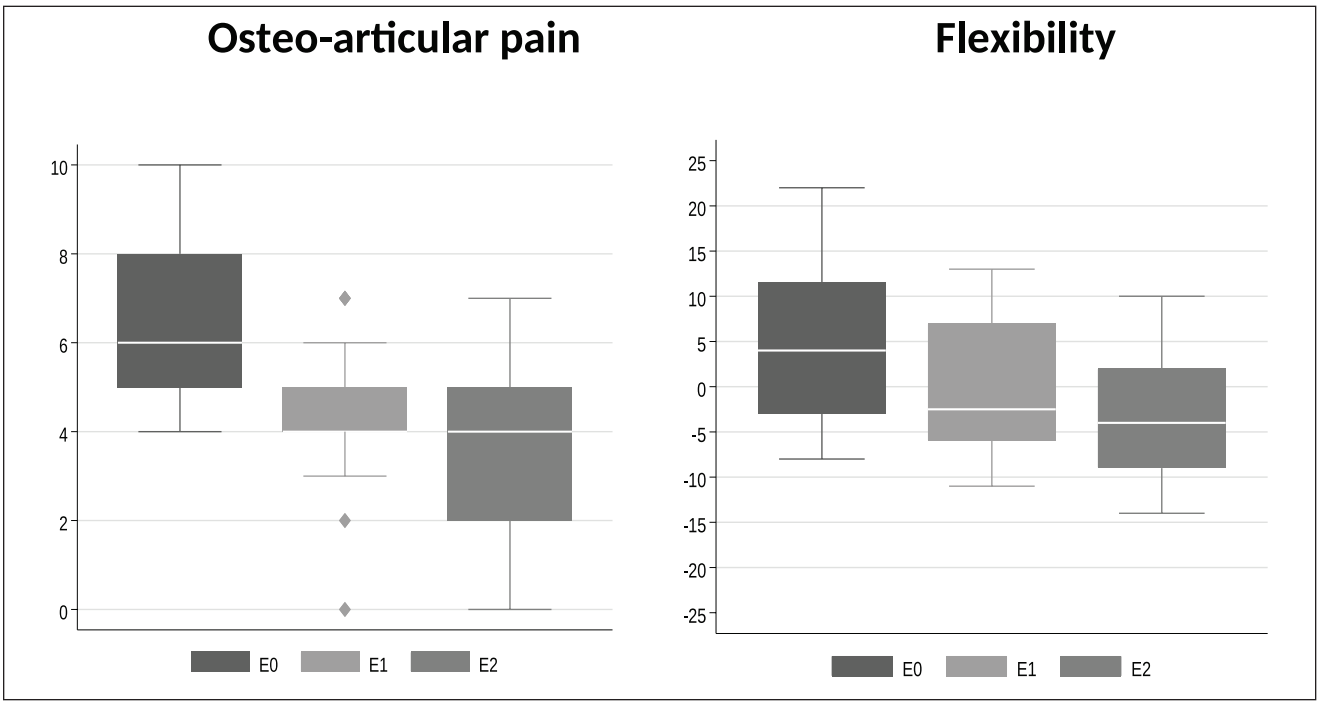

Figure 2. Osteo articular pain and flexibility values by visit.

mainly supervised sessions with limited information on how at-home sessions were organized and assessed. Thus, our study appears original in combining supervised and at-home practice sessions. We promoted a reduced cumulated duration of supervised sessions in favor of an increased duration for at-home practice. Thus, the recommended ratio was 1:1 for the P1 period and 1:2 for the entire study. PE was integrated to encourage autonomy and thus to allow a reduced number of supervised sessions. This could be of particular interest for patients living far from the hospital and for whom there are limited resources and healthcare facilities.

In addition, our study showed a significant reduction in OAP between E0 and E1 and between E0 and E2. The rapid reduction in OAP intensity, which lasted over the whole intervention, highlights the short-term efficacy of our protocol. The benefit was observed very early, thus keeping patients' motivation and adherence. These findings are in accordance with other studies showing the beneficial effect of yoga on HT-induced pain in BC patients.[23,24] Moreover, a reduction of OAP for at least 2 VAS points at final evaluation was reported for 58% of patients. The remaining 42% had no change in pain intensity or a weaker (only 1 point) reduction. Women were asked to differentiate between pain linked to HT and other types of pain. However, some women reported that, regardless of pain intensity, the nature of pain and their personal approach to accept the pain have somewhat changed. This was illustrated for example by the following statements: « *I feel better in my body* », « *I accept the pain, I live with it* », « *I have learnt to force myself less, and to listen more to my body* ». It should be indicated that adherence to the intervention also depends on multiple other factors such as working outside of the home, marital status, having children in the home and availability of support with childcare. These data suggest the intervention of several psychological components. Therefore, the use of more elaborated multi-dimensional pain scales, such as *Brief Pain Inventory* would be in our view essential for future studies.[38,39] Indeed, management of HT-induced pain is multifactorial and the qualitative exploration of Galantino et al already indicated the importance of emerging themes, such as empowerment, community, sharing, and relieved stress.[40]

Although the study was not designed to compare effects of yoga practice among patients under AI or TM, as indicated in the results section, there were not statistical differences with nonparametric tests between 2 groups for any of parameters studied. However, it should be indicated that the drop in the absolute values of pain and flexibility was somewhat more significant in the AI group than TM group. Thus, the drop between E0 and E1 or between E0 and E2 were more significant for the AI group ($p < .0036$ and $< .0099$) than for the TM group ($p < .03$ and .05), respectively. Similar observation was done in the amelioration of the flexibility between E0 and E1 and between E0 and E2: $p < .0011$ and .0015 for group AI, respectively and $p < .13$ (NS) and .011, respectively for TM group. While no such differences were found for the satisfaction, our data cannot exclude the possibility of additional different effects as function of the hormonal treatment. These data should be interpreted however with caution since the number of

patients in each group were low and different among treatment groups. Further studies on larger sizes would be necessary to conclude on these aspects.

The adverse effects in this study also deserve discussion. Indeed, no adverse effects were reported related to the yoga practice. It should be however indicated that adverse effects were noted related with the HT, which did not enter in the scope of this feasibility study. While no differences were found between AI and TM groups for OAP, hot flashes, weight gain, nausea, insomnia, headache and migraine, some significance was observed for fatigue (86.7% grade 1 in AI group and only 33.3% in TM group, $p < .021$). Although differences might exist between 2 groups, very likely these were due to the hormonal treatment since they were present already at the inclusion and did not appear during the yoga practice. They were classified as gastro-intestinal effects (nausea—grade 2 or diarrhea—grade 1) and musculo-skeletal abnormalities (pain—grade 1) found for AI group and rather musculo-skeletal abnormalities (pain—grade 2) and vascular manifestations (hot flashes—grade 1) for the TM group.

Limitations

The main limitation of our study was the lack of a randomized control group to test the efficacy of intervention. Indeed, this one arm study was performed with the objective to evaluate feasibility, which, given the commitment required from patients, was a crucial step in such interventional studies. Even under these conditions, our observation on pain reduction and amelioration of flexibility as well as the degree of satisfaction were concordant with the adherence rate. Further comparative group studies would be necessary to confirm these observations in quantitative terms. Another limitation would be the relative small sample size, which was however statistically powered in this study and which remains comparable to other studies evaluating feasibility of yoga interventions.[22,34] Finally, the heterogeneity of patient population regarding the used HT (TM as selective modulator of estrogen receptors *vs* AI) could also be considered as a limitation. This is explained by the main criterion for inclusion as the presence of HT-induced OAP regardless the molecule used in the HT. Thus, although no significant differences were detected between these 2 groups concerning adherence, pain, flexibility of satisfaction, potential differences could exists, which deserve further more specific investigation.

Conclusion

This study highlighted the feasibility of offering an intervention to BC women experiencing pain from HT combining supervised yoga sessions by a physiotherapist with PE based on the concept of implementation intentions for at-home yoga practice. Our findings suggest that our intervention is highly feasible, safe and well appreciated by the patients. The effectiveness of this intervention on pain and other factors affecting patients' QOL are currently evaluated in an on-going randomized controlled trial.

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Declaration of Conflicting Interests

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