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Original Research Article

Teaching cancer patients undergoing chemotherapy in the National Health Service to use daily self-moxibustion to reduce chemotherapy-induced pancytopenia: a feasibility study

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ABSTRACT

Introduction Cancer patients receiving myelosuppressive chemotherapy risk developing chemotherapy-induced pancytopenia (neutropenia, anemia, thrombocytopenia) with possible negative impact on survival due to dose delays or reductions. Moxibustion, the use of heat to stimulate acupuncture points, is a traditional East Asian intervention that may have potential to reduce pancytopenia. This study explored the feasibility of teaching chemotherapy patients in a National Health Service (NHS) cancer center a 10-minute daily intervention. It also aimed to obtain preliminary data to assess the completion of chemotherapy according to both dosage and schedule and assess any reduction of chemotherapy toxicities. **Methods** This uncontrolled, single-arm study aimed to recruit breast, colorectal or gynecological cancer patients undergoing chemotherapy regimens for which granulocyte-colony stimulating factor (G-CSF) is not indicated. The primary outcome was concordance with daily self-administered moxibustion (starting 7–10 days before commencing chemotherapy and continuing for three weeks after the final cycle) measured by daily moxibustion diaries. Secondary measures included blood counts, variation to planned chemotherapy schedule, health-related quality of life measured by functional assessment of cancer therapy (FACT)–general, FACT–anemia, and FACT–neutropenia, patient activation measure (PAM-13), chemotherapy-related toxicities, and adverse events of moxibustion. **Results** Twenty-five participants were recruited. Of a potential 2944 applications, 1369 were recorded; overall concordance rate was 46.5% (individual range 4%–96%). Main reasons for non-concordance included chemotherapy-related sickness, fatigue, and forgetfulness. There were no serious adverse events. The intervention was acceptable to some patients and oncology healthcare professionals. Challenges to collecting and analyzing data using the outcome measures were identified. **Conclusion** This was the first known attempt in the West to research using self-applied moxibustion in a conventional cancer care setting. The results indicate this intervention is generally acceptable and that it is possible to recruit to a study. The challenges identified inform recommendations for future study design.

KEYWORDS

cancer, moxibustion, chemotherapy, integrative oncology, self-care, neutropenia, anemia, thrombocytopenia

CITE THIS ARTICLE

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1. Introduction

Myelosuppressive chemotherapy puts cancer patients at risk of developing chemotherapy-induced pancytopenia. This is an umbrella term that comprises neutropenia (lowered neutrophils), leukopenia (reduced white blood cells), anemia (lowered red blood cell count), and thrombocytopenia (lowered platelet counts). Chemotherapy-induced neutropenia is of particular concern, as it predisposes patients to severe or febrile neutropenia. Febrile neutropenia is a potentially life-threatening complication which may incur antibiotic use, hospitalization, increased mortality, as well as negatively impacting quality of life and increasing healthcare costs.[1-5]

Severe or febrile neutropenia may have important consequences on the survival rates of people with cancer, potentially leading to treatment delays, dose reductions, substitution of less toxic but potentially less effective chemotherapy regimens, or cessation of chemotherapy altogether.[3,5] Nearly 50% of people prescribed chemotherapy for cancer receive less than 85% of the planned dose.[6,7]

Since 1994, granulocyte-colony stimulating factors (G-CSFs), such as filgrastim and pegfilgrastim, have been recommended as prophylaxis for cancer patients who are at high risk of febrile neutropenia and who are receiving myelosuppressive chemotherapy,[4,8] with detailed guidelines published by major oncology organizations.[9-11] However, G-CSF is not routinely used for all chemotherapy regimens or for all tumor types (such as colorectal or gynecological cancers), and is not routinely used for treatment in metastatic or late stage cancers. Additionally, G-CSF is expensive[4] and is associated with toxicities such a medullary bone pain, fatigue, fever, and muscle aches.[5,12]

While febrile neutropenia typically develops in the first cycle of chemotherapy, with incidence decreasing from the subsequent cycles,[1] anemia associated with myelosuppressive chemotherapy is reported to affect 19.5% of patients in cycle 1 rising to 46.7% by cycle 5.[13] A Japanese study of gynecologic cancer patients reported grade 3-4 anemia in over 50% of patients, with 90% of patients having had at least one chemotherapy treatment delayed due to anemia.[14]

Chemotherapy-induced thrombocytopenia is also associated with myelosuppressive chemotherapy. Causing bruising and bleeding, it is reported to occur in 10%–36% of patients with solid tumours[15] and if severe, it too may cause delays, dose reduction or discontinuation of chemotherapy. Severe instances are particularly associated with advanced metastatic cancers.

Moxibustion may have potential in reducing the risk of chemotherapy-induced pancytopenia. A component of traditional Chinese acupuncture, it uses the heat generated by the smoldering herb *Artemisia argyi* Lévl. et Vant.

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(*A. argyi*, Ai, common name mugwort) to stimulate specific locations on the skin, known as acupuncture points. Commonly combined with acupuncture needling, it may also be used on its own. Widely used throughout China and other East Asian countries, studies have reported that it may lessen the adverse effects of radiotherapy and chemotherapy,[16-18] alleviating side effects such as fatigue,[19,20] nausea and vomiting,[21,22] diarrhoea,[22] and pain.[16,23] Laboratory studies on animals have reported improved immune cell function,[24] while several clinical studies report higher white blood cell (WBC) counts, hemoglobin concentration, lymphocyte counts, and platelet counts in subjects receiving moxibustion compared to control arms receiving no treatments.[16,18,25] A study comparing moxibustion with G-CSF reported that while the latter increased white blood cell count more than moxibustion, it was associated with fatigue, sore muscles, fever, and abnormally high WBC counts at the end of a nine day treatment period. However, eight days after the end of treatment, the moxibustion group had a higher mean WBC count than the G-CSF group.[16]

This current study explored the feasibility of introducing a novel intervention, moxibustion, to patients undergoing chemotherapy for breast, gynecological and colorectal cancers in a National Health Service (NHS) cancer center. It aimed to assess the feasibility of teaching NHS chemotherapy patients a 10-minute protocol to apply moxibustion daily to an acupuncture point on the leg, Zusanli (ST36) (Figure 1).[26] It also aimed to assess whether this intervention has the potential to reduce the incidence and/or severity of chemotherapy-induced pancytopenia, facilitate completion of chemotherapy according to schedule, and mitigate chemotherapy-induced side effects.

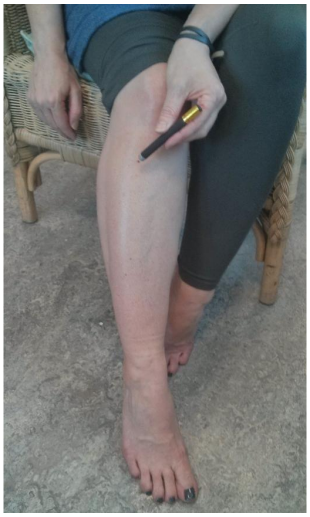

Figure 1 Health improvement practitioner demonstrating application of indirect moxibustion to acupuncture point Zusanli (ST36)

2. Methods

2.1. Ethical approval and setting

This study, conducted in compliance with the Helsinki Declaration,[27] is badged with the National Cancer Research Network (UKCRN; Study ID:19916). NHS Research Ethics Committee (REC) (London – Fulham REC, ref: 15/LO/1571) and local research & development approval were obtained. The NHS REC approved subsequent amendments to the protocol in March and July 2016. This paper adheres to the Standards for Reporting Interventions in Clinical Trials of Moxibustion.[28]

Study recruitment took place from February 2016 through October 2017 at Mount Vernon Cancer Center (MVCC), East and North Hertfordshire NHS Trust in the United Kingdom.

2.2. Study design

Full details of the protocol for this uncontrolled single site feasibility study using mixed methods have been published; the study flow diagram is re-presented in Figure 2.[26]

2.3. Sample size calculation

A formal calculation was not conducted. Recommended sample sizes vary depending on the objectives of a study,[29] and there are few recommendations for single arm studies. In multi-arm studies, a sample of 30 per group is considered adequate for establishing feasibility.[30] We estimated that 25 was a feasible number to recruit within the financial and time constraints of the project.

2.4. Participants

The study aimed to recruit 25 participants from cancer patients seen by oncologists based at MVCC, and who served associated district general hospitals. The oncologist informed the patient of the study and, if interested, obtained their verbal agreement to pass their details to the study's health improvement practitioner (HIP).

The HIP contacted the patient to invite their participation, supplied them with a Patient Information Sheet and screened the patient for eligibility. The HIP also examined patient notes on clinic days and peripherally inserted central catheter (PICC) line fitting appointments to identify further potential participants.

The study had broad eligibility criteria. Eligible participants were aged 18 to 75 with breast, gynecologic, or colorectal cancer. They were about to commence chemotherapy for which G-CSF is not routinely indicated. They also had a life expectancy of over 6 months, capacity to give informed consent, and capacity to understand and carry out the procedure for self-moxibustion.

Individuals with stage IV cancer were excluded if they were about to commence third- or fourth-line chemotherapy. Other exclusion criteria were a hematological cancer diagnosis, metastatic bone cancer, or cognitive impairment that would impact the participant's ability to safely administer self-moxibustion, or lymphedema in the lower body, or other concomitant severe medical problems preventing participation.

Eligible, interested patients were invited to an intake interview with the HIP, who demonstrated the procedure, and on obtaining written consent, proceeded to teach the intervention to the participant.

2.5. Intervention

Ideally, seven to ten days prior to the participant commencing chemotherapy, the HIP taught them the procedure. This included how to locate ST36, how to apply and use moxibustion safely, and how to complete study paperwork. She provided a kit containing the items needed, including a week's supply of moxibustion (Figure 3). At a follow-up appointment scheduled for one week later, the HIP assessed the participant's ability to administer the procedure correctly and safely, answered any questions, and provided a further supply of moxibustion.

2.6. Amendments to the protocol

After commencing recruitment, it was found that many individuals were diagnosed and seen first at their district general hospital and did not visit the main project site (MVCC) until a few days before the start of chemotherapy. Other potential participants were identified after their first course of chemotherapy when they attended MVCC to have a PICC line inserted. This scheduling inhibited recruitment according to the protocol. Thus, a substantial amendment to the protocol was applied for in July 2016 to extend the recruitment window from seven to ten days prior to chemotherapy to up to the end of the first cycle of chemotherapy (amendment approved by London-Fulham Research Ethics Committee, September 23, 2016). A previous amendment (February 2016) addressed minor changes to the participant information sheet.

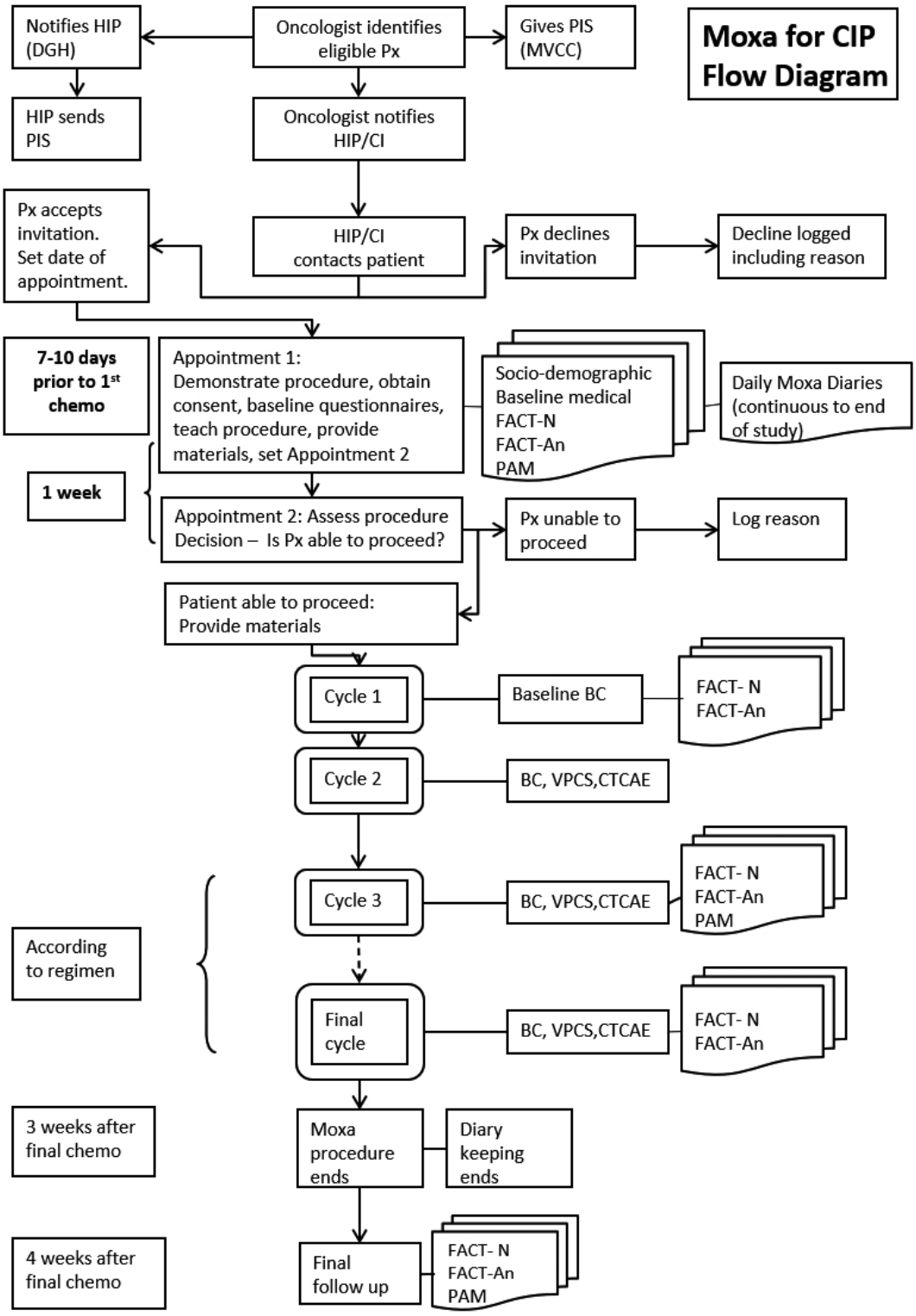

Figure 2 Study design

Notes: BC: blood count; Chemo: chemotherapy; CI: chief investigator; CIP: chemotherapy induced pancytopenia; CTCAE: common terminology criteria for adverse events; DGH: district general hospital; FACT-An: functional assessment of cancer therapy–anemia; FACT-N: functional assessment of cancer therapy–neutropenia; HIP: health improvement practitioner; MVCC: Mount Vernon Cancer Center; PAM: patient activation measure; PIS: patient information sheet; VPCS: variation to planned chemo schedule.

2.7. The intervention according to STRICTOM standards for reporting moxibustion interventions

The principal investigator (BdV), a UK licentiate of acupuncture with 18 years' experience, trained the HIP to self-administer moxibustion (which the HIP then chose to do for some time before the study commenced) and to train participants to do so. She was available to support the HIP through the duration of the study.

The procedure used indirect warming technique bilaterally to acupoint

Figure 3 Moxibustion kit

Notes: It contains (from upper left) box of moxibustion, timer, extinguisher, daily moxibustion diary, "A Patient's Guide: Using moxibustion to reduce the side effects of chemotherapy", (center left to right) memory stick containing video of how to moxibustion, moxibustion lighter, surgical pen for marking point.

ST36 (Figure 4). This involved stimulating the point by holding a burning cigar-shaped moxibustion stick (KX-06 MAXIM Mini-Smokeless Moxibustion, 10 sticks per box, 9.5 cm in length × 1 cm in diameter, produced exclusively for Phoenix Medical Ltd., Chelmsford, United Kingdom) approximately 3 cm from the skin for three minutes each on the left and right legs (Figure 1). Participants were instructed to obtain a gentle warming without any burning sensation, adjusting the distance of the stick accordingly if the sensation became too hot or was not sufficiently warm. Transient reddening of the skin was expected.

Participants were advised to carry out the procedure in a well-ventilated space, positioning themselves so they could access ST36 easily. For some participants, this could be done in a sitting position or sitting upright with legs outstretched before them. Some participants with mobility problems were unable to reach the point easily and relied on a family member to administer the moxibustion.

No other interventions were administered. Participants were trained in an NHS cancer support and information center and subsequently self-administered treatment in their homes. They were provided with a video demonstrating the procedure, available on a memory stick in their kits and online https://tinyurl.com/s5ak685m and a leaflet detailing how to carry out the procedure "Using moxa to reduce the side effects of chemotherapy: a patient's guide" (Appendix 1). The leaflet included instructions on what to do in case of burns.

2.8. Outcome measures

Outcome measures and the rationale for their use have been published previously; a summary of the intended measures is presented in Table 1.[26]

2.9. Statistical analysis

Most of the statistical analyses were frequency counts or percentages. A percentage concordance for each participant was calculated using a count of the total number of days on which they could potentially have administered moxibustion and the actual number of days it was administered. An overall percentage concordance for all included participants was also calculated.

The relative dose intensity (RDI) for each participant was calculated to assess adherence to the planned chemotherapy schedule. The RDI is a summary measure commonly used to describe dose delays and/or reductions occurring with a chemotherapy regimen.[31] It is the percentage of the delivered dose intensity of chemotherapy relative to the planned dose intensity. It enables both total dose and total time taken to be combined into a single value ranging from 0% to 100% where 100 represents full dose given on schedule with no alterations.[32] An RDI less than 85% is a clinically significant reduction from planned or standard therapy and could compromise treatment intent.[6,33,34]

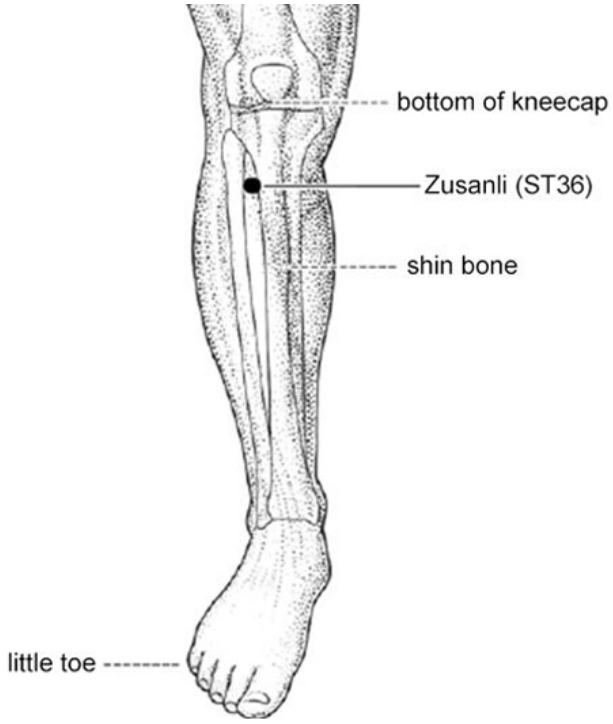

Figure 4 Location of Zusanli (ST36) (Adapted with permission from Deadman P, Al-Khafaji M, Baker K. *A Manual of Acupuncture*. Hove, UK: Journal of Chinese Medicine Publications; 1998: 158. Copyright 1998 Journal of Chinese Medicine Publications.)

FACT questionnaires were analyzed according to the developers' instructions using IBM SPSS Statistics (version 22, IBM Corp., Armonk, NY).[35-37] Comparisons for change over time were made using paired *t* tests. It was intended to analyze the 13-item patient activation measure (PAM-13) according to the developers' instructions.[38]

3. Results

3.1. Demographics and characteristics of participants

Of 54 patients approached, 25 consented and were recruited to the study (Figure 5). Eleven who originally appeared eligible proved to be ineligible for reasons including receiving chemotherapy at another hospital, bone metastases, leg lymphedema, decision to prescribe chemotherapy reversed by the oncologist, and previous history of three or more regimens of chemotherapy. Four of the eight who declined gave their reasons as concern that the smell of moxibustion would worsen existing nausea ($n = 1$), feeling overwhelmed and unable to take on anything more ($n = 2$), and skepticism about the intervention ($n = 1$).

Recruitment of the target 25 participants was completed in November 2017; sociodemographic and clinical characteristics are presented in Table 2. None of the participants had experienced or used moxibustion prior to the study.

Fifteen participants (60%) were receiving chemotherapy for early disease or in an adjuvant setting and ten (40%) had advanced or metastatic disease. A wide variety of chemotherapy regimens were recorded (Figure 6).

3.2. Primary outcomes

Feasibility of teaching NHS chemotherapy patients to self-administer

Table 1 Outcome measures

Outcome	Measure	Interval
Primary outcomes		
Concordance with moxibustion regimen	Daily moxibustion diary	Daily: from 7–10 days prior to first chemotherapy treatment until 1 month after last chemotherapy treatment.
Safety	Incident count from participant report, moxibustion diaries and CTCAE	Ongoing throughout the study period.
Secondary measures		
Blood counts, specifically hemoglobin, white blood cells, neutrophils, and platelets	Full blood count	According to chemotherapy schedule (usually fortnightly for colorectal, three-weekly for breast and gynecologic)
Variation to planned chemo schedule	Patient records: changes to dosage and time intervals between cycles	As above
Chemotherapy-related toxicities	CTCAE	Prior to each cycle of chemotherapy
Quality of life	FACT-G, FACT-N and FACT-An	Baseline, Cycle 1, Cycle 3, Cycle 6 (or final treatment); 1 month after end of chemotherapy
Patient self-management	Patient activation measure	Baseline, Cycle 3, 4 weeks after final chemotherapy
Concurrent therapies	Recording whether participants took or had therapies that affect blood cell counts, including steroids, iron supplements and other dietary supplements, blood and platelet transfusions.	Ongoing throughout the study period.

Notes: FACT-An: functional assessment of cancer therapy–anemia; FACT-G: functional assessment of cancer therapy–general; FACT-N: functional assessment of cancer therapy–neutropenia; CTCAE: common terminology criteria for adverse events.

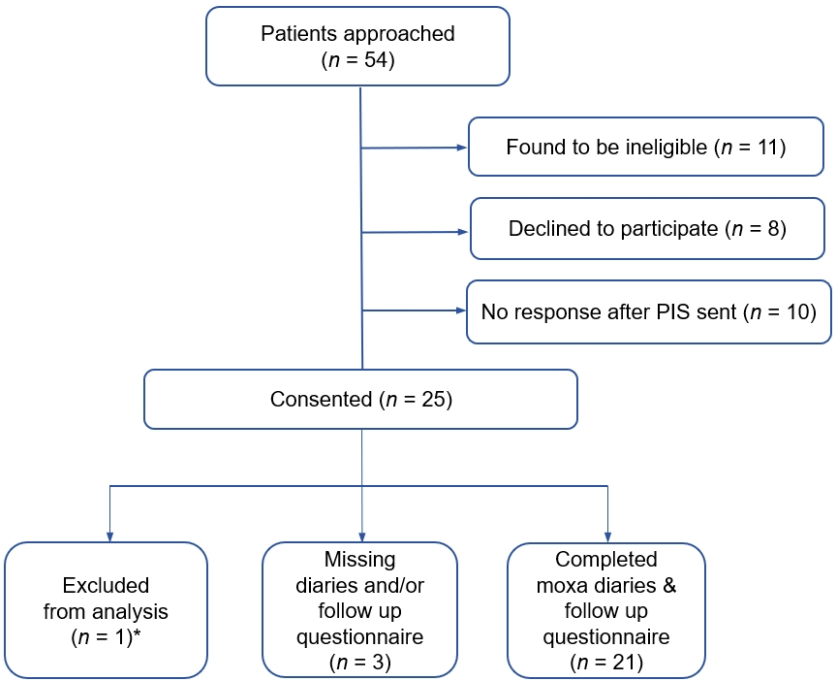

Figure 5 Recruitment flow

Notes: PIS: patient information sheet. * indicates chemotherapy withdrawn almost immediately after consent, therefore ineligible.

moxibustion was assessed using the recruitment figures (Figure 5), daily moxibustion diaries, and safety data. All participants were assessed to be capable of self-administration at the one-week assessment.

3.2.1. Completion of daily moxibustion diaries

Fifteen participants completed daily moxibustion diaries more than 50% of the time, even if on some days they reported not using moxibustion (red) as opposed to missing data (blue) (Figure 7). Of the remaining nine, three participants did not provide any information on their diaries.

3.2.2. Concordance with moxibustion protocol

Of the 25 participants, 17 commenced moxibustion prior to or during their first chemotherapy cycle, while eight began after the first cycle but before the second cycle. One participant discontinued chemotherapy after consenting but before receiving moxibustion training (Figure 5). Twenty-one participants returned sufficient usable data for analysis (Figure 5).

Table 2 Demographic and clinical characteristics at baseline

Characteristics	Total (n = 25)
Age, years	
Mean (standard deviation)	56.8 (13.3)
Range	21-74
Marital status, n (%)	
Single (never married)	7 (28)
Married (first marriage)	12 (48)
Divorced	3 (12)
Widowed	3 (12)
Race/ethnicity, n (%)	
Asian – (British Asian, Chinese, India, Sri Lanka)	6 (24)
Black (African, British, Caribbean)	2 (8)
White	17 (68)
Educational qualifications, n (%)	
Less than compulsory	1 (4)
Compulsory	10 (40)
Post compulsory	5 (20)
University	2 (8)
Post-graduate	7 (28)
Current employment status, n (%)	
Retired	9 (36)
Not working	5 (20)
Working part-time	3 (12)
Working full-time	8 (32)
Tumor type, n (%)	
Breast (female)	2 (8)
Colorectal	13 (52)
Male	*7 (28)*
Female	*6 (24)*
Gynecological	10 (40)

No participant was 100% concordant. Days on which moxibustion was used ranged from 2 to 184. The total number of potential applications was calculated to be 2944; there were 1369 recorded applications, giving an overall 46.5% concordance rate. The individual range was 4% minimum to 96% maximum, giving a concordance rate of over 75% in 19% (n = 4) of participants (Figure 8).

3.2.3. Reasons for non-concordance

Participants recorded 357 days of not using moxibustion in their diaries. Reasons for non-concordance were collected from the comments section and are presented in Table 3. Where participants noted more than one reason for not applying moxibustion, only the first reason is counted (e.g., "was tired and forgot" is counted as "tired").

3.2.4. Safety and severe adverse events

Safety was assessed from verbal patient reports to the HIP, notes in diaries, and focus group feedback. There were no recorded or reported severe adverse events associated with moxibustion usage. While there were no burns, three participants reported mild discomfort or singeing of leg hairs when the moxibustion stick was held too close to the skin. Participants reported that this was the result of inattentiveness during the procedure. One participant reported mild skin discoloration.

Other safety issues included cracks in the moxibustion sticks (Figure 9) raising concerns about potential burning or fire hazard if the tip fell off (although this did not actually happen). One participant reported the fire alarm sounding in their apartment block while applying moxibustion; however, it transpired this was not related to moxibustion (smokeless moxibustion had been chosen to avoid the possibility of triggering smoke alarms).

3.3. Secondary measures

3.3.1. Blood counts and frequency of toxicities

Frequency of chemotherapy-related toxicities are presented in Table 4. Blood counts are not routinely carried out mid-cycle or after the final cycle of chemotherapy unless a patient is unwell. They are routinely taken a few days before the next cycle is due, by which time any low counts occurring at mid-cycle may have resolved and were then unreported.

Episodes of chemotherapy-induced pancytopenia were assessed over 130 cycles. Grade 2 or above neutropenia is known to have occurred in 30 cycles.

3.3.2. Variation to planned chemotherapy schedule

The RDI ranged from 12.5% (n = 1) to 100% (i.e. no dose reductions and no delays and thus the desired outcome, n = 6), with a median of 88% (Figure 10).

	Colorectal					Gynaecological				Breast	Total
N = participants	13					10				2	25
	8	1	1	2	1	7	1	1	1	2	25
Regimen name	FOLFOX[1]	FOLFOXIRI (OP)[2]	Fluoropyrimidine/Oxaliplatin	Capecitabine	XELOX	Carboplatin Weekly Paclitaxel[3]	Cisplatin Weekly Taxol	Carboplatin	Carboplatin Gemcitabine	Paclitaxel[4]	
Oxaliplatin	8	1	1		1						11
5FU/Folate	8	1									9
Irinotecan		1									1
Fluoropyrimidine			1								1
Capecitabine				2	1						3
Carboplatin						7		1	1		9
Paclitaxel						7				2	9
Cisplatin							2				2
Gemcitabine									1		1

Figure 6 Chemotherapy regimens by tumor type

Notes: FOLFOX: folinic acid, fluorouracil (5-FU), and oxaliplatin; FOLFOXIRI (OP): folinic acid, 5-FU, oxaliplatin, and irinotecan (oxaliplatin + protracted venous infusion of 5-FU); XELOX: Xeloda (capecitabine) + oxaliplatin. [1] indicates one participant who also underwent panitumumab treatment; [2] indicates that treatment was switched to the folinic acid, 5-FU, and irinotecan (FOLFIRI) regimen following one cycle (i.e., oxaliplatin excluded); [3] denotes three participants who received concomitant bevacizumab administration; [4] denotes the concurrent administration of Herceptin (trastuzumab).

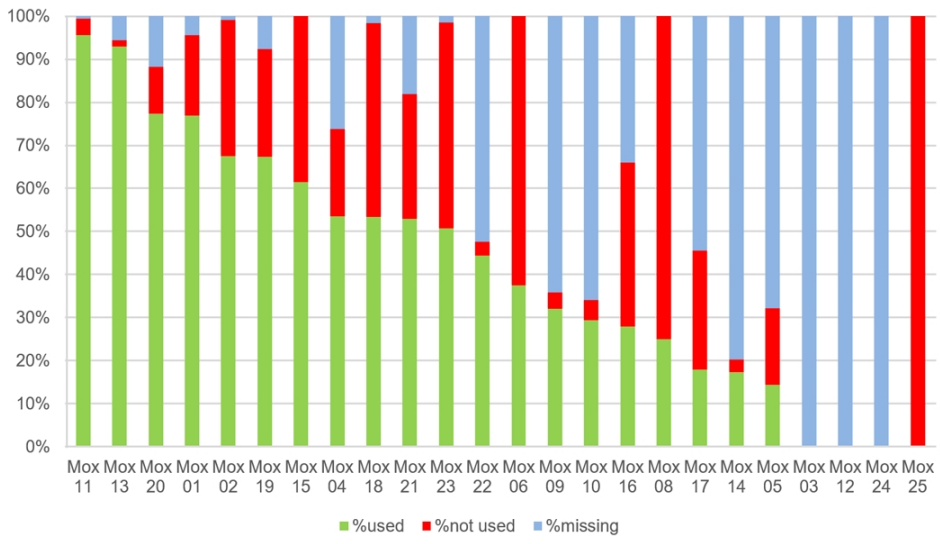

Figure 7 Completion of daily moxibustion diaries

Table 3 Reasons for non-concordance recorded on daily moxibustion diaries

Reason	Number of occurrences (%)
No reason given	76 (21.3)
Feeling sick (usually associated with chemotherapy)	60 (16.8)
Tired	56 (15.7)
Issues with moxibustion (e.g., difficulty lighting, smell)	32 (9.0)
Day off/fed up/bad day	30 (8.4)
Forgot	27 (7.5)
On holiday/day out	25 (7.0)
Hospital admissions/appointments/tests	16 (4.5)
Having chemotherapy	10 (2.8)
Weather[*]	10 (2.8)
Reason given unclear	10 (2.8)
Miscellaneous (e.g., bereavement, busy day, flu vaccine)	5 (1.4)
Total	357 (100.0)

Notes: [*]one participant chose to administer moxibustion out-of-doors (to avoid disturbing elderly parents); hence bad weather was a factor in their concordance.

Table 4 Known or reported frequency of toxicities

Toxicity	No. of episodes	No. of participants
Chemotherapy-induced pancytopenia		
Grade 3 neutropenia at mid-cycle	5	4
Grade 4 neutropenia at mid-cycle (neutropenic sepsis)	1	1
Grade 3 anemia	4	3[*]
Grade 3 thrombocytopenia	0	0
Other toxicities (CTCAE Grade 3 or above)		
Chemotherapy-induced peripheral neuropathy		2
Grade 3 vomiting		1
Grade 4 diarrhea		1[**]

Notes: CTCAE: common terminology criteria for adverse events; No.: number. [*] Two participants received blood transfusions. [**] Due to causes other than chemotherapy.

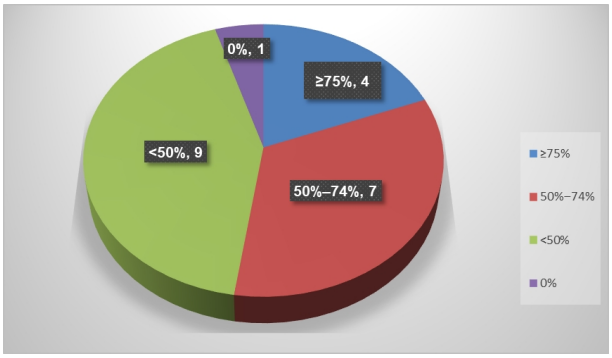

Figure 8 Concordance with the daily moxibustion protocol (n = 21)

Figure 9 Cracked moxibustion stick: a potential burn and fire risk

3.3.3. Quality of life

Functional assessment of cancer therapy (FACT)–general (FACT-G), FACT–anemia (FACT-An), and FACT–neutropenia (FACT-N) scores were calculated at baseline for all 25 participants. There were no significant differences in baseline scores between the 21 included participants and the four who were excluded from further analysis.

Not all participants completed questionnaires at all time points. Also, due to the variation in the number of cycles of chemotherapy across participants (from one to 18 cycles), baseline scores were compared with those collected on the day of attendance of the third cycle, thus covering the first two cycles of treatment.

For 16 patients, there were no clinically significant changes in the scores on any of the questionnaires at this time point. However, it was noted that all questionnaires showed that quality of life was declining. For 10 participants who completed a last follow-up questionnaire three weeks after chemotherapy finished, there was an improvement in FACT-G from 58.3 to 65.6 which was not significant (P = 0.12 on a paired t test). This was also reflected in improved scores on the FACT-An subscale (53.3 to 57.8, P = 0.34) and the FACT-N subscale (52.8 to 55.77, P = 0.50).

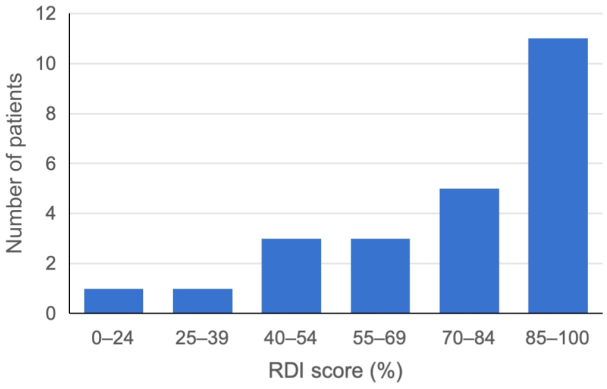

Figure 10 RDI scores for 24 participants

Notes: RDI: relative dose intensity.

3.3.4. Patient self-management (PAM-13)

According to the developers, uncalibrated sum scores on the PAM-13 questionnaire can range from 13 to 52. Uncalibrated baseline scores in our patient sample ranged from 28 to 39 with 12 of the 25 participants scoring 39 by "agreeing" to all 13 items. A further 10 participants scored 36 to 38. For this reason, we did not proceed with the full scoring as the questionnaire did not appear to have any discriminatory value in this cancer population.

3.4. Acceptability of intervention

Qualitative data regarding acceptability of the intervention were collected in one focus group with participants, and with interviews with oncology healthcare professionals. These were conducted at the end of clinical phase of the study.

3.4.1. Acceptability to participants

A member of the Supportive Oncology Research Team external to the study facilitated the focus group, which was attended by four participants and the spouses of two participants. The facilitator took written notes of the discussion. A further five participants were interviewed individually, providing qualitative data from nine of the 25 participants, comprising four gynecological and five colorectal (of whom four were male). These were analyzed manually by the principal investigator, who also reviewed participants' comments on diaries and the notes made by the HIP.

Participants' opinions on the interventions were mixed. Many said they found using moxibustion was helpful. Some perceived improvements in their energy level and noted that their energy diminished on days when they did not use moxibustion. Enhanced empowerment and time for self were also noted as beneficial aspects. Others found it difficult to gauge benefit, especially participants whose toxicities were mild. Overall, participants were pleased to have taken part in the study.

Remembering was a key challenge noted by participants, who felt it was important (although difficult) to establish and maintain a routine. Using the moxibustion could also be problematic. Some participants experienced difficulties lighting the moxibustion sticks, while gauging the heat was also said to be difficult. Although smokeless moxibustion had been chosen to reduce irritation by smoke or its smell, some found the smell of the moxibustion a problem.

3.4.2. Acceptability to oncology healthcare professionals prior to the study

Prior to study set-up, the principal investigator collected oncology healthcare professionals' views of this novel intervention. She gathered a range of responses, many of which were positive. In general, they were keen to have something to offer the many cancer patients who "want to do something for themselves". Two oncologists at Mount Vernon Cancer Center were active supporters of the study; two others wanted their patients to have access to it but were unable to refer their patients (one was outside the catchment area; the other had insufficient resources to assess and refer patients).

There were also negative views. One decision maker expressed concern that researching this unconventional intervention risked damaging the hospital's reputation. One oncologist said they would find it hard to recommend it to patients, as they struggled to believe that the intervention would have any effect on blood counts; they could not "see a biological rationale of how moxibustion can have a clinically relevant effect on chemotherapy-induced myelosuppression."

3.4.3. Acceptability to oncology healthcare professionals after study

The HIP interviewed eight healthcare professionals, comprising five consultant oncologists and three specialist oncology nurses.

Views were generally positive, although qualified. It was thought that moxibustion was a non-invasive way to give patients a sense of control and ownership during chemotherapy treatment. Again, it was mentioned that: "Patients like doing something for themselves". However, it was felt that this was an intervention for some, rather than all, patients.

Most thought that more evidence was needed about benefits. Although one oncologist said that "in spite of inconclusive evidence, this approach should not be abandoned" the majority expressed the view that the intervention was a placebo, with no rationale for scientific benefit.

4. Discussion

To our knowledge, this is the first study in the West to research the use of self-applied moxibustion in a conventional cancer care setting. The key aim of this study was to explore the feasibility of introducing a novel intervention, moxibustion, to patients undergoing chemotherapy treatment for breast, gynecological, or colorectal cancer in an NHS cancer center. The results indicate that this intervention is generally acceptable to cancer patients and their oncology healthcare professionals, and that it is possible to recruit to a study. However, several challenges were identified and are discussed below.

4.1. Strengths of this study

Acceptability of the intervention was a key finding of this study. Nearly half of the cancer patients approached decided to participate in the study. This demonstrates a high level of interest in this novel intervention. Additionally, oncology health care professionals were broadly supportive, and although many thought any effects were possibly due to placebo, they felt that this was an intervention that could empower patients who wish to do something for themselves during the chemotherapy stage of treatment.

Safety of the intervention was also an important finding, as there were no burns reported in the recorded 1369 applications of moxibustion. Minor incidents of mild discomfort or singeing of leg hairs were largely the result of inattentiveness during the self-administered procedure. The participants who experienced these cited reasons other than chemotherapy-induced cognitive impairment ("chemo-fog") for this inattentiveness. For example, the participant who administered the intervention out-of-doors reported being distracted by watching birds rather than the moxibustion stick.

4.2. Practical challenges: primary measures

4.2.1. Recruitment

The organizational structure of the local health care service made it difficult to recruit patients before chemotherapy started, as treatment was often prescribed at the district general hospital local to the patient. For these patients, their first attendance at the study site (Mount Vernon Cancer Center) was on the day of their first dose of chemotherapy.

In addition, it is known to be difficult to enroll patients between the time of cancer diagnosis and the initiation of chemotherapy.[39] The cancer center was cautious about introducing new interventions when patients were about to start chemotherapy, as they are under considerable pressure and finding it difficult to cope at this time.

These factors impacted the ability to recruit patients seven to ten days

before their first cycle of chemotherapy. It was thus necessary to amend the original protocol and widen the window of recruitment to the end of the first cycle.

4.2.2. Concordance

Concordance with the daily procedure was challenging. Whilst 19% of participants administered moxibustion on over 75% of occasions overall less than half of the possible applications were administered. This study illustrates the difficulty for some of administering a daily practice whilst coping with the demands of chemotherapy treatment and its attendant side effects of fatigue and sickness. Sending daily reminders via text might improve concordance in a future study, as the element of forgetfulness would be minimized. However, the challenges of feeling ill with chemotherapy side effects, as well as fatigue, would remain. Our findings are also an important reminder that people undergoing chemotherapy lead busy lives which may make adopting a daily practice difficult.

4.2.3. RDI

Fifty-five percent (13/24) of the study sample had an RDI less than 85%. This is consistent with the finding that approximately 50% of patients report an RDI of less than 85%.[34] Given the concordance rate with the moxibustion protocol, no claims can be made about the role of the intervention on this RDI.

4.2.4. Dose

This study raises important questions about dose, duration, and frequency, and whether daily application is necessary. The decision to prescribe daily application was partly based on classical Chinese medicine texts that prescribe daily application of moxibustion to ST36 to preserve and maintain health.[40] Staebler, whose original protocol inspired this study, also prescribed daily application.[41] In addition to frequency, there are dose-related questions to be explored. This includes the intensity of the application, that is, how many acupuncture points should be used, and for how long the moxibustion should be administered in individual applications. The overall duration of the regimen also needs to be explored.

Moxibustion is commonly used in China to reduce the side effects of cancer treatments and improve quality of life. However, a Cochrane review of 29 randomized controlled trials involving 2560 participants reported a wide variety of methods of application and dosage.[16] Methods cited include direct moxibustion (placing a moxibustion cone directly on the skin) and indirect moxibustion, which includes using a moxibustion stick (as in the current study) or placing a burning moxibustion cone on a medium (salt, ginger, or herbal preparation) to separate it from the skin. Protocols ranged from using three moxibustion cones directly placed on five acupuncture points daily for five to ten days to using a moxibustion stick for 10 to 30 minutes each on multiple acupoints for 5 to 50 days. One study used moxibustion for two hours per treatment, three times per week with a duration of 126 days.

By comparison, the intervention in the current study seems minimal; however, the aim was to devise a self-administered protocol that had the potential to be incorporated into a cancer patient's daily life. This protocol took less than ten minutes per day yet was still a challenge to incorporate into daily life for some of the study participants.

4.2.5. Issues with moxibustion

Thin (1 cm in diameter) smokeless moxibustion sticks were chosen for their qualities of not emitting smoke, of having minimal odor, and for being easier to light than standard (1.2–1.5 cm) smokeless moxibustion sticks. However, the study revealed numerous practical issues with these.

The moxibustion sticks are brittle, and many were found to be broken on delivery. Participants also reported cracks in the sticks, which posed a potential burn risk. Some participants reported difficulty lighting the sticks, and some reported that they found the smell unpleasant.

The need to add further safety information to the patient information leaflet was also identified. This included clarification that administering the procedure was inappropriate in a hospital setting, and that it should not be used in proximity to oxygen or other gas supplies.

To minimize these moxibustion-related issues, electrical moxibustion-pens would be an alternative to consider. However, they are expensive and there is a paucity of research into their effectiveness and safety in a cancer population.

4.3. Practical challenges: secondary measures

In addition to monitoring participant concordance with the moxibustion protocol, this study aimed to enable systematic monitoring of the impact of daily moxibustion on blood counts, variations to planned chemotherapy schedules, chemotherapy-related toxicities, and quality of life. The level of concordance with the protocol and questionnaire return made evaluating the impact of daily moxibustion difficult. However, through the process of data collection and analysis, the study identified challenges and factors that could be improved for future studies.

4.3.1. Blood counts

Cancer patients do not routinely have blood counts mid-cycle so incidents of chemotherapy-induced pancytopenia may be under-reported. Their incorporation was discussed during study design; however, it was decided that this would add an invasive and undesirable stressor into participants' lives and could potentially increase exposure to infection at the nadir of the cycle.

4.3.2. Variation to planned chemotherapy schedule

Three tumor types including breast, gynecological, and bowel, were chosen with the aim of ensuring that sufficient participants could be recruited to the study. This brought with it a wide range of chemotherapy regimens. The differing number of cycles (from one to 18) impacted the ability to conduct a comparative analysis of the outcome measures, particularly over multiple measurement points. To reduce confounding variables, it may be better if a future study was confined to a single disease site and chemotherapy regimen.

4.3.3. Chemotherapy-related toxicities

There was considerable variance in the levels of detail in the patient notes on the common terminology criteria for adverse events (CTCAE), often depending on who was writing the notes. Where care between cycles of chemotherapy was delivered at another hospital it was also difficult to collect clinical information. These circumstances made collecting systematic information on chemotherapy-related toxicities challenging.

It must also be noted that people undergoing chemotherapy have dose reductions and delays for toxicities other than hematological (e.g. peripheral neuropathy, abnormal liver function tests or urea and electrolytes, and/or non-cancer related comorbidities) which confound analysis.

4.3.4. Quality of life (FACT-G, FACT-N, and FACT-An)

Quality of life was measured using the FACT series of questionnaires. Recruiting participants receiving treatment for early-stage disease and participants treated for advanced or metastatic disease across of range of tumor sites led to a large variation in baseline scores.

FACT-G detected change post-treatment, as expected. Only small changes were seen on FACT-N and FACT-An. This may be due to the low recorded number of cases of anemia (n = 4) and neutropenia (n = 6), and that their occurrence did not necessarily occur at the time the questionnaires were administered. Additionally, participants may have been neutropenic mid-cycle and have recovered by the time of their next scheduled pre-chemotherapy blood test.

4.3.5. Patient self-management (PAM-13)

The PAM-13 is a measure that assesses patient knowledge, skills, and confidence for disease self-management. It was used in this study to assess whether it could potentially serve as a tool to identify cancer patients who were likely to comply with a self-help measure. However, the data collected

did not seem reliable and thus it did not seem worth incurring the high license costs for full analysis. Recent evaluation suggests that PAM-13 may not be a suitable questionnaire for use with a cancer population.[42]

4.4. Recommendations for a future study

For future studies we recommend the focus should be on a single tumor type where RDI is shown to have an impact on outcomes (e.g. metastatic breast cancer, resected colon cancer).[43,44] Consideration should be given to limiting the study to the same or similar chemotherapy regimens. A balance should be sought between the dose, ease of use, safety, and acceptability of moxibustion. Systems should be set in place to send reminders to carry out the procedure.

It is interesting to note that recommendations for trial designs for prevention of chemotherapy-induced peripheral neuropathy (published subsequent to the current study) identified many of the issues that our study identified, including recruitment of cancer patients prior to the start of chemotherapy, the preference for choosing a single cancer site and chemotherapy regimen, and the challenges of conducting a preventative study.[45]

5. Conclusions

This study was the first stage in assessing whether self-administering moxibustion to ST36 can reduce chemotherapy-induced pancytopenia. It focused on assessing the feasibility of teaching the intervention to patients undergoing chemotherapy in a conventional cancer treatment center. This feasibility study identified numerous challenges relating to the study design, delivery of the intervention, and collecting and analyzing data. This information is valuable for informing the design of future studies. The main take home message is that this intervention can be used safely by cancer patients and is of interest to many of them.

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Data Availability

All data supporting the findings of this study are available within the article and its Electronic Supplementary Material.

Author Contribution Statement

Beverley de Valois: Conceptualization, funding acquisition, methodology, project administration, supervision, visualization, writing – original draft, and writing – review & editing. **Teresa Young**: Conceptualization, data curation, formal analysis, funding acquisition, methodology, supervision, visualization, writing – original draft, and writing – review & editing. **Clare Scarlett**: Data curation, formal analysis, investigation, and writing – review & editing. **Friedrich Staebler**: Methodology and writing – review & editing. **Rob Glynne-Jones**: Resources and writing – review & editing.

Use of AI Statement

None.

Declaration of Competing Interest

The authors have no competing interests to declare that are relevant to the content of this article.

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