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Research Article

Perceptions of Breast Cancer Survivors Participating In a Chinese Herbal Medicine Study: An Exploratory Narrative Study

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Abstract

Objective: Survivors report Hot Flushes/Night Sweats (HF/NS) as the most debilitating side-effect of breast cancer endocrine therapy with limited treatment options. The aim of the investigation was to gather information, not available in quantitative outcome measures, including narrative data of women's experiences of HF/NS and personal experience of participating in a Chinese Herbal Medicine (CHM) trial to alleviate this bothersome side-effect. This is an important pilot feasibility study to evaluate the potential benefit of trialling a novel Chinese medicinal product for a symptom of HF/NS identified as an unmet need for breast cancer survivors and may help inform future studies.

Participants and Methods: Semi-structured focus groups were conducted with 8 breast cancer survivors with hot flush symptoms. All women had been randomised to participate in a CHM clinical trial for alleviation of HF/NS. A discussion guide was employed to provide insights regarding symptom experience, hot flush impact on quality of life, and qualitative data related to the acceptability and feasibility of CHM as a management option for HF/NS. Digitally recorded narratives were analysed using thematic analysis.

Results: Our analysis confirms CHM acceptability is complex. The taste was deemed "not pleasant", however, the driver of hot flush reduction helped maintain adherence. Additionally, after completing their primary care participants reported a feeling of insecurity and not knowing where to turn for help with side-effects of treatment. These findings reveal that survivorship has its challenges and can impact quality-of-life with psychosocial and physiological implications long-term. Categories identified included 'give it a go', 'avoidance and acceptance', 'routine and reward', 'transitioning to survivorship'.

Conclusion: Focus group findings report CHM through the hospital setting provided an additional safety measure. Drivers for acceptability of CHM included commitment to the trial, the belief that it would work, taking a more active role in their well-being and feeling valued as a participant in the trial. Other themes include opportunities for better transition to survivorship and management of adverse effects.

Keywords: Breast cancer; Chinese herbal medicine; Hot flushes; Qualitative; Quality of life; Vasomotor symptoms

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Abbreviations

BrCa - Breast Cancer
CHM - Chinese Herbal Medicine
CIM - Complementary and Integrative Medicine
HF/NS - Hot Flushes/Night Sweats
OTC - Over-The-Counter
QoL - Quality of Life

Introduction

Breast cancer survival is increasing worldwide due to improved detection and treatment [1]. However, this growing number of survivors has led to increased concern to optimise Quality of Life (QoL) after recovery [2-4]. Vasomotor symptoms (hot flushes/night sweats) are the most reported and debilitating side-effect experienced by this group of women which may occur due to a) ovarian ablation b) chemotherapy c) radiation therapy d) natural menopause e) adjuvant endocrine therapy [5-9]. Currently there is no standard management for Vasomotor Symptoms (VMS) which are reportedly worse in survivors prescribed endocrine-disrupting therapy (including estrogen antagonists and aromatase inhibitors) for 5-10 years post-diagnosis [6,10-12]. Severe hot flushes interfere with daily life and often lead to poor adherence or discontinuation of potential life-saving medications [13-15]. Many of these women turn to Complementary and Integrative Medicine (CIM) to address their needs [16-18].

Methods

Ethics and recruitment

The focus groups were a sub-study involving participants of a CHM randomised clinical trial conducted through the oncology clinics of three hospitals located in Sydney, Australia during 2018-2019 [19]. All hospitals were under the jurisdiction of the South Western Sydney Local Health District who granted ethical approval as an addendum to the main clinical study (SWSLHD HREC/17/LPOOL/25).

Participants

Criteria for inclusion in the focus group were any consented participant, regardless of whether they had completed the full study.

To reduce bias women were included if they had been randomised and started the study regardless of participation duration. Participants were advised of confidentiality and anonymity. Other inclusion criteria for the trial included > 18 years of age, female, diagnosed with Stage I to III breast cancer and completed primary stage of treatment, experiencing bothersome hot flushes/night sweats, not taking other medication for hot flushes/night sweats, if taking endocrine-disrupting drugs stable for at least 2 months, able to give informed consent. Thirteen women who had been randomised to the CHM study were approached to take part. Two women did not answer the invitation, 2 declined to participate due to other commitments, 1 responded but failed to attend the focus group.

Demographic and clinical information for participants was collected at the beginning of the clinical trial. The women were aged from 46 to 64 years of age and diagnosed with clinical Stage I to III breast cancer and had completed their primary care (surgery, chemotherapy and radiation). All women participating in the focus groups were prescribed adjuvant hormonal therapy for Hormone Receptor (HR) positive primary breast cancer. At the time of diagnosis 1 was pre-menopausal, 4 were peri-menopausal and 3 were post-menopausal. All participants were given written and verbal information about the study and written informed consent for the focus group was obtained at the same time as consent for the clinical trial.

Focus group interviews

This exploratory study involved 8 participants in two separate focus groups. This is a small pilot study, therefore, it may be difficult to obtain enough data to reach saturation and make definitive conclusions. However, samples sizes in qualitative research tend to be small in comparison to quantitative research [20]. Sandelowski reports "an adequate qualitative sample size is one that permits - by virtue of not being too large - the deep case-orientated analysis that is a hallmark of all qualitative inquiry and that results in by virtue of not being too small - a new and richly textured understanding of experience" (p.525). The focus groups are loosely aimed at collecting data about the participants' personal perspective of participating in the trial, including their experience of taking the intervention [21]. I asked myself the provisional question "What do I want to know about this study" and found that I wanted answers to questions about why or why not people participated or stayed in the study, the experience of being in the study, insights into how hot flushes impacted in their day-to-day life, if they perceived any benefit from the intervention or from being a participant and how they obtained information regarding treatment side-effects. These initial questions helped shape the more specific questions to explore a range of themes for the discussion guide (Table 1). This framework may help provide answers to questions relating to feasibility of CHM trials, participating in a trial, the experience of breast cancer, living with a chronic condition and use of herbal medicine or natural products after a cancer diagnosis.

The interview prompts are presented in Table 1.

This type of semi-structured interview employs a guiding theme with probing open-ended sub-questions but allows participants to pursue or respond in their own manner allowing for the discovery of new information [22]. The moderator had extensive knowledge of the topic under discussion and developed an interview guide to foster dialogue relevant to the study aims (Table 1). The research aims were based on a review of the literature reporting on the needs and experiences of women previously diagnosed with breast cancer. These aims are presented below:

The focus groups aim to:

- To explore the trial participants' perceptions of VMS and their impact on their life
- To explore how their oncologist's involvement may have affected their participation in the study
- To explore how the trial participants perceived the intervention
- To identify why some trial participants withdrew from the study
- To explore the trial participants perceptions of benefits or not from the intervention
- To identify what women diagnosed with breast cancer perceive as barriers or facilitators to their healthcare needs
- To explore what information breast cancer survivors would like to have available about CIM and how they would like this information disseminated

Analytical methods

A grounded theory approach was used to obtain participant-led data [23]. Grounded theory is a method of systematically collecting and analysing qualitative data to discover emerging themes [24]. A theme or a code is a word or a short phrase that is a key attribute of narrative information [22].

S. No	Discussion Guide
1	What was your initial reaction when CHM was suggested by your oncologist > Did you have any concerns > if yes what were they?
2	Would you have used herbal medicine from another source > i.e. not suggested by oncologist at hospital but over-the-counter, something on the internet, suggestion from family/friend or CAM practitioner?
3	What were your main reasons for joining the study?
4	How did you find the taste and smell of the intervention? Did they smell and taste similar?
5	Did you feel a level of safety taking the intervention through a hospital setting with pathology tests and oncologist support > any other comments?
6	Tell me about your hot flushes/night sweats, what do you experience when you are having a hot flush/night sweat?
7	What strategies do you use when you are having a hot flush/night sweat?
8	Do you feel that exercise, stress or food/drinks you ingest may influence hot flushes i.e. coffee, tea, alcohol, spicy foods and if so, in what way?
9	Did the intervention help with the hot flushes/night sweats> if so in what way> have any changes lasted?
10	Do you wish to continue with the intervention now that the study period is over> if yes what factors would influence your use of CHM for hot flushes?> if no why not?

Table 1: Interview prompts.

This type of qualitative research allows for interaction between researcher and participant and is participant experience driven [22]. All data was digitally recorded with additional reflexive notes made if necessary. To reduce bias data was transcribed verbatim immediately after the focus groups then read and re-read several times by the principal researcher (DP) before analysis commenced [25,26]. Using the principles of constructivist grounded theory (DP) commenced with inductive content analysis - manually highlighting key words or phrases significant to the studied phenomenon [27]. This variation of grounded theory is based on Glaser and Strauss's (1967) model, which used coding, memo-writing and theoretical sampling [27]. However, it employs methodological innovations to bring grounded theory into critical inquiry [28]. One of the ways it does this is by pursuing emergent questions or developing strategies during the research process [28]. Secondly, by employing self-reflection and how we as researchers may affect the research process and our rapport with the research participants [28,29]. Charmaz explains, "it is a construction between participants and observer, the observer's interpretation of the data, the observers' reading of the data, the observer's rendering of the data" [30]. By way of explanation, how the positioning of our beliefs, language and culture may influence our research and our relationships with our research participants [28,31]. Reflexivity will help address any biases which may include being a Chinese medicine practitioner and a trial co-ordinator as well as being a member of the group being studied i.e., a breast cancer survivor [29,32]. This unique position has helped develop a rapport with the women as I have the knowledge of what it feels like to be a survivor thereby putting me in a position where I can better understand and be aware of their experiences via the 'shared experience' [29,33]. On the other hand, this position may potentially construct biases via my personal beliefs and deeper understanding of the subject. Harding's concept of methodological self-consciousness makes us see our work through different eyes by writing critical reflections [34]. By employing reflexivity and maintaining a distance my interpretation of the data should expand my existing perspectives to that conveyed by the women [35].

From this, over-arching categories and repetitive concepts were extracted, compared and connected [22,36,37]. Common themes were identified and constantly reviewed to check that developing philosophical assumptions were correct, simultaneously linking them to my general reflections. The emerging categories were integrated into themes and labelled. The process was an iterative process, transcripts were read and re-read to confirm and refine presenting themes, collating and comparing between presenting concepts [22,36]. The second author (XZ) read the transcripts and independently reviewed the findings to ascertain validity of identified concepts and themes. Both authors (DP) and (XZ) collaborated, discussed and developed the themes and subthemes to ensure rigour.

Results

Perspectives of cancer survivors

Eight women with breast cancer took part in the study. Several themes and relationships emerged from the data. The themes provide an insight into the experience of hot flushes, how to manage them and their impact on quality of life in survivorship, the experience of participating in a CHM study including safety, taste and outcomes of the intervention and support services in survivorship. Themes were placed into categories including 'give it a go', acceptance of hot flushes and avoidance of triggers, cool down, carry on and communicate, safety, routine and reward, transitioning to survivorship (Figure 1).

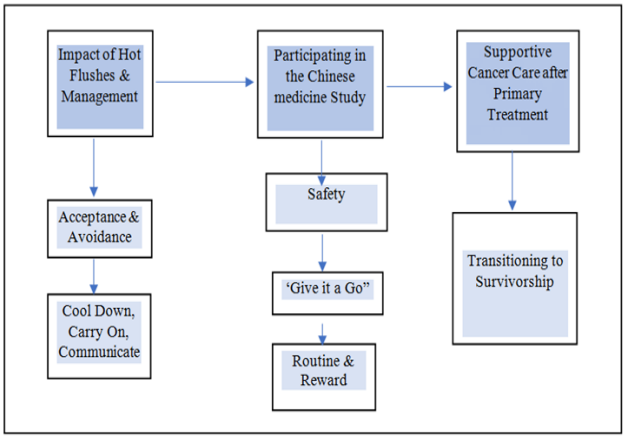

Figure 1: Diagram of themes and categories.

Theme 1: Impact of hot flushes and their management

"Cool-down, Carry-on and Communicate"
"Acceptance and Avoidance"

The over-arching theme of hot flush impact and management contained two subthemes: "cool-down, carry-on and communicate" and "acceptance and avoidance" - the women learnt to accept their unique situation, however, they employed strategies to help keep cooler by avoidance of triggers for hot flushes.

Mostly the women had learned to employ practical strategies to help with management and impact of hot flushes. These included wearing layers of clothing so that they could remove them as needed, carrying a fan or using electric fans or air-conditioning as much as possible. Some communicated with their work colleagues and friends about the hot flushes to help reduce embarrassment in these situations. At night they threw covers off and had cool showers or went outside to cool down. Most of the women avoided alcohol and coffee as they triggered hot flushes and exercise was also avoided due to the added impact of feeling hot and sweaty. In summary, the women adopted many approaches for coping with debilitating hot flushes including a change of attitude to acceptance and self-help strategies. Some of these strategies resulted in avoidance of exercise and dietary triggers. Hot flushes affected leisure activities due to their impact on appearance and mood. Disrupted sleep from hot flushes/night sweats resulted in fatigue which also impacted their social engagements.

"*Jacket on, jacket off, people hand me paper towels and tissues. I don't go red -*
"I just get really hot and perspire" (n=1)
"It interferes with sleep, so throwing off covers and getting up continuously - interrupted sleep. You do feel tired the next day though" (n=8)
"I have air-conditioning going on and off all night" (n=5)
"I know that if I have coffee or wine that it is going to hit me. I tend to avoid going out with friends as it goes hand in hand. Even with exercise - ten minutes later I know they (hot flushes) are going to hit me.

I get sweaty and hot, so I avoid it. I don't even want to go out, after 8 o'clock I am just too fatigued" (n=1)
*"I have a little portable fan on my desk at work. I have told people about my problem and they turn it on for me. I don't wear make-up as it just melts off -that sort of impact on how you present yourself***"** (n=1)

Theme 2: Participating in the Chinese herbal medicine study

"Give it a go"
"Safety"
"Routine and Reward"

The women decided to join the Chinese medicine study and "give it a go" in the hope that trying something new may reduce their HF/NS hot flushes/night sweats. Personal motive was the main reason as they expressed desperation in their desire to reduce the unwanted side-effect. Many did not wish to take another pharmaceutical due to perceived or potential side-effects. The women expressed safety concerns about using over-the-counter remedies for menopausal symptoms and felt reassured of the safety of the CHM as it was referred by their oncologist, conducted at the hospital and they underwent regular pathology tests during the study.

The taste of the intervention was a barrier to acceptability. The CHM and placebo provided in the study was in powder format to be mixed with warm water and taken orally as a tea, twice daily. Most of the participants disliked the taste of the CHM/placebo (two withdrew from the study as they could not tolerate the taste; others diluted the powder with juice or gave themselves a reward afterwards). Participants found the appearance and smell of the intervention and placebo were similar, but one tasted more bitter than the other. Some women expressed the desire for the intervention to be available in capsule format. Other barriers that may influence long-term use, outside of the trial, were potential financial cost, quality and safety of the intervention and ease of availability.

The sub-theme of "routine and reward" also emerged from the analysis. Despite the unpalatable taste of the intervention some of the participants reported they started to look forward to the routine of taking the intervention twice daily - this was the first identified facilitator of acceptability. The second facilitator of acceptability included participants reporting a reduction in hot flush severity and wished to continue taking the intervention, with one participant also stateing a reduction in stress levels. This reduction in symptoms was perceived as a reward. Commitment to the trial, the belief that it would work, taking a more active role in their well-being and feeling valued as a participant in the trial where found to be mediators of acceptability.

Five of the women cited "desperate" as their primary motive (n=5)
"*anything is better than nothing, lots of people say it (Chinese herbal medicine) works for a variety of things, so yes, willing to give it a go*" (n=5)
"*I was open to it, accepting of anything; give it a shot, why not?*" (n=2)
"*My doctor said it is either 'Effexor' (an anti-depressant) or this (Chinese herbal medicine trial). I didn't want to take another prescription drug, so I thought - I'll give it a go*" (n=1)
"*I felt a level of safety in general because of the hospital setting*" (n=8)
"*I felt safe having the pathology tests at different intervals*" (n=6)
"*The first one was terrible. I tried it with juice and then chocolate milk and that seemed to work. It was so bitter. The taste was different in the second lot, though they smelt and looked the same*" (n=1)
"*I felt I started to look for it as it started to become part of my daily routine. I don't drink tea or coffee so it was herb time*" (n=1)
"*I felt it was my morning and afternoon ritual. Though I feel if it is successful that it should be compounded into a capsule so that it would be easier to take or perhaps enhance the flavour*" (n=1)
"*I felt it was not unpleasant to the point the gagging, but I rewarded myself afterwards with a piece of chocolate*" (n=1)
"*Cost would definitely influence my use*" (n=4)
"*Yes, cost would be a factor, $20 per week would be ok, otherwise for long-term use it would be difficult to pay more*" (n=3)
"*I would like it to be easily available and to know that what you are getting is safe, tested and best quality*" (n=4)

Theme 3: Supportive Cancer Care after Primary Treatment

***"Transitioning to survivorship"*:** In the theme "*transitioning to survivorship*" the women expressed challenges they faced after their treatment and reliance on their medical team concluded. Patients are often monitored only annually after active treatment. They reported feeling nurtured during the active stage of treatment, however, they felt a bit lost as to who to go to for their concerns as they moved to a transition period. The new phase of survivor was bewildering for most as they were unsure how to easily access suitable options regarding side-effects of treatment and adverse psychosocial issues. They did not want to waste the time of the oncologist's but felt a lack of readily available support in this transition period and expressed concerns regarding the need for some ancillary care

"*excellent support during and just after diagnosis and acute treatment. However, if you have any issues down the track it is hard to get help. I saw my GP and went back to see the oncologist. I needed answers - you do feel a bit cut off once treatment is finished. My GP didn't know a lot about after-effects of radiation*" (n=1)

"*the doctors do a fantastic job, but once acute treatment is over you feel a bit abandoned. I understand that they are busy and other patients are needing their time, but side-effects are dismissed as part of the treatment.You don't get much help or advice then*" (n=4)

"*there is no discussion about what you are doing e.g., if you are taking vitamins, no advice on diet even with the breast cancer nurse*" (n=5).

"*Yes, more information about alternative therapies would be useful. I wasn't game to try any other remedies due to safety concerns*" (n=4).

The categories and themes are presented in table 2.

Discussion

The findings provide data on the impact of HF/NS on quality of life, subsequent coping mechanisms and the experiences of participating in a trial with a novel therapeutic intervention.

With increased survivorship after breast cancer the need for effective management of symptoms and side-effects is important as quality of life is a major objective in oncology care [38,39]. Using in-depth focus group techniques this study explored the lived experiences of breast cancer survivors after participating in a CHM medicine study for managing HF/NS and explored the impact of HF/NS on everyday life.

	Main Themes Identified
Chinese herbal medicine decision-making experience - initial reaction to study	"Give it a go - anything is better than nothing"
Reasons for joining study	"felt safe as it was through hospital" "Pathology tests made me feel safer" "desperate – we can't take HRT"
Hot flushes/night sweats - impact on QoL	Sleep, anxiety regarding social relationships and work, appearance, exercise, levels of fatigue were all negatively influenced. Feelings ranged from an inability to cope with the distress to acceptance of the side-effect or avoidance of triggers
Taking control - Self-care strategies Intervention - taste	Cool down, carry on and communicate No one found the intervention pleasant or easy to drink. Although some looked forward to the ritual with a reward afterwards
- outcome	Some participants were not sure if the intervention helped in either arm of the study, others felt severity of hot flushes and night sweats was reduced. One participant said stress levels felt less.
- continuation	Ease of availability and cost may prevent long-term usage
Burden of attending study visits	No participant found it a burden to attend or fill out the forms
Seeking treatment information	Transitioning to survivorship –Participants felt well-supported during acute stage of BrCa treatment; but felt more support should be provided for side-effects including hot flush management. Transitioning into survivorship - identified a need for a survivorship plan
- information on CIM	Participants felt that it would be valuable to have evidence-based information regarding CIM treatments after BrCa, particularly relating to alleviation of side-effects.

Table 2: Main categories and themes identified.

HF/NS are the most reported and the most debilitating side-effect of treatment after breast cancer and there is a major gap in their management after a diagnosis [7,10,11,40-42]. Many survivors do not want to take another pharmaceutical due to potential side-effects and Hormone Replacement Therapy is contra-indicated due to risk of recurrence [43].

The first research aim was to explore how HF/NS impacted daily life. All participants reported the experience was stressful and impacted on sleep and how their work and social lives were changed. The women described how they learned to employ practical strategies to deal with management of HF/NS as outlined in the narratives above. Although they reluctantly had to accept HF/NS as part of their life, they avoided exercise and social engagements due to how HF/NS impacted on appearance and mood. Disrupted sleep also resulted in fatigue and impacted their ability to attend social engagements. Similar to other studies the findings have highlighted the negative impact that HF/NS have on daily QoL of breast cancer survivors [2,44,45].

Participants were asked if their oncologist's involvement helped in their decision to participate in the study. Although the women were struggling with their HF/NS they did not wish to take another pharmaceutical but were also reluctant to take over-the-counter remedies due to safety concerns after their diagnosis. The referral from their oncologist, with the study being conducted in a hospital including regular pathology tests, helped alleviate any participant concerns about the safety of the Chinese herbal medicine.

Another aim of the study was to identify what breast cancer survivors perceive as barriers or facilitators to their healthcare needs. An important theme uncovered during the study included the 'lived experience' of cancer survivors as they transition from patient to survivor [46,47]. They were living with their diagnosis daily but desired to have a better quality of life [48,49]. The women expressed concerns regarding unmet needs for treatment side-effects, their impact on daily quality of life and who to turn to for advice.

The women valued their relationship with their oncologist and satisfaction with their acute primary care, however they expressed concern and frustration about the transition process post-treatment and the need for more support for physical and emotional side-effects [50]. Their perspectives included confidence in their medical treatment but a feeling of being overwhelmed and vulnerable as the intense primary treatment period ceased. It has been previously reported that patients can transfer the burden of medical decision-making to their physician during the treatment period as they learn to accept their diagnosis [51]. At conclusion of primary care, the women in this study reported feeling a bit lost, having developed a dependency on the medical staff and a routine of sometimes daily visits to the hospital. Other studies have reported similar findings, with patients feeling as if their safety net had been taken away as they finish primary treatment and try to come to terms with their new reality [52-54].

The findings may provide guidance for healthcare policy through added support for addressing treatment side-effects and provision of survivorship care planning with evidence-based information. It was clear from the stories shared during the focus groups that survivorship, including learning how to live with side-effects and the process of transitioning from patient to survivor, required additional support after the acute phase into recovery. Additional sources of support (medical and non-medical) may help with co-ordination of care and a smoother transition. Similar plans have been studied and implemented in other countries to reduce impact on physical and psycho-social well-being during this period [55-58].

The final and main aim of the focus groups was to inform regarding acceptability of the intervention and perceived benefits and/or burden of participating in the trial. Our findings revealed that the unpalatable taste of the powder herbal mixture was a problem. The clinical trial did have some withdrawals due to the taste of the intervention. In principle, the taste of the intervention was not acceptable, however, participants continued for a variety of reasons. These mediators of acceptability included commitment to the study, reduction in HF/NS, confidence in the safety of the intervention through the hospital setting, taking a more active role in their well-being and feeling valued as a participant in the trial.

Future studies may need to focus on feasibility and acceptability, perhaps offering the intervention in two forms - powder and encapsulated - to help maintain participation. Many of the participants desired

to continue with the CHM after the study concluded, as they found a reduction in the severity of their HF/NS, but cited cost as the major obstacle with ease of availability and quality control as additional concerns. None of the participants found it a burden to maintain the study visits every 4 weeks and wished to honour their commitment to the completion of the study. These findings provided an insight into the acceptability of the intervention which may help inform the design of future Chinese herbal medicine studies regarding feasibility, acceptability and compliance.

Five main narrative themes emerged from the data - 'give it a go', 'acceptance and avoidance', 'cool down, carry on and communicate', 'routine and reward' and 'transitioning to survivorship".

Strengths and Limitations of the Study

This qualitative study aimed to explore why a Chinese herbal medicine may or may not be feasible to alleviate hot flushes after a breast cancer diagnosis. The use of focus groups enabled us to explore patients' experience of participating in a Chinese herbal medicine study in a hospital setting and provided rich narrative accounts of their involvement in the trial. Before presenting our conclusion, we would like to report that a potential limitation of this study is the moderator of the focus groups was also involved with the running of the trial and is a breast cancer survivor and a Chinese medicine practitioner. However, to help reduce potential reporting bias narrative accounts were encouraged from the participants, which were transcribed verbatim and analysed using self-reflexivity by the moderator (DP) and a co-author (XZ). A potential limitation of this exploratory study was the small number of participants in the focus groups (n=8). All participants were from aculturally diverse urban setting in Australia; however, themes may not extrapolateto breast cancer survivors in different cultures and settings.

Conclusion

Qualitative research aims to understand more about health conditions and may help inform feasibility of interventions and the reasons participants join trials. Breast cancer survivors report debilitating HF/NS after treatment with limited treatment options. Evidence-based information regarding treatment options is urgently needed for this cohort as many women turn to CIM to relieve their symptoms but are faced with conflicting information. The focus groups explored experiences about managing HF/NS, their impact on daily life and the experience of participating in a Chinese herbal medicine study. The results highlight the impact of HF/NS on QoL and the challenges related to this. Joining the CHM study was driven by their desperation to try anything for reducing their HF/NS symptoms. This study also explored self-strategies for coping with this side-effect and the impact of breast cancer treatment on quality of life, long term. Patient perspectives on participating in a CHM trial in a hospital setting were explored including facilitators and barriers of acceptability of the intervention. This study may add to existing literature regarding patient perspectives on living with a chronic condition and long-term management of hot flushes, an unmet need in this cohort. These findings may focus more attention on this debilitating and bothersome side-effect of conventional treatment, further research in this area is suggested. Additionally, these results may help inform feasibility and clinical practice for future CHM studies.

Conflict of Interest Statement

As a medical research institute, NICM Health Research Institute receives research grants and donations from foundations, universities, government agencies, individuals and industry. Sponsors and donors also provide untied funding for work to advance the vision and mission of the Institute. (DP) practices as a Chinese medicine practitioner in private practice. The project that is the subject of this article was undertaken as part of PhD for (DP) (see under Financial Support).

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Ethical Approval

Ethical approval was obtained from South Western Sydney Local Health District as an addendum to the main RCT study (Approval No. SWSLHD, HREC/17/LPOOL/25 granted 15 May, 2017).

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Author Contributions

Conceptualization, Dianna Porter; Data curation, Dianna Porter, Xiaoshu Zhu; Formal analysis, Dianna Porter and Xiaoshu Zhu; Methodology, Dianna Porter; Project administration, Dianna Porter; Supervision, Xiaoshu Zhu, Alan Bensoussan and Paul De Souza; Writing - original draft, Dianna Porter and Xiaoshu Zhu; Writing - review & editing, Dianna Porter, Xiaoshu Zhu, Alan Bensoussan and Paul De Souza.

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