

Implementing a nurse-delivered cognitive behavioural therapy intervention to reduce the impact of hot flushes/night sweats in women with breast cancer: A qualitative process evaluation of the MENOS4 trial

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Abstract

Background: Hot flushes and night sweats are life-altering symptoms experienced by many women after breast cancer treatment. A randomised controlled trial (RCT) was conducted to explore the effectiveness of breast care nurse (BCN)-led group cognitive behavioural therapy (CBT). This paper reported findings from a qualitative process evaluation to optimise the CBT intervention and explore the determinants of implementation into routine practice.

Methods: Qualitative process evaluation occurred in parallel with the RCT to explore patient and healthcare staff experiences and perspectives using semi-structured interviews pre-and post-intervention. Normalisation Process Theory (NPT) informed data collection, analysis, and reporting of findings. The analysis involved inductive thematic analysis, NPT coding manual and subsequent mapping onto NPT constructs.

Results: BCNs (n=8), managers (n=2), surgeons (n=3) and trial participants (n=8) from six sites took part. All stakeholders believed group CBT met a need for non-medical hot flushes/night sweats treatment, however, had little exposure or understanding of CBT before MENOS4. BCNs believed the work fitted with their identity and felt confident in delivering the sessions. Despite little understanding, patients enrolled onto group CBT because the BCNs were trusted to have the knowledge and understanding to support their needs and despite initial scepticism, reported great benefit from group-based participation. Both managers and surgeons were keen for BCNs to take responsibility for all aspects of CBT delivery, but there were some tensions with existing clinical commitments.

Conclusions: Both healthcare staff and patient participants believe BCN-led group CBT is a beneficial service but barriers to long-term implementation into routine care suggest there needs to be multi-level organisational support.

Trial registration: NCT02623374 – Last updated 07/12/2015 on [ClinicalTrials.gov](https://www.clinicaltrials.gov) PRS

Contributions To The Literature

- This research will generate evidence for developing future patient-centred CBT
- This research will inform the development of nurse-led services to be further tested in hybrid effectiveness-implementation trials.
- Findings from this evaluation report implementation determinants that can help the development of future implementation strategies to bridge the gap between research and practice.

Background

Up to 85% of women experience hot flushes and night sweats after breast cancer treatment that can continue for more than 5 years and have a significant impact on daily life and quality of sleep [1].

A structured cognitive behavioural therapy (CBT) programme was trialled as an additional service outside of existing usual care as a phase III individually randomised controlled trial (RCT) vs treatment as usual with a formal process evaluation (called MENOS4) [2]. The CBT was based on the MENOS CBT protocol for menopausal hot flushes/night sweats [3, 4] that has been effective in reducing the impact of these symptoms in several RCTs of women going through the menopause transition and for women who have had breast cancer and in different treatment modalities, including group, self-help and online CBT. In the current study, CBT was delivered by trained breast care nurses (BCNs) to patients in a group setting. BCNs were chosen to deliver the intervention because they had the potential to provide a cost-effective solution and were deemed favourable in a previous MENOS trial [5]. Furthermore, group CBT has been shown to result in greater improvements in mood and quality of life, compared to self-help CBT in a study of women going through the menopause transition [6].

BCNs received CBT training from a clinical psychologist over two consecutive days (6 hours per day) as close to the first patient group as possible, with an optional telephone top-up. The training consisted of evidence-based information and practical skills to run the group CBT sessions by examining how behaviour and thinking can have a significant impact on women's experience of hot flushes/night sweats and help develop strategies with the women to manage them. Supportive delivery material was provided in the form of presentation slides, handouts, and notes, including a sleep diary and relaxation CD, which the nurses also completed as part of their training, from a published treatment manual [7].

MENOS4 results demonstrated that CBT is effective in relieving hot flushes/night sweats in women who have had breast cancer. There was a significant (46%) reduction in the mean hot flush/night sweat problem rating score from randomization to 26 weeks in the CBT arm compared with a 15% reduction in the usual care arm. Secondary outcomes, including frequency of hot flush/night sweat frequency, sleep, anxiety, and depression all improved significantly. These results suggest that specialist nurses can be trained to deliver CBT effectively for the alleviation of troublesome menopausal symptoms in women following breast cancer in a clinical setting. However, CBT for these women is not widely available and is rarely offered to women suffering from these symptoms in routine practice [2].

This process evaluation aimed to explore the experiences of key stakeholders involved in MENOS4 and how and in what ways the intervention was implemented to understand influential contextual factors on nurse-delivered CBT. The overarching purpose of the process evaluation was to understand the potential feasibility of routine care implementation. Normalization Process Theory (NPT) [8, 9] was used to interpret the data and facilitate an understanding of how the intervention can be normalised in NHS hospitals.

Methods

Evaluation design

This was a parallel qualitative process evaluation nested within an RCT (Fig. 1). Individual randomisation meant that all sites and stakeholders interviewed had the experience of implementing nurse-delivered

CBT. For the MENOS4 protocol refer to Fenlon et al (2018) [10], for the RCT refer to Fenlon et al, 2020. [2].

Bespoke post-intervention semi-structured interviews with BCNs, managers and surgeons were conducted to explore experiences of delivering the intervention, including barriers and facilitators to implementation and how they were tackled. Post-intervention interviews also took place with trial participants to gain insight into the personal experience of group CBT.

The trial was approved by the University of Southampton and received a favourable opinion from the Health Research Authority Research Ethics Committee and has followed SRQR guidelines (supplementary material file 1).

Choice of normalization process theory for process evaluation

Normalization process theory (NPT) is a theory of implementation that consist of four constructs; coherence, cognitive participation, collective action, and reflexive monitoring (Table 1).

Table 1
NPT constructs with descriptions

NPT construct	Description
Coherence	Individual and collective sense-making people do when faced with implementing a practice
Cognitive Participation	Relational work that people do to build and sustain a community of practice around the intervention
Collective Action	Operational work people to enact practices (e.g. an intervention)
Reflexive Monitoring	Appraisal work that people do to assess and understand what, if any, affect the practice has had on them and the people around them

NPT was chosen because it allows the identification of multi-level influences on implementation due to the focus on the inter-relationship between social and structural constraints and agency [11], which was in line with the aim of this process evaluation and has been operationalised through the data collection and sense-making of findings.

Participants

All BCNs who delivered the workshops were invited to interview after the completion of at least one group.

Managers with organisational responsibility and surgeons responsible for breast care services (both thought to have a potential impact on implementation) were identified through the BCNs and with permission, were contacted and invited to interview.

All consenting MENOS4 patients from each centre were approached after the 9-week questionnaire return.

Data Collection

Post-intervention interviews were conducted between June and July 2018 by an experienced female research fellow working with the core research team, who was not involved in the delivery of the RCT. With consent, they were recorded on dictaphone and transcribed verbatim where identifiers were replaced with pseudonymised identities. Interviews lasted approximately 30 minutes and took place at varying times once the intervention was complete. Interviews were conducted using NPT-informed topic guides (supplementary material file 2–4).

Breast Care Nurses

BCN interviews focused on their role, including relation to women with menopausal symptoms, prior understanding of CBT, the experience of delivering group CBT (including recruitment) and support required to incorporate the work to deliver the CBT into their existing workloads.

Manager

Topics covered with managers included the processes of encouraging CBT take-up, how patients access it, the potential for running the intervention in routine practice, the extent to which CBT for hot flushes/night sweats is a priority and whether it will continue beyond the trial.

Surgeons

Surgeon interviews covered current role, understanding of CBT, relationships with BCNs, post-intervention approaches for helping patients with hot flushes/night sweats, indirect human (time, staffing) and physical (room booking, consumables) resources for running group CBT, and the potential for running the intervention in routine practice.

MENOS4 participants

Lastly, patients were interviewed to gain an understanding of their experiences of participating in the CBT group, including motivation for enrolling on the trial.

Data Analysis

Data analysis was completed by CB, who was independent of the RCT. Transcripts were read for error checking and familiarity purposes and identifying transcript content was anonymised at this time. A combination of Microsoft Excel and NVivo 12 was used to store and analyse the interview data. The data were initially analysed using thematic analysis for inductive exploration and development of an initial coding framework, this was done to ensure findings emerged from the data and were not manipulated to fit the theory. To ensure that contextual factors were adequately included in the analysis CRM recoded pseudonymised transcripts using an independently developed and validated NPT Coding Manual [12]. In the final stages, findings were mapped onto the NPT framework. There were no themes that did not map

onto the four constructs of NPT and subsequent interpretation of findings ensued, including highlighting patterns, meaning and associations.

Iterative discussion about coding mapping took place with DF, MH and CM. Quotes were chosen to provide evidence of interpretation of the data and provide a deeper understanding of the interviewees' thoughts and beliefs.

Results

A total of 21 participants were interviewed (Table 2). A surgeon and two managers from two separate sites were unresponsive to email invitations, and 2 surgeons and 2 managers were not identified from two further sites.

Table 2
Number of patient and stakeholder interviews
conducted per site

Site no.	Patient	BCN	Surgeon	Manager
1	0	1	1	1
2	2	2	0	0
3	1	2	1	1
4	0	2	0	0
5	3	1	1	0
6	2	2	0	0
Total	8	10	3	2

The following four themes were identified and mapped onto NPT constructs (Table 3).

Table 3
Themes mapped onto NPT constructs

NPT construct	Theme	Theme description
Coherence	Group CBT met a need for non-medicalised hot flushes/night sweats treatment	The intervention was perceived to have the ability to meet a patient need
Cognitive Participation	Surgeons, BCNs and patients were keen on the provision of nurse-delivered CBT to meet patient demand	There was mutual agreement amongst implementers that BCNs should lead the intervention
Collective Action	BCNs were a trusted source for the delivery of CBT but need multi-level support to operationalise the work	Multi-level factors enable the operational work (e.g. clinic cover)
Reflexive Monitoring	Some BCNs and patients continued to benefit beyond the intervention	There was a lasting application of the CBT skills learnt

Coherence: Group CBT met a need for non-medicalised hot flushes/night sweats treatment

Nurses, surgeons, and patients had had very little, if any, prior CBT training, but identified a need for alternative non-medicinal treatment options for hot flushes/night sweats from the volume and severity of symptoms presented by patients.

..patients would come in with these problems all the time, I can't sleep, the hot flushes, and you feel so helpless and you want to give them information.

BCN

The need for this hot flushes/night sweats treatment was echoed by patients, who were initially sceptical of the trial due to a lack of understanding of how CBT works. They were willing to try it because they felt frustrated by previously ineffective, unsuitable or temporary treatment options and the impact that hot flushes/night sweats were having on their quality of life.

I did think how on earth is CBT going to - I didn't know very much about CBT..it's a type of counselling, isn't it? How on earth are you going to do that in a group? Are you going to be expected to talk about your childhood or something? I don't know [chuckling].

Patient

..It was anything at that point. By the time I was asked..when a nurse approached me, I'd had enough of not being able to sleep.

Patient

It should be noted that despite the need, recruitment was not as successful as staff had initially hoped. From the interviews conducted, the causes of suboptimal recruitment were due to the level of

commitment required by patients, mainly the weekly meeting face-to-face at a specific time, and the group-based CBT. Also, a group run service in practice could be quicker to recruit outside of the trial, which required allocation of half the women to CBT and half to a control arm.

Participating staff and patients felt that providing patient CBT in a group setting would foster a supportive and encouraging environment and be resource efficient for the hospital organisation.

..we have so many people that phone up with hot flushes and night sweats and not being able to cope, it can take you an hour on the phone and if we're getting three or four of these a week, that's literally four hours out of your day where you could be doing a session that could..actually save time in the long-run.

BCN

Some of the interviewed patients initially felt anxious about the prospect of being in a group due to the embarrassing nature of hot flushes/night sweats, but later felt the great benefit in being able to give and receive support through shared experience.

".. it's intimidating to go to a group session. I mean, a lot of people do find hot flushes so embarrassing, and they're really self-conscious..It's kind of like catch 22; you want to go because you want to get the help, but then you think, oh, God, everyone's judging me. Then it's like, like-minded people, everyone's in the same boat."

Patient

I think being in a group is essential.

Patient

Cognitive Participation: Surgeons, BCNs and patients were keen on the provision of nurse-delivered CBT to meet patient demand

Although only three surgeons were interviewed, most viewed CBT as a potential tool in helping to ensure a cancer-free patient can live a good quality of life, despite a lack of direct impact on their work.

I think most clinicians wouldn't really be fussed, because it doesn't mean it's something that affects them. However..I think it's very important that all issues should be dealt with and, if they are as a result of treatment that you've instituted, it's even more important, and it's just a case of the best and most effective way of doing that.

Surgeon

I think it's really important. It's all very well saying to a woman, 'I've cured you of cancer', but if you've given them a really rotten quality of life in doing so, then you've not really done your job very well. I always say to my patients, 'It's that balance about making sure that you're cancer-free, but also making sure that you've still got a life at the end of it'.

Surgeon

As a resource management strategy, surgeons discussed the potential for patient-driven services and appointments for long-term follow-up. Patients agreed there may be unnecessary follow-up appointments scheduled because of a perceived lack of need for health services at later appointments, however, both patients and BCNs felt a higher level of supervision would be needed for less communicative and proactive patients to ensure they were not suffering in silence. This is a valid concern because some patients felt it may come across as unappreciative if they expressed the trouble they were having with their hot flushes/night sweats, driven by 'survivor's guilt' [13] and a juxtaposition to their gratitude for being cancer-free.

I think a lot of people would tend to think that because you're alive after having a diagnosis of cancer, then you know, you're making a fuss about menopausal symptoms..you're complaining about them when you're actually alive and other people are not.

Patient

Across all sites, the BCNs took responsibility for the implementation of the RCT and the operationalisation of the work. When asked who should have responsibility for the running of a CBT service, all stakeholders chose BCNs. BCNs delivering the workshops experienced benefits from upskilling and the emotional reward felt for delivering the service they felt suited their role, and surgeons expressed a natural fit with existing nurse-led cancer survivorship services. Both managers and surgeons had an awareness of MENOS4, however, the crucial role of identifying, engaging and delivering to patients was taken on by the BCNs.

I'm aware of it. I'm the named PI for that here, but it's the breast care nurses who've really been running the show, and I've let them get on with it and be happy. I've been really happy that they've been doing it, actually.

Surgeon

Patients were confident in the BCNs ability to deliver CBT due to their existing knowledge and familiarity with breast cancer and felt indifferent about whether the BCNs were already known to them.

I think it was really good to be done by the nurses, because they really understood exactly what we'd all gone through. They'd seen it....So, they really knew what we were going through, what were the problems, and how people dealt with it, so they were very familiar, and I thought that was important.

Patient

Collective Action: BCNs were a trusted source for the delivery of CBT but need multi-level support to operationalise the work

Data collected from the interviews explored the resources and practical nuances of delivering the intervention. CBT delivery was accepted by BCNs because it fitted within the scope of current work and resonated with the reason they became a nurse. The CBT training and supportive materials (e.g. relaxation audio recording) received by BCNs fulfilled their needs to confidently deliver the service, but for the intervention to be adopted into routine care, support is necessary at multiple levels to overcome implementation barriers.

First, a mixed approach to advertising was effective. BCN, with the support of some surgeons, actively identified patients during appointments, and paper-based advertising (e.g. leaflets and newspaper advertising) increased reach and prompted an enquiry from patients during BCN contact time. However, patients believed that a lack of understanding could lead to scepticism of CBT, i.e. a psychological therapy for physical symptoms. To tackle this, MENOS4 patients recommended promoting recruitment through participant quotes and word of mouth through cancer-support networks which highlighted the importance of the cancer community in educating and increasing awareness.

Somebody who's been through a similar situation to them, and then has been on this training and has really seen the benefits from it. I think that's always a good endorsement..

Patient

My friend, who's a little bit older than I am.. had seen it on the news. And her suggestion was, 'you go on the trial. You go and see about it and you can tell me what I need to do'.

Patient

In MENOS4, research staff conducted trial procedures including informed consent and baseline data collection. Some BCNs felt this created a disjoint in communication with patients that could have been a recruitment barrier. However, it should be noted that outside of a trial BCNs or delegated members of the team would be able to both recruit and conduct the groups, which would avoid such issues.

Beyond the identification and engagement of patients, several organisational barriers to adoption were identified, the most common being resource and capacity.

Resource is tightly constrained in the NHS, and although BCNs are deemed to have autonomy, MENOS4 at times created friction with current work demands put upon them by clinics and MDT meetings. Conflicting demands were temporarily managed by reliance on peer support or authoritative buy-in (senior manager or clinician) to release them from clinic and support capacity for individual agency. Department managers were supportive of BCN-led services with the caveat that they needed to continue managing their existing workload. As a compromise, BCNs often completed work for MENOS4 in their own time because they deemed the intervention an important part of patient care.

There'd be no way to take work time, just because of the pressures we've got with clinics and just general, our workload is just... Everybody's is immense, isn't it, so you couldn't take time out of your day to prep,

no.

BCN

To adopt CBT as a routine service, medics, managers and BCNs would work together to create a business case that would need to show that the investment in the resource is worthy of the clinical outcome.

BCNs were concerned that NHS decision-makers might deem CBT a “luxury” or “flowery stuff”. BCNs believe services at the hospital should be patient-led and backed by research and felt that hospital organisations are led by a metric-driven prioritisation process that demotes the priority of “alternative” and psychological therapies.

Managers and surgeons expressed similar concerns for adoption, with consideration given to how to communicate a favourable financial outcome that would be appealing to organisational board members.

I haven't got any problem writing something for the Board to consider..like I said the financial impact would be the backfilling of the clinical teams, their time and whether or not the organisation is prepared to support that.. From a quality perspective, I think that they would but from a financial element of it, depending on the cost they may not

Manager

Many sites offered cancer-survivorship services and complementary therapies, but none focused on the specific management of hot flushes/night sweats. To help manage resources, nearly all BCNs suggested condensing and integrating CBT into existing services.

We've been talking about, the Move Forward programme is an afternoon for four weeks. We have talked about maybe, if this is taken up by the NHS, we could slot it on to the end for those few that - because then you've got a captive audience.

BCN

An alternative consideration for secondary care implementation involved integrating services with primary care and community services to identify patients and distribute the impact on resource, respectively, and was thought to have the potential to hold mutual benefit for service providers and those in need of hot flushes/night sweats treatment.

I mean it could be something that we could approach the CCG for... That's an option and that's certainly something that we would look at if we were doing an appraisal of it to take it forward. We would look at alternative of joint working or if there's somebody in the community that we could actually tap into.... if we approach the CCG and said, 'Okay then how about us going 50/50? We'll share it with you, we'll share the cost

Manager

Last, scheduling of the intervention was a challenge for all groups recognised by the BCNs and patients because of the heterogeneity of the population (e.g. age, employment status, dependants). Groups held during the day did not capture working patients, but groups held before or after 9am and 5pm respectively, had traffic and family commitments to contend with.

We were doing it at the end of a day. 1) Because we thought we'd get more of the ladies to come, but 2) during the day, you've got clinics and other things going on.

BCN

I think, if they're younger and they're working, I think the time commitment's difficult for them; and I think for - certainly for one of ours in the group - it was very difficult timing; because it was half past four 'til six - which you would think was quite a good time - but [city name], if you've got to get anywhere at half past four, it's absolute gridlock.

Patient

Reflexive monitoring: Some BCNs and patients continued to benefit beyond the intervention

CBT skills learnt were being transferred into different contexts by BCNs and patients during and after the trial.

“To be perfectly honest, I have to say both myself and [nurse colleague name] have found that with some of our really anxious patients, and also with our patients with menopausal symptoms, we're using the stuff. “

BCN

Yes, I use that a lot for lots of things. When I'm feeling stressed as well, I use that breathing, and the 'it's a thought, not a fact', lots of things like that. There's been lots of stress in my life in the last couple of weeks, so that's been really, really helpful as well.

Patient

Outside of the constraints of a trial, BCNs would like to deliver CBT as part of existing survivorship programmes in a less clinical environment and more informal manner to encourage engagement and evoke a positive association with the service. This doesn't mean that the hospital site itself is an issue, as patients felt this was a suitable place, but that the space the intervention was being delivered should be different to other parts of the hospital (e.g. soft furnishings).

I do think not necessarily happening in a hospital environment is the best... Also, patients coming back to this environment, it's like revisiting what's happened and they don't like coming on annual visits never mind coming for a couple of weeks. I think if we could change the...One of the ladies did say about the layout the one day, didn't she? She said, 'Oh, it's like being back in school because the one room we had.

BCN

Finally, patients perceived MENOS4 to be of great benefit because it added structure, social support, perspective, materials for reflection and a means to identify triggers and manage hot flushes/night sweats, which ultimately led to a sense of control and increased quality of life.

Life, completely, yes! It's given me control back. I mean, that sounds really silly, but it has. It's kind of - my new normal isn't different to my old normal, but no, I've got control back, and that's what CBT did.

Patient

Discussion

This qualitative process evaluation revealed that nurse-delivered group CBT is acceptable to stakeholders and has the potential to be implemented as an NHS-provided service if BCNs are given multi-level support. This support appears to depend on the extent to which services are receptive to, and will adopt, an intervention that may be considered a luxury that does not have a high impact on their performance metrics.

Different responsibilities were identified for the various peer groups to enable the BCN to deliver the service (Table 4).

Table 4
Peer group implementation responsibilities

Peer group	Role
Manager	Support the BCNs in understanding what their role and associated responsibilities are and work collaboratively to develop an effective business case to board members.
Medic	A key decision maker for implementing a new service and facilitates discussions that enable BCNs to streamline their duties so that work can be re-directed work to administrative/ other supporting members of staff.
Breast Care Nurse	Reflect on current responsibilities to facilitate the re-direction of work and ensure additional work is not taken on that is not congruent with their role. Communicate the need for new services to managers and operationalise the work.
Patient	Create awareness of/demand for a service and communicate needs (or lack of) to optimise patient care.

Surgeons, although they acknowledged the importance of the implications of hot flushes/night sweats, are not actively treating women who would be considered cancer-free. BCNs held primary responsibility for the initial implementation and operationalisation of work at the cost of either giving additional workload to peers or completing tasks outside of work hours. The verbal support from senior staff creates a conflicting message that initially suggests BCNs have the individual agency to trial and lead

new patient services, but with little to no organisational investment and friction with an existing workload, this becomes pseudo-agency. Consequently, there may be friction between BCNs individual values (wanting to provide patient-centred services) and the expectations of their managers and employers (e.g., clinics and team meetings). Moreover, the priority-setting values of secondary care organisations are unlikely to support new services that do not at least meet financial equipoise, which is not the same priority-setting values BCNs share. These areas of conflict are especially important findings, given that BCNs working in their own time is not sustainable and not being able to work to their values is a major cause of burnout in Oncology nurses [14].

To mitigate this area of tension, alternative methods may be a viable option, such as integration with existing services or the use of alternative staff. It should be noted however that a major motivator for patients to receive a treatment they understood little about was the belief in the BCNs as a trusted source. Decision-makers implementing the service should be cautious when considering alterations to advertisement and delivery to mitigate the impact on patient uptake and engagement. Furthermore, the CBT training and material received was sufficient for BCNs to feel confident in delivering the service and apply newly learnt skills both personally and to other patients for menopause and anxiety, implying that there is a range of application for CBT. As a result, BCN-led CBT facilitated closer engagement with patients and developed their professional role. The importance of this is facilitated by existing literature that demonstrates that the concept of partnership was integral to patients' self-control and ownership of symptom management and the nurses' ability to meet the needs of patients, elicit clinical information and coordinate care [15, 16].

Some patients initially began the group-based CBT with scepticism due to a lack of understanding and familiarity, but with experience, they highlighted that it was an important part of the service that fostered peer support and encouragement, showing that this method of delivery is acceptable.

Finally, pro-active patient demand for long-term follow-up, as opposed to scheduled appointments, was suggested by sites to relinquish some capacity; however, some patients in this group express 'survivors guilt' and may not proactively communicate side effects of treatment for fear of seeming unappreciative and ungrateful for being cancer-free. To combat this, links with primary care, trusted advertisement (e.g. cancer networks) and targeted follow-up for less expressive patients should be considered.

In summary, based on this NPT-informed process evaluation the findings suggest group CBT be a needed and accepted means to treat hot flushes/night sweats in breast cancer survivors. Strategies facilitating the adoption of the service into hospital Trusts included incorporating group CBT within existing survivorship services and re-directing departmental workload to provide BCNs with the resource to deliver the service. However, to achieve adoption and sustainability several coordinated patient, staff and organisational level factors need to be negotiated, highlighting the challenges of implementation within a complex resource-constrained healthcare system.

Limitations

The study had limitations in that the numbers of surgeons and managers were very small due to a lack of availability. Secondly, we examined the intentions and perceived feasibility of implementing CBT into normal practice within a clinical trial which may have affected managers/surgeons' views about implementation. Similarly, at the time the participants did not know the outcomes of the trial, which were very positive, at the time of interview.

Conclusion

All stakeholders felt that group CBT was appropriately delivered by the BCNs and was wholly beneficial at an organisational, staff and patient level. The primary barrier to routine care adoption is adding the service to already stretched BCN time; however, with multi-level support, CBT to manage hot flushes/night sweats in breast cancer survivors is feasible despite current constraints.

Abbreviations

BCN Breast Care Nurse

CBT Cognitive Behavioural Therapy

NHS National Health Service

NPT Normalisation Process Theory

Declarations

Ethics approval and consent to participate

This evaluation has been performed in accordance with the Declaration of Helsinki

Ethical approval for this research has been obtained through National Research Ethics Service South Central - Hampshire A Research Ethics Committee and HRA (ref. [16/SC/0364), and from the University of Southampton ref. number: 19245. All participants provided informed consent to participate in the qualitative interview.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available to protect the identity of the participants but are available from the corresponding author on reasonable request.

The topic guides used to inform the interviews are available as supplementary material.

Please direct all data enquiries to the corresponding author.

Competing interests

The authors declare that they have no competing interests

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JN, DF and MH contributed to the trial design. CM and DF were involved in developing the topic guides. CB analysed and interpreted the data with DF, CM and MH. All authors were involved in preparing the manuscript and approved the final version to be published.

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References

1. Fenlon DR, Corner JL, Haviland J. Menopausal hot flushes after breast cancer. *Eur J Cancer Care*. 2009;18(2):140–8.
2. Fenlon D, et al. Effectiveness of nurse-led group CBT for hot flushes and night sweats in women with breast cancer: Results of the MENOS4 randomised controlled trial. *Psycho-oncology*. 2020;29(10):1514–23.
3. Hunter MS. Cognitive behavioral therapy for menopausal symptoms. *Climacteric*. 2021;24(1):51–6.
4. Hunter MS, Chilcot J. Is cognitive behaviour therapy an effective option for women who have troublesome menopausal symptoms? *Br J Health Psychol*. 2021;26(3):697–708.
5. Balabanovic J, Ayers B, Hunter MS. Cognitive Behaviour Therapy for Menopausal Hot Flushes and Night Sweats: A Qualitative Analysis of Women's Experiences of Group and Self-Help CBT. *Behav Cogn Psychother*. 2013;41(4):441–57.
6. Ayers B, et al. Effectiveness of group and self-help cognitive behavior therapy in reducing problematic menopausal hot flushes and night sweats (MENOS 2): a randomized controlled trial. *Menopause*. 2012;19(7):749–59.
7. Hunter M, Smith M. *Managing hot flushes and night sweats: A manual for health professionals*. London, UK: Routledge; 2015.
8. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology*. 2009;43(3):535–54.
9. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC Health Services Research*, 2006. **6**(1).
10. Fenlon D, et al. MENOS4 trial: a multicentre randomised controlled trial (RCT) of a breast care nurse delivered cognitive behavioural therapy (CBT) intervention to reduce the impact of hot flushes in women with breast cancer: Study Protocol. Volume 18. *BMC Women's Health*; 2018. 1.
11. May CR et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science*, 2018. **13**(1).
12. May CR et al. Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development. *Implementation Science*, 2022. **17**(1).
13. Glaser S, Knowles K, Damaskos P. Survivor guilt in cancer survivorship. *Soc Work Health Care*. 2019;58(8):764–75.
14. Nwanya M, Rowberry D. The importance of understanding burnout: an oncology nurse perspective. *Br J Nurs*. 2021;30(10):S8–S14.

15. Chan EA, et al. Patients' perceptions of their experiences with nurse-patient communication in oncology settings: A focused ethnographic study. PLoS ONE. 2018;13(6):e0199183.
16. Kerr H, Donovan M, McSorley O. Evaluation of the role of the clinical Nurse Specialist in cancer care: an integrative literature review. European Journal of Cancer Care, 2021. 30(3).

Figures

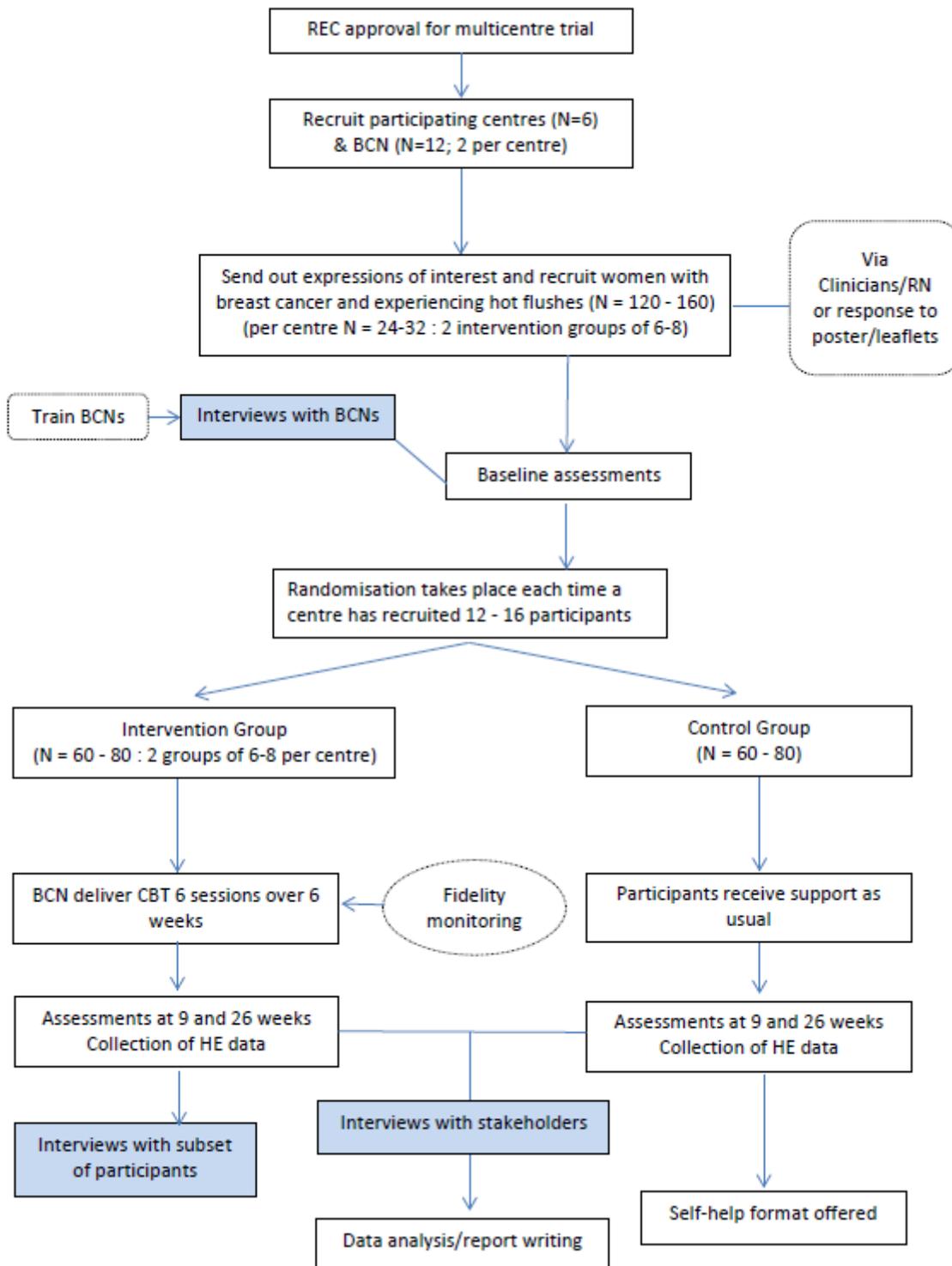


Figure 1

MENOS 4 Trial Schema

Supplementary Files

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- [MENOS4MedicandManagerTopicGuide.pdf](#)
- [MENOS4NurseTopicGuide.pdf](#)
- [MENOS4PatientTopicGuide.pdf](#)
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