Self-help cognitive behaviour therapy for working women with problematic hot flushes and night sweats (MENOS@Work): a multicentre randomised controlled trial.

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ABSTRACT

Objective: To examine the efficacy of an unguided, self-help CBT booklet on hot flush and night sweat (HFNS) problem rating, delivered in a work setting.

Methods: Women aged 45-60 years, having 10 or more problematic HFNS a week, were recruited to a multicentre randomised controlled trial, via the occupational health/human resources departments of eight organisations. Participants were 1:1 randomised to Self-Help CBT (SH-CBT) or No Treatment Waitlist Control (NTWC). The primary outcome was HFNS problem rating; secondary outcomes included HFNS frequency, work and social adjustment, sleep, mood, beliefs and behaviours, and work-related variables (absence, performance, turnover intention and work impairment due to presenteeism). Intention-to-treat analysis was used, and between-group differences estimated using linear mixed models.

Results: 124 women were randomly allocated to SH-CBT (n=60) and NTWC (n=64). 104 (84%) were assessed for primary outcome at 6 weeks and 102 (82%) at 20 weeks. SH-CBT significantly reduced HFNS problem rating at 6 weeks (SH-CBT versus NTWC adjusted mean difference, -1.49; 95% CI, -2.11 - -0.86; $p < 0.001$) and at 20 weeks (-1.09 95% CI, -1.87 - -0.31; $p < 0.01$). SH-CBT also significantly reduced HFNS frequency at 6 weeks; improved work and social adjustment, sleep, menopause beliefs, HFNS beliefs/behaviours at 6 and 20 weeks; and reduced work impairment due to menopause-related presenteeism at 20 weeks, compared to the NTWC. There was no difference between groups in other work-related outcomes.

Conclusions: A brief, unguided self-help CBT booklet is a potentially effective management option for working women experiencing problematic HFNS.

Keywords: Menopause; Work; Menopausal symptoms; Hot flushes; Cognitive behaviour therapy; Vasomotor symptoms; RCT

What we already know

Menopausal symptoms - hot flushes and night sweats (HFNS) - are particularly difficult for women to deal with at work, due to embarrassment, discomfort and some aspects of the work environment. Cognitive behaviour therapy (CBT) for HFNS is an effective non-medical intervention that can help women to manage these symptoms. CBT is effective when delivered in groups or as a self-help booklet, but CBT is not generally available to employees in the workplace.

What this study adds

This study demonstrates that an unguided self-help CBT approach can be effective in reducing the impact and frequency of HFNS experienced by working women. In addition, work and social functioning and sleep problems improved to a greater extent for those receiving SH-CBT compared to NTWC, and there were benefits to wellbeing and reports of somatic symptoms at 20 weeks. While there was no difference between the groups in work related outcomes (absence, performance, turnover intention), there was an improvement in the SH-CBT group's perceived work ability in spite of menopause-related difficulties (presenteeism) compared to NTWC.

INTRODUCTION

With rising employment rates for women and an ageing profile of the workforce in the UK and most European countries, increasing numbers of women will be working during their menopause transition and postmenopause.[1,2] As a result there is growing interest in improving the health and wellbeing of working women, and retaining and increasing the numbers of experienced older women in the workplace. Recent recommendations and guidance also stress the importance of improving the experience of menopause for working women.[3-5] There are over 3.5 million women in employment aged between 50 and 65 in the UK[6] and, given that menopause (final menstruation) occurs on average between the ages of 50–51 and the menopause transition can last for up to ten years,[7] a significant proportion of female workers will be experiencing menopausal symptoms. While many women go through the menopause with few problems, approximately 20-30% have troublesome symptoms that impact on their quality of life.[8,9] Hot flushes and night sweats (HFNS) are the main menopausal symptoms and these are particularly difficult to manage in work contexts, due to physical discomfort, social embarrassment and the effects of disturbed sleep.[10] As well as hot flushes, women have been found to report that tiredness, memory/concentration, and loss of confidence are problematic at work.[11]

Women are generally reluctant to disclose their menopausal status, particularly at work, where embarrassment and fear of ridicule is common, and self-control is highly valued. Hot flushes may draw attention to menopausal status, particularly during formal meetings, when working with men and/or younger adults or in hot environments.[10,12-13] Discussion about the menopause at work is widely perceived as taboo[14] and consequently, despite women's reported experiences, there is a lack of awareness about menopause in work settings.

Although an under-researched area, several cross-sectional studies have examined the impact of work environment on experience of menopause, as well as the impact of menopause upon work performance. There is some evidence that menopausal symptoms can have an effect on work experience, e.g. perceived performance, and that certain work situations and physical working environments, such as aspects of work design and temperature, and work stress, can increase the intensity of

menopausal symptoms.[11,15-21] However, Jack and colleagues in a recent systematic review[22] concluded that while some working women who had bothersome menopausal symptoms reported impaired work outcomes, the overall evidence was inconclusive. Moreover, surveys of work-related stress in the UK[23] suggest that women aged 45-54 report more work-related stress than mid-aged men or women of any other age group. There are likely to be complex relationships between work-related stress and the experience of menopausal symptoms.[24]

Griffiths and colleagues[11] conducted a study of 896 women employed in ten UK-based organisations. Women suggested several areas requiring organisational change in order to improve women's experience of menopause at work; these included: (i) greater awareness among managers about menopause as a possible occupational health issue, (ii) flexible working hours, (iii) access to information and sources of support at work, and (iv) attention to work place temperature and ventilation. The current study aims to address (iii) as outlined in the study protocol paper.[25]

Hormone therapy (HT) is an effective medical treatment for menopausal symptoms[26] but not all women want to take it due to contraindications and personal preference. Cognitive behaviour therapy (CBT) is recommended for anxiety and depression during the menopause[26] and a CBT intervention has been developed to help women to manage HFNS,[27-30] that is based on a theoretical model[31] supported by recent empirical studies.[32-34] HFNS can be potentiated by stress and are exacerbated by negative beliefs and behavioural reactions. The intervention therefore includes psychoeducation and evidence-based CBT strategies to reduce stress, and to manage hot flushes, night sweats and sleep. CBT for HFNS has been found to be effective in reducing the impact of HFNS, i.e. how problematic they are, in several clinical trials,[27-29] frequency of night sweats[27] and physiologically monitored HFNS.[35] CBT was recommended as an effective treatment for vasomotor symptoms in a recent position statement on non-hormonal interventions, by the North American Menopause Society.[36]

Group CBT and self-help CBT (a self-help booklet containing the same information with a breathing/relaxation CD) formats for HFNS have been shown to be equally effective in reducing the impact of HFNS;[27] however, group CBT had more impact on mood and quality of life. Self-help CBT has also been found to produce similar levels of improvement when delivered with minimal guidance.[30] Although CBT

interventions for HFNS are available in self-help and group formats,[37-38] there have not been any previous work based trials and CBT interventions for HFNS are not yet widely accessible to women at work.

We hypothesised that CBT will be more effective than no treatment in: (i) reducing the impact of HFNS (problem-rating),[11] and (ii) reducing HFNS frequency, moderating menopause beliefs, HFNS beliefs and behaviours, improving mood, sleep, work and social adjustment, and work outcomes (work absence, presenteeism, job performance, and turnover intention).

METHODS

The trial is reported in accordance with the CONSORT guidelines for randomised controlled trials[39] and is described in detail in a trial protocol paper[25] (trial registration: ClinicalTrials.gov identifier: NCT02623374). Ethical approval was obtained from Kings College London Research Ethics Committee (Psychiatry, Nursing and Midwifery Research Ethics Subcommittee, reference: RESCMR-14/15-0475).

Participants and procedure

Eight organisations, from public and private sectors, participated in the study. Organisations volunteered to take part in response to talks given at conferences or other occupational health-related events, and by direct contact. Each participating organisation had a 'gatekeeper' who was responsible for disseminating recruitment materials (posters, leaflets, emails) within the organisation. The research team also gave presentations within organisations to raise awareness of the project and invite eligible women, who self-referred, to take part.

Participants were menopausal women with problematic HFNS. Inclusion criteria were: women, employed within participating organisations, English speaking, aged 45-60 years, having problematic HFNS for at least 2 months (scoring above 2 on the Hot Flush Rating Scale[7], minimum frequency of 10 a week), and having no

current major physical or mental health problems that would compromise participation.

Potential participants contacted the trial coordinator by telephone or email and were provided with a verbal description of the study, and if interested to proceed, were screened by telephone. Those eligible were sent a participant information sheet, consent form and a baseline questionnaire, with a self-addressed and stamped envelope to return the signed and dated consent form, and questionnaire. Data were collected at Kings College London and participating organisations. Participants who returned signed consent and baseline questionnaires were randomly allocated into one of two arms: treatment or control (figure 1). Randomisation was performed using Microsoft Excel with a ratio of 1:1, stratifying by recruiting centre. Participants allocated to the treatment group were posted the self-help booklet. Data entry was performed by a researcher blind to group allocation and statistical analysis by the trial statistician who was also blind to treatment condition.

Participants were asked to completed follow-up questionnaires at 6 weeks and 20 weeks post-randomisation. A prize draw of £50 Amazon voucher (or similar) was offered as an incentive to complete all three questionnaires. The participants in the Self-help CBT arm were also invited to take part in an evaluation interview via telephone after returning the final follow-up questionnaire.

Intervention

The Self-Help CBT booklet (SH-CBT) was adapted from the self-help booklet used in the MENOS2 trial[27,37] (see protocol paper[25]). The booklet was adapted and shortened, with additional sections covering work stress and how to discuss menopause at work. Pilot work was conducted to assess the acceptability, content and format of the intervention and questionnaires, as well as the delivery method. We also explored potential barriers and difficulties for women using the SH-CBT intervention. Telephone interviews were conducted with working menopausal women (n=10) who had been sent the booklet from four of the participating organisations. Women noted that having the word *menopause* on the front cover might cause embarrassment and reduce use of the booklet. The preferred delivery of the self-help intervention and questionnaires was in paper form, although several mentioned that an online option might be preferred, by some women. Feedback was addressed; modifications included adding content about how to have conversations with line managers at work, an

infographic that can be given to a line manager when attempting to have the discussion, removal of the word *menopause* from the front page, and adding examples from work situations throughout the booklet. The final revised booklet and questionnaires were also reviewed by an advisory group (comprising working menopausal women, academic researchers, trade union representatives, employers) and minor amendments/corrections made.

The final SH-CBT intervention was an A5 sized, colour booklet with instructions and four chapters (with information, exercises and homework tasks) to be completed over four weeks. Chapters covered psycho-education about menopause and HFNS, stress management, breathing/relaxation, and learning cognitive and behavioural strategies to help manage HFNS, stress and sleep, with individual goal setting and weekly homework. A relaxation and breathing exercise was also provided on a CD, which was included with the booklet, together with an infographic.

Participants in the no treatment waitlist control (NTWC) condition did not receive SH-CBT during the treatment phase but were sent the SH-CBT booklet after the 20 week assessment, off-trial. All participants were able to access their general practitioner and other health care options.

Measures

Demographic information (age, ethnicity, height, weight, education, relationship and employment status), smoking, alcohol intake and exercise behaviour, menopausal status (menopause transition/postmenopause), treatment experience, and work variables (type of job, working hours, shift working, age and gender of work colleagues) were recorded at baseline. All data was self-reported.

Primary outcome

The primary outcome was *HFNS Problem Rating*[10] at 6 weeks and 20 weeks post randomisation. Problem rating was measured by a subscale of the Hot Flush Rating Scale as used in the MENOS2 trial,[27] containing three items: "To what extent do you regard your flushes/sweats as a problem?"; "How distressed do you feel about your hot flushes?" and "How much do your hot flushes interfere with your daily routine?" Items are measured on a 10 point scale ranging from 1 to 10, with high scores indicating more problematic hot flushes; a two point change on this scale is

generally considered clinically significant.[27-28] Cronbach alpha (α) for this measure was 0.83 at baseline.

Secondary outcomes

HF Frequency: HFNS frequency was measured with the Hot Flush Rating Scale[7], which records of the number of HFNS experienced in the previous week.

HFNS Beliefs and Behaviours: A shortened version of the Hot Flush Belief Scale[40] and the Hot Flush Behaviour Scale[41] were used (see supplementary file in Protocol paper[25]). Beliefs were measured using a mean score of 10 items, producing three sub-scales: beliefs about HF in a social context (at baseline, α=0.89); coping/control over HF (α=0.73); and beliefs about NS and sleep (α=0.60). Behaviours were measured from a mean score of 6 items producing two sub-scales: avoidance behaviour (at baseline, α=0.80) and positive behaviours (α=0.48). Responses ranged from 0 (strongly disagree) to 5 (strongly agree).

The *Menopause Representations Questionnaire* (MRQ)[42] was used to assess women's cognitive representations of the menopause with respect to identity (attribution of symptoms to menopause), consequences, and control/cure. The MRQ comprising of 37 items, using a 5 point Likert scale ranging from strongly agree (5) to strongly disagree (1). Mean scores on the subscales are calculated. Cronbach alpha for the subscales at baseline were: identity .80, negative impact .74, new phase .67, relief .47, control/cure .77.

The *Revised Women's Health Questionnaire* (WHQ)[43] was used to measure perceptions of physical and emotional health. The revised WHQ has 23 items and has been found to have the same if not improved psychometric properties than the original in a recent study in a recent study.[44] The following subscales examined in this study: anxiety/depression, wellbeing, somatic symptoms sleep problems, and memory/concentration (baseline α=0.62, 0.66, 0.68, 0.62, 0.72, respectively).
A single item measure of sleep quality was added from the *Pittsburgh Sleep Quality Index (PSQI),*[45] which is a self-rated questionnaire assessing sleep quality over a 1-month time interval using a 4-point Likert scale (1= "Very bad" to 4 = "Very good").
The *Work and Social Adjustment Scale* (WSAS) [46] is a five-item scale used to measure functional impairment at home, work and in social situations attributed to a specific problem (menopausal symptoms). Items are measured from 0 (no

impairment) to 8 (very severely impaired) and summed to produce a final score out of 40 (α=0.88).

Work related outcomes:

Absenteeism is the total number of days affected by work absence in the last 4 weeks attributed to the menopause. The number of days off work due to symptoms, the number of days arrived to work late, and the number of days left work early due to their menopause were summed to create this variable.

Job performance was measured using a single item 5-point Likert scale, 1 (poor) to 5 (excellent) where participants were asked to rate their perceived performance in relation to others.

The *Stanford Presenteeism Scale*[47] was used to measure menopausal women's perceptions of being physically present at their jobs, but experiencing decreased productivity and below-normal work quality due to their menopause. Using 6-items, the average scores on a five point Likert-type scale, ranging from strongly disagree (1) to strongly agree (5) were calculated (α=0.79). Higher scores suggest low perceived work impairment due to the menopause.

Turnover intention was measured using an existing 4-item measure[48], with 5-point Likert scales, to assess the employee's intention to leave the organisation (α=0.81). A higher score suggests a greater intention to leave the organisation.

Any medical, non-medical and over the counter treatments used and health services accessed for menopause during the treatment phase (post randomization) were logged at the 20 week follow-up.

Analysis of additional variables: attitude to menopause at work, disclosure, job stress and job satisfaction, resilience, intention to reduce working hours or stop working because of the menopause, will be reported elsewhere, together with a mediation analysis.

Sample size

Based on previous studies,[27-28] a total sample size of 80 participants, 40 per arm, are required to detect 2 points difference in HFNS mean score at 6 weeks using regression analysis controlling for baseline level of the outcome, with a 90% power at 2 tailed significance 0.05 level, assuming equal SD (3.0) for both groups and correlation between baseline and follow up measures at 0.4 for the purpose of being conservative. After taking into account 20% loss to follow up rate, a total sample size of 100 is required, 50 per arm.

Statistical analysis

Group comparisons were carried out using the (modified) intention-to-treat principle, with participants providing data on at least one post-randomisation assessment analysed in the group to which they were randomised. Treatment effects for the primary (HFNS problem rating) and secondary outcomes were estimated using linear mixed models. The post-randomisation values of the outcome variables at 6 and 20 weeks were included as the outcome. Indicator variables for time, group, and a time by group interaction term and a recruiting centre indicator variables were included as covariates to allow treatment effects to vary by group at the two post-randomisation assessments. A random intercept for each participant was included to account for the repeated assessment of the outcome variable. Adjusted mean differences are presented unstandardised (i.e. original scale units) and as a standardised mean differences (i.e. standard deviation units; SMD) where the adjusted mean difference is divided by the pooled standard deviation of the outcome at baseline.

Prior to estimating the treatment effects, the suitability of the variables for analysis was considered by inspecting their distributions by group at each time points. Residual diagnostics were performed for the mixed effects models to confirm the assumption that outcome variables follow an approximately normal distribution was not violated.

The maximum likelihood estimator employed produces unbiased and efficient estimates of the treatment effect when missing outcome data arises at random conditional on the covariates included (i.e. missing at random). Sensitivity analyses were performed by comparing the treatment effect estimates to those where missing outcome assessments were imputed using the last observed value of the outcome (i.e. last observation carried forward). In addition, for the primary outcome, additional

sensitivity analysis was performed using a pattern-mixture model approach to determine the impact of a range of reasonable missing data scenarios on the treatment effect estimate.[49]

The recorded evaluation interviews were transcribed and a thematic content analysis was performed using the software NVivo (version21). Categories were developed under four main themes, including the impact of the intervention, reasons for the impact and for no impact experienced, perceptions of the intervention's content and delivery, and suggestions for improvement.

RESULTS

Participants

124 participants were randomised from eight, public (n=6) and private sector (n=2), organisations in the UK. Of these, 106 (85.5%) completed at least one post-randomisation assessment and were included in the (modified) intention-to-treat analysis. Overall attrition was below 20%, but it was higher in the SH-CBT group compared to the NTWC group with 60 (93.8%) and 46 (76.7%) included in the analysis, respectively. Participant flow through the trial is shown in figure 1.

Table 1 presents demographic information at baseline. Women were, on average, 54 years old and 70% were of white ethnicity. The sample was fairly healthy, with the majority rating their general health as good to excellent (85%). Over two-thirds were non-smokers and were drinking less than 7 units of alcohol per week. Most women exercised at least twice a week (68%). Women generally did not have a current mental or physical health problem (85%), nor were receiving treatment for breast cancer (95%). They had experienced their last menstrual period (LMP) on average 4 years before entering the study. Four per cent (n=5) were taking hormone therapy (HT), and 18% (n=20) were prior HT users; 32.5% (n=40) were taking over the counter remedies or medication for the menopause and 23% (n=29) had sought medical help for menopause in the past 6 months.

Just over three-quarters (83%) of women worked full-time, with regular hours, not shift work. The majority worked in non-manual jobs (82%), with both male and female colleagues (65%) having a mixed age range (73%). At baseline, the number of days affected by absence (including whole days, arriving to work late, leaving work early), that women attributed to menopause averaged 2 days (mean=1.80, sd=4.22) at baseline, over the past 4 weeks. Half (50.8%, n=63) had disclosed that they were

going through the menopause to a line manager, but only 9.7% (n=12) disclosed that menopause was a reason for any work absence. The majority rated their work performance as very good or excellent (79.9%, n=91).

[INSERT TABLE 1 AND FIG 1 HERE]

Outcomes

At baseline women reported having an average of 56.24 (range 0-245) HFNS per week, and these were rated as problematic (mean 6.5/10); the average duration of HFNS was 35 (SD=32.6) months (range 2 to 192 months).

Primary outcome

Unadjusted and baseline adjusted mean differences are shown in Table 2. The adjusted mean difference in the primary outcome HFNS Problem-rating, controlling for baseline level, was -1.49 ($p<0.001$) in favour of the SH-CBT group at 6 weeks, and -1.09 ($p<0.01$) at 20 weeks. These differences translate to a moderate to large effect sizes of d=-0.77 and -0.56, respectively (Table 2 and Fig 2).

No selection bias due to differential attrition by baseline problem rating was apparent. There was only a small difference in HFNS Problem-rating mean baseline scores in the NTWC group between those completing (N=60) and not completing (N=4) at post-randomisation assessment, and therefore included in the analysis: 6.80 versus 7.33. Similarly, there was only a small difference in baseline scores in the SH-CBT group between those completing (N=46) and not completing (N=14) at post-randomisation assessment: 6.25 versus 6.10. Those who did not complete were significantly more likely to be of non-white ethnicity (Pearson chi square=4.38, $p<0.05$), not in a relationship, chi-squ=5.61, $p<0.05$) and to score higher on HFNS avoidance behaviour (Mean rank=85.89) to those included (Mean rank=58.53), $U = 1375$, $z = -3.056$, $p<0.01$, and not receiving treatment for any major physical or health problem (Chi square=6.63, $p<0.01$). There were no significant differences in HFNS frequency or problem rating.

Sensitivity analysis was conducted to determine the impact of missing data at post-randomisation assessments on the estimated treatment effect size at 6-weeks. The last observation carried forward approach including all randomised participants indicated a more conservative effect size of 0.51. A pattern-mixture model approach was

employed to examine the sensitivity of the treatment effect as a result of the higher attrition in the SH-CBT group. This suggested that those with missing data in the intervention group would have had to experience worsening of 3 points on average relative to their baseline values to reduce the treatment effect to non-significant. Such a difference appears implausible.

[INSERT TABLE 2 and FIG 2 HERE]

Secondary outcomes

In addition to the significant moderate to large effect on the primary outcome there was a significant effect on HFNS frequency at the 6 week and the 20 week assessment, effect sizes 0.39 and 0.31 respectively. HFNS frequency was highly variable; total HFNS frequency reduced on average by 24% SH-CBT, 0.5% NTWC at 6 weeks, and by 35.5% SH-CBT and 15% for NTC at 26 weeks.

There was a significant effect of SH-CBT on levels of functioning measured by the Work and Social Adjustment Scale (WSAS)[46] at both 6 and 20 week assessments. There were significant group differences in WHQ wellbeing and somatic symptom scores at 20 weeks, and in sleep problems at 6 and 20 weeks. Similarly, significant improvements in sleep quality were recorded at 6 and 20 weeks as assessed by the Pittsburg Sleep Quality Index.[45] (see Table 2 and Fig 2).

Large and moderate significant effects were observed for the beliefs about menopause and beliefs/behaviours about HFNS. SH-CBT participants viewed menopause as more controllable and curable and as a new phase (MRQ control/cure and new phase subscales) significantly more than NTWC at both 6 and 20 week assessments. Effects on other MRQ subscales were small and generally non-significant. Moderate to large significant effects were observed for the three HFNS beliefs scales and for the positive behaviours subscale. The effect on avoidant behaviours was small and non-significant.

In relation to work variables, effects were generally small and non-significant for absence (days affected by any absence in past 4 weeks and attributed to menopause including whole days, arriving to work late, leaving work early), performance, and turnover intention. However, for presenteeism (Stanford Presenteeism Scale[47]) at 20 weeks, the effect of SH-CBT compared to NTWC was significant and approaching a large effect size. Those receiving SH-CBT had higher scores at 20 weeks than the

NTWC group, indicating lower perceived work impairment due to the menopause for the SH-CBT group.

Use of services and medication

Since starting the study (randomisation to 20 week assessment), 14% (n=6) of the SH-CBT and 15% (n=9) of the NTWC participants had sought medical help, on average once, for menopause symptoms - a nonsignificant difference. One woman (SH-CBT group) was prescribed antidepressants for anxiety/mood swings; in the NTWC group, two were prescribed HT, one the contraceptive pill and two changed type of hormone therapy. Eight (NTWC=7, SH-CBT=1) had used non-medical or herbal treatments since starting the study: homeopathy (n=1 NTWC), evening primrose oil (n=3 NTWC), red clover (n=1 NTWC), sage tablets (n=1 NTWC) and Menopace, one participant from each group).

Adherence and acceptability

At the 6 week follow-up assessment, 61% (n=27) of SH-CBT participants had read the entire self-help booklet, and an additional 21% (n=9) more than half. The majority (82%, n=32) had used the relaxation/breathing exercise at least 1-2 times a week or more, at the onset of a hot flush (82%, n=37) and to help manage a stressful situation at work (71%, n=25). Similarly, at 20 weeks, 65% (n=28) of SH-CBT participants had read all of the self-help booklet, and 26% (n=11) more than half. Relaxation/breathing was reportedly still being used by 79% (n=33) at least 1-2 times a week or more.

At 6 weeks 89.4% (n=42) rated the self-help booklet as being helpful in coping with their menopause symptoms at work; 23.4% (n=11) moderately and 31.9% (n=15) very/extremely helpful. At the 20 week assessment 88.1% (n=35) rated the self-help booklet as helpful in coping with their menopause symptoms at work; 26.2% (n=11) moderately and 45.2% (n=19) very/extremely helpful.

Evaluation interviews

Twenty-seven women were interviewed at the end of the trial from the intervention group. We originally intended to select 50% of transcripts for

analysis,[22] but as only 27 women took part in interviews, all their data were included. The majority, 82%, felt that the intervention had impacted positively on their experience of HFNS, 48% mentioning a reduction specifically in HFNS frequency. Positive benefits were reported to life in general (63%), and to working life (52%). Since the start of the trial, 37% had talked about their menopause to their line manager.

Reasons given for improvements in general to life included: changing perceptions about the menopause and having a better understanding, exercising self-care, and having the confidence to talk and to be open about their menopause. Positive changes to working life were attributed to addressing HFNS triggers identified during the SH-CBT, feeling less bothered or focused on symptoms, using the breathing techniques and letting go, and also having more confidence at work. Participants who did not experience any impact from the intervention stated it was because they were already doing things to help manage symptoms anyway they did not follow the self-help or their HFNS had improved.

In terms of the self-help booklet content, the main aspects that the participants mentioned as being helpful, were that it was informative, particularly the materials on managing HFNS, e.g. addressing thoughts, the CBT approach, and identifying triggers; they also liked the dairies and interactive elements of the booklet (e.g. exercises to complete). Other helpful aspects included having testimonials and perceptions of others presented in the booklet, the breathing exercise and CD, the goal setting section, as well as the general design and structure of the booklet. Approximately two thirds liked the hard-copy format of the booklet; however, some thought that having an online version or an app for smart phones could be offered in the future.

DISCUSSION

The aim of this multicentre study was to investigate the impact of a brief, unguided, self-help CBT intervention on HFNS, for women having problematic menopausal symptoms in the work context. When compared to a no-treatment control group, unguided self-help CBT significantly reduced HFNS problem

rating with moderate to large effect sizes and improvements were maintained at 20 weeks post-randomisation. These results are consistent with findings from previous randomised controlled trials of CBT for HFNS, when delivered in-group and guided self-help booklet formats. [27-30] However, it is noteworthy that this study implemented a considerably briefer version of SH-CBT with no additional support, and in a work, rather than a clinical context.

HFNS frequency also reduced at both time points and group differences were significant at both 6 weeks and 20 weeks. Percentage reduction in frequency of 24% (6 weeks) and 35.5% (20 weeks) was broadly similar to that found in previous studies of guided self-help; [27,30] relatively small changes were evident for the NTWC group. In the MENOS 2 trial[27] HFNS frequency assessed by sternal skin conductance monitoring also significantly improved following CBT, suggesting that changes might occur at both subjective and physiological levels.[35] The significant improvements on the Work and Social Adjustment Scale (WSAS) scores at both 6 weeks and 20 weeks post-randomisation compared to the control group, provide evidence of the secondary benefits of SH-CBT to functioning at work, home, leisure, and in social situations. The WSAS is routinely used in primary care psychology services in the UK and has been found to reflect a distinct social functioning factor and to be sensitive to treatment effects.[50] There were significant group differences in wellbeing and somatic symptoms at 20, but not at 6, weeks; but not anxiety/depression nor memory/concentration subscales of the Revised WHQ. However, WHQ sleep problems subscales scores and sleep quality significantly improved following SH-CBT at 6 and 20 weeks. The CBT intervention includes advice and strategies to improve sleep and CBT is an effective treatment for insomnia.[51]

CBT for HFNS targets cognitions (catastrophic or shameful thoughts in social contexts, worries about the consequences of night-time wakening), overly negative beliefs about menopause, behavioural reactions, and stress/well-being. Mediation analyses of previous trials have shown that CBT appears to work by changing symptom perceptions and cognitive appraisals (women's perceptions, attitudes and beliefs about menopause and symptoms) and well as using helpful behavioural strategies.[33-34] Consistent with this work, we found significant changes in beliefs and behaviours about HFNS following SH-CBT, suggesting that the treatment is

targeting relevant cognitions and behaviours. More general beliefs about the menopause, reflected in MRQ subscales negative impact, control/cure and new phase subscales, also showed significant between group differences at both 6 and 20 week assessments.

The current findings therefore lend support to the cognitive model of HFNS.[31] The social aspects of these beliefs – relating to social meanings about the menopause and concern about other people's views when having hot flushes - are relevant because women report embarrassment and fear of ridicule particularly in work contexts.[10,12,13] More positive/neutral beliefs about menopause, e.g. that symptoms are controllable and that menopause can herald a new life phase, are associated with more positive and helpful beliefs about HFNS, e.g. that others may not think negatively about them, that women have strategies to cope with them; and, in turn, positive and neutral beliefs about HFNS are associated with less problematic HFNS.[32,40-41]

The majority of women (80%) rated their work performance as very good or excellent at baseline. Presenteeism, using the *Stanford Presenteeism Scale*,[45] measures menopausal women's perceptions of productivity and work impairment due to their menopause while being physically present at work. Higher scores suggest low perceived work impairment due to the menopause; i.e. women are at work and managing any work impairment so that their performance is not affected. The SH-CBT group obtained significantly higher scores than NTC at 20 weeks. It is possible therefore that the strategies learnt from the SH-CBT might enable women to manage their HFNS so that they have less impact on their work. HFNS become less problematic and social and work functioning improves. The relationships between improvements in HFNS and presenteeism will be explored in a future publication.

The lack of impact on additional work outcomes may relate to the timeframes used in the trial. It is possible that 20 weeks post-randomization, or approximately 16 weeks post treatment, was insufficient time for changes in work adjustment to occur. For example, the significant between group difference in presenteeism was only found at 20 weeks and not at 6 weeks.

Alternatively, problematic HFNS may not impact on all work outcomes in similar ways. The workplace is a complex environment; the experience of HFNS may interact with several employee related and work-related factors. A review by Jack and colleagues[22] identified that the work environment, both physical and

psychosocial, may influence women's experience of menopause. Further analysis of the potential moderating effect of a number of work related factors (work environment, job satisfaction and job stress) is planned.

Overall, our results suggest that an unguided, self-help CBT approach may be efficacious as a low intensive treatment option for working women with problematic menopause symptoms. The levels of frequency and problem-rating HFNS at baseline were very similar to the levels of well women and breast cancer patients recruited into clinical trials,[27-29] and the improvements following this low-intensity version of SH-CBT were robust and sustained. Comparable recommended non-hormonal treatments for HFNS involve several sessions of treatment, e.g. 5-12 sessions of hypnosis and 8 sessions of mindfulness:[36] while hormonal and non-hormonal medical treatments involve appointments and ongoing prescription charges. The intervention involves no health professional time and is likely therefore to be cost effective; however, a health economic analysis is recommended. The intervention appeared to be acceptable in terms of feedback reported during interviews, and the women's reports on what was helpful were consistent with qualitative data collected during the MENOS2 trial.[52]

Strengths and limitations

The trial was adequately powered, there were no adverse events, relatively low levels of attrition during the trial period, and adherence to the SH-CBT was reasonable. The SH-CBT was piloted and modified in response to feedback. Unexpectedly, dropouts were higher in the SH-CBT than the NTWC condition, which is a limitation. Most women in the SH-CBT arm who dropped out reported time pressures as the main problem for not completing the self-help intervention and questionnaires. It is possible that the women in the NTWC arm may have been more likely to persist in the study because they were expecting to obtain the SH-CBT off trial at the end of the study. Participants who dropped out were more likely to be non-white, not in a relationship, to have higher baseline HFNS avoidance behaviour scores, and not having any current treatment for any major physical or mental health problem. In previous trials, ethnicity either did not moderate the effects of CBT,[34] or when it did it was women of non-white ethnicity who were more likely to benefit from CBT.[33] It is

possible that the self-help booklet was less appealing or acceptable to some women, who may have had less support, and, for others, being avoidant about HFNS could reflect a more general strategy (i.e. avoiding the self-help book designed to help manage HFNS). Pilot work was conducted to assess the acceptability, content and format of the intervention and questionnaires, as well as the delivery method, and adjustments made, but we did not actively target women from a range of ethnic groups. Further exploration is needed into the acceptability of the booklet, its format, and the level of individual or group support in different organisations, in order to increase adherence to the intervention.

Assessment of work outcomes relied on subjective rather than objective measures. However, obtaining formal sickness absence data and standard measurements of job performance for different job roles in heterogeneous workplaces is a complex matter and was beyond the scope of this study. Further, this might have been perceived, by participants, as compromising the anonymous nature of their responses.

Implications and future research

The trial findings have implications for various key stakeholders; employers, occupational health professionals, trade union representatives, and other professionals with a role in workplace health and wellbeing, may wish to make self-help CBT available to staff who have bothersome menopause symptoms. Similarly, policy makers should ensure that sufficient awareness and provision of information and help is offered to staff who may be experiencing menopause-related difficulties at work, in line with recent recommendations.[1,3-5,53]

Several suggestions for future research have been mentioned above. The format and level of detail of the provision of information for working women could be considered in future research; for example, whether briefer information is made available for all staff, with SH-CBT offered to those who have problematic symptoms. The needs and working environments of organisations are likely to vary. SH-CBT is available in book format [37] and workshops or groups could be offered using the manual for health

professionals.[38] It may also be of interest to explore the effect of self-help for other symptoms reported by women at work (e.g. confidence, fatigue) in more detail, and to clarify the extent to which these are affected by, or interact with for example work stress and HFNS. Recommendations for improving the experience of menopause at work include changes at an individual level and at an organisational level.[3-5] Similarly, we would predict that the SH-CBT intervention for women with troublesome menopausal symptoms might be more effective when offered in the context of a broader strategy to improve awareness about menopause in general, to reduce stigma and to make appropriate changes to work environment.[53]

CONCLUSIONS

To our knowledge this is the first study to develop and evaluate an unguided, self-help intervention specifically to help menopausal women to manage HFNS in the workplace. The results suggest that SH-CBT is an effective and acceptable low-intensity, non-medical intervention for problematic HFNS that has additional effects on work and social adjustment and on presenteeism. The study is timely, and has important implications for employers and other stakeholders who have a responsibility to provide resources for working women.

REFERENCES

1. Griffiths A, Ceausu I, Depypere H, Lambrinoudaki I, Mueck A, Pérez-López FR, van der Schouw YT, Senturk LM, Simoncini T, Stevenson JC, Stute P. EMAS recommendations for conditions in the workplace for menopausal women. *Maturitas* 2016 31;85:79-81.
2. Payne S, Doyal L. Older women, work and health. *Occupational Med* 2010;172-177.
3. Griffiths A, Hunter MS. Psychosocial factors and menopause: The impact of menopause on personal and working life. In Davies SC, *Annual Report of the Chief Medical Officer 2014,* The Health of 51%. London: Department of Health 2015.
4. Griffiths A, MacLennan S, Wong, YYV. *Work and the Menopause: A Guide for Managers.* A Report for the British Occupational Health Research Foundation (BOHRF), 2010. Available from: https://www.nottingham.ac.uk/hr/guidesandsupport/equalityanddiversitypolicies/documents/workandthemenopause-aguideformanagers.pdf
5. Physicians FoOMatRCo. *Guidance on menopause and the workplace*. London, UK: Faculty of Occupational Medicine and the Royal College of Physicians; 2016.
6. Office for National Statistics. *Labour Market Statistics*. London: Office for National Statistics. August 2017.
7. Hunter MS, Gentry-Maharaj A, Ryan A, Burnell M, Lanceley A, Fraser L. et al. Prevalence, frequency and problem rating of hot flushes persist in older postmenopausal women: impact of age, BMI, hysterectomy, lifestyle and mood in a cross sectional cohort study of 10,418 British women aged 54-65. *Brit J Obstet Gynaecol* 2012;119:40–50.
8. Porter M, Penney GC, Russell D, Russell E. Templeton A. A population based survey of women's experience of the menopause. *Brit J Obstet Gynaecol* 1996;103:1025–1028.
9. Ayers B, Hunter MS. Health-related quality of life of women with menopausal hot flushes and night sweats. *Climacteric* 2012;15:1–5.
10. Hunter MS, Liao KLM. A psychological analysis of menopausal hot flushes. *Brit J Clin Psychol* 1995; 34:589-599.
11. Griffiths A, MacLennan SJ, Hassard, J. Menopause and work: An electronic survey of employees' attitudes in the UK. *Maturitas* 2013; 76:155-159.
12. Smith MJ, Mann E, Mirza A, Hunter MS. Men and women's perceptions of hot flushes within social situations: are menopausal women's negative beliefs valid? *Maturitas* 2011;69:57-62.
13. Reynolds F. Distress and coping with hot flushes at work: implications for counsellors in occupational settings. *Counselling Psychol Quarterly* 1999;12(4):353–61.
14. Paul J. *Health and safety and the menopause: working through the change*. London: Trades Union Congress; 2003. Available from: http://www.tuc.org.uk/workplace/tuc-6316-f0.pdf
15. Gartoulla P, Bell RJ, Worsley R, Davis SR. Menopausal vasomotor symptoms are associated with poor self-assessed work ability. *Maturitas* 2016;31(87):33-9.
16. Geukes M, van Aalst MP, Nauta MC, Oosterhof H. The impact of menopausal symptoms on work ability. *Menopause 2012*;19:278-82.

17. Whiteley J, daCosta DiBonaventura M, Wagner J-S, Alvir J, Shah S. The impact of menopausal symptoms on quality of life, productivity, and economic outcomes. *J Women's Health* 2013;22 (11):983-999.
18. Sarrel P, Portman D, Lefebvre P, Lafeuille M_H, Grittner AM, Fortier J, et al. Incremental direct and indirect costs of untreated vasomotor symptoms. *Menopause* 2014;(22)3:260-66.
19. Kleinman NL, Rohrbacker NJ, Bushmakin AG, Whiteley J, Lynch WD, Shahet SN. Direct and indirect costs of women diagnosed with menopause symptoms. *J Occup Environmental Med* 2013 55;4:465-70.
20. Bariola E, Jack G, Pitts M, Riach K, Sarrel P. Employment conditions and work-related stressors are associated with menopausal symptom reporting among perimenopausal and postmenopausal women. *Menopause* 2017;9; 24(3):247-251.
21. Woods NF, Mitchell ES. Symptom interference with work and relationships during the menopausal transition and early post-menopause: observations from the Seattle midlife women's health study. *Menopause* 2011;18(6):654–1.
22. Jack G, Riach K, Bariola E, Pitts M, Schapper J, Sarrel P. Menopause in the workplace: What employers should be doing. *Maturitas* 2016;31(85):88-95.
23. Health and Safety Executive (HSE) *Management Standards Indicator Tool,* 2013. Available from: http://www.hse.gov.uk/stress/standards/pdfs/indicatortool.pdf
24. Matsuzaki K, Uemura, H, Yasui T. Associations of menopausal symptoms with job-related stress factors in nurses in Japan. Maturitas 2014; 79: 77-85.
25. Hunter MS, Hardy C, Norton S, Griffiths A. Study protocol of a multicentre randomised trial of self-help cognitive behaviour therapy for working women with menopausal symptoms (MENOS@Work). *Maturitas* 2016; 92:186-192.
26. National Institutes of Health and Care Excellence (NICE). *NICE guidance on Diagnosis and Management of Menopause*, November 2015.
27. Ayers B, Smith M, Hellier J, Mann E and Hunter MS. Effectiveness of group and self-help cognitive behaviour therapy to reduce problematic menopausal hot flushes and night sweats (MENOS 2): a randomized controlled trial. *Menopause* 2012;19:749-759.
28. Mann E, Smith MJ, Hellier J, Hamed H, Grunfeld B, Hunter MS. Efficacy of a cognitive behavioural intervention to treat menopausal symptoms following breast cancer treatment (MENOS 1): a randomised controlled trial. *Lancet Oncol* 2012;13(3):309–318.
29. Duijts SFA, van Beurden M, Oldenburg HSA, Hunter MS, Kieffer JM, Stuiver MM, et al. Efficacy of cognitive behavioural therapy and physical exercise in alleviating treatment-induced menopausal symptoms in patients with breast cancer: results of a randomized controlled multicentre trial. *J Clin Oncol* 2012;30(33):4124-4133.
30. Stefanopoulou E, Hunter MS. Telephone-guided Self Help cognitive behaviour therapy for menopausal symptoms. *Maturitas* 2014;77(1):73-77.
31. Hunter MS, Mann E. A cognitive model of menopausal hot flushes. *J Psychosom Res* 2010;69:491-501.
32. Hunter MS, Chilcot J. Testing a cognitive model of menopausal hot flushes and night sweats. *J Psychosom Res* 2013;74(4):307-12.

33. Chilcot J, Norton S, Hunter MS. Cognitive behaviour therapy for menopausal symptoms following breast cancer treatment: who benefits and how does it work? *Maturitas* 2014;78(1):56 – 61.
34. Norton S, Chilcot J, Hunter MS. Cognitive behaviour therapy for menopausal symptoms (hot flushes and night sweats): moderators and mediators of treatment effects. *Menopause* 2014;21(6):574-78.
35. Stefanopoulou E and Hunter MS. Does pattern recognition software using the Bahr monitor improve the sensitivity, specificity, and concordance of ambulatory skin conductance monitoring of hot flushes? *Menopause* 2013; 20 (11): 1133-1138.
36. Position Statement: Non-hormonal management of menopause-associated vasomotor symptoms: 2015 position statement of The North American Menopause Society. *Menopause* 2015; 22(11):1-20.
37. Hunter MS, Smith M. *Managing Hot Flushes and Night Sweats: a Cognitive Behavioural Self-Help Guide to the Menopause*. East Sussex, UK and NewYork: Routledge, 2014.
38. Hunter MS, Smith M. *Managing Hot Flushes with Group Cognitive Behaviour Therapy: an Evidence Based Treatment Manual for Health Professionals*. East Sussex, UK and New York: Routledge, 2014.
39. Dunn G, Emsley R, Liu H, Landau S, Green J, White I, et al. Evaluation and validation of social and psychological markers in randomised trials of complex interventions in mental health: a methodological research programme. Health Technol Assess 2015;19: 93.
40. Rendall MJ, Simmons LM & Hunter MS. The Hot Flush beliefs Scale: a tool for assessing thoughts and beliefs associated with experience of menopausal hot flushes and night sweats. *Maturitas* 2008; 60: 158-169.
41. Hunter MS, Ayers B, Smith M. The Hot Flush Behaviour Scale (HFBehS): a measure of behavioural reactions to menopausal hot flushes and night sweats. *Menopause* 2011;18 (11):1178-83.
42. Hunter MS, O'Dea I. (2001) Development of the Menopause Representations Questionnaire. *Psychol Health Med* 6, 65-76.
43. Girod, I, de la Loge C, Keininger D, Hunter MS. Development of a revised version of the Women's Health Questionnaire. *Climacteric* 2011; 9:1, 4-12.
44. Katainen RE, Engblom JR, Vahlberg TJ, Polo-Kantola P. Psychometric properties of the Finnish version of the Women's Health Questionnaire. *Menopause* 24 (8): 923-931.
45. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiat Res* 1989; 28:193-213.
46. Mundt JC, Marks IM, Shear MK, Greist JM. The work and social adjustment scale: a simple measure in impairment functioning. *Brit J Psychiat* 2002;180:461-464.
47. Koopman C, Pelletier KR, Murray JF, Sharda CE, Berger ML, Turpin RS, et al. Stanford Presenteeism Scale: Health status and employee productivity. *J Occup and Environmental Med*, 2002;44:14-20.
48. Shore LM, Martin HJ. Job satisfaction and organizational commitment in relation to work performance and turnover intentions. *Human Relations* 1980;42(7):625-638.
49. White IR, Kalaitzaki E, Thompson SG. Allowing for missing outcome data and

incomplete uptake of randomised interventions, with application to an Internet-based alcohol trial. *Statistics in Med* 2011;*30*(27):3192–3207.

50. Zahra D, Qureshi A, Henley W, Taylor R, Quinn C, Pooler J, et al. The work and social adjustment scale: Reliability, sensitivity and value. *Int J Psychiatry Clin Pract* 2014;18(2):131-138.

51. McCurry SM, Guthrie KA, Morin CM, Woods NF, Landis CA, Ensrud KE, et al. Telephone-Based Cognitive Behavioral Therapy for Insomnia in Perimenopausal and Postmenopausal Women With Vasomotor Symptoms A MsFLASH Randomized Clinical Trial. *JAMA Intern Med.* 2016;176(7):913–920.

52. Balabanovic J, Ayers B and 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 Cog Psychotherapy* 2013; 41(4):441-57.

53. Hardy C, Griffiths A, Hunter MS. What do working menopausal women want? A qualitative investigation into women's perspectives on employer and line manager support. *Maturitas* 2017;31(101):37-41.

Table 1. Baseline demographics, health, and job status of participants

Participant demographics		SH-CBT (N=60)	NTWC (N=64)	Total (N=124)
Age	Mean (SD)	54.04 (3.17)	54.10 (3.53)	54.09 (3.4)
Ethnicity	White British	42 (70.0%	45 (71.4%)	87 (70.7%)
	Black British	11 (18.3%)	14 (22.2%)	25 (18.3%)
	Other	7 (11.7%)	4 (6.4%)	11 (8.9%)
Menopausal status	Menopause transition	11 (20%)	20 (35.7%)	31 (27.9%)
	Postmenopause	44 (80%)	36 (64.3%)	80 (72.1%)
	Last menstrual period (months) Mean (SD)	48.29 (54.16)	35.68 (51.69)	42.04 (53.09)
	Hysterectomy	10 (17.0%)	6 (10.0%)	17 (14.0%)
	Oophorectomy	3 (5.0%)	6 (10.0%)	9 (7.0%)
Relationship status	Single	11 (18.3%)	15 (25%)	27 (21.8%)
	Married/Partnered	42 (70.0%)	37 (57.8%)	79 (63.8%)
	Divorced/Separated/ Widowed	7 (11.7%)	11 (17.2%)	18 (14.5%)
Education	Left school at 16	16 (26.7%)	17 (28.3%)	34 (28.1%)
	Left school at 18	7 (11.7%)	4 (6.7%)	11 (9.1%)
	Degree	37 (61.6%)	39 (65%)	76 (62.8%)
Employment	Full-time	46 (76.7%)	56 (89.1%)	103 (83.0%)
	Part-time	14 (23.3%)	7 (10.9%)	21 (17.0%)
Smoking	Non smoker	38 (64.4%)	26 (40.6%)	64 (52.0%)
	Past smoker	14 (23.7%)	26 (40.6%)	40 (32.5%)
	Current Smoker	7 (11.9%)	12 (18.8%)	19 (15.4%)
Exercise	Rarely/Never	4 (6.8%)	6 (9.4%)	10 (8.1%)
	Once a week or less	13 (22.1%)	16 (25.0%)	29 (23.4%)
	2-3 times a week	26 (44.1%)	24 (37.5%)	50 (40.7%)
	4-6 times a week	9 (15.3%)	11 (17.2%)	20 (16.3%)
	Every day	7 (11.9%)	7 (10.9%)	14 (11.4%)
Alcohol	None	21 (35.6%)	22 (34.4%)	43 (35.0%)
	1-13 Units	31 (52.5%)	37 (57.8%)	68 (55.3%)
	14+ Units	7 (11.9%)	5 (7.8%)	12 (9.8%)
BMI	Mean (SD)	25.66 (4.91)	28.26 (4.12	27.04 (4.67)

Table 2. Unadjusted and adjusted group differences for primary and secondary outcomes

			SH-CBT			NTWControl					Adjusted mean difference		
	Time	N	Mean	SD	N	Mean	SD	Difference	SE	p-value	Lower 95%CI	Upper 95%CI	Effect size
HF/NS Problem Rating	Baseline	46	6.25	1.97	60	6.80	1.90						
	6 weeks	44	4.38	2.21	60	6.16	2.31	-1.49	0.32	0.001	-2.11	-0.86	0.77
	20 weeks	42	4.36	2.29	59	5.80	2.30	-1.09	0.40	0.01	-1.87	-0.31	0.56
HF/NS Frequency	Baseline	46	53.13	34.34	60	54.28	38.11						
	6 weeks	44	40.59	26.05	59	54.02	43.00	-14.01	5.05	0.01	-23.91	-4.10	0.39
	20 weeks	43	34.28	27.62	59	46.03	37.92	-11.36	5.26	0.05	-21.66	-1.05	0.31
WSAS	Baseline	46	12.74	9.77	60	12.67	8.44						
	6 weeks	44	8.52	8.24	59	10.90	8.09	-2.36	0.83	0.01	-3.98	-0.74	0.26
	20 weeks	43	8.65	8.65	57	11.81	8.39	-2.89	0.98	0.01	-4.80	-0.98	0.32
Sleep Quality	Baseline	44	1.82	0.81	60	1.85	0.82						
	6 weeks	44	1.30	0.67	58	1.69	0.78	-0.41	0.11	0.001	-0.63	-0.20	0.51
	20 weeks	42	1.40	0.77	58	1.66	0.78	-0.24	0.10	0.05	-0.44	-0.03	0.29
WHQ anxiety/depression	Baseline	45	67.53	22.12	60	63.01	19.97						
	6 weeks	44	70.90	22.30	60	64.12	22.31	2.88	2.59	ns	-2.20	7.96	0.14
	20 weeks	42	74.85	23.97	58	66.10	21.42	4.81	2.78	ns	-0.64	10.26	0.23
WHQ wellbeing	Baseline	45	71.11	15.65	60	66.94	19.47						
	6 weeks	44	71.40	19.72	60	67.92	19.58	1.70	2.55	ns	-3.31	6.71	0.09
	20 weeks	42	75.79	16.44	57	67.54	17.30	6.62	2.40	0.01	1.91	11.33	0.37
WHQ somatic symptoms	Baseline	45	50.37	23.93	60	47.67	21.43						
	6 weeks	44	53.48	24.42	60	49.22	22.74	2.71	3.11	ns	-3.39	8.80	0.12
	20 weeks	42	58.41	22.47	57	49.94	20.04	8.38	2.80	0.01	2.90	13.86	0.37
WHQ memory & concentration	Baseline	45	45.92	28.09	60	41.31	24.39						
	6 weeks	44	48.47	26.91	60	42.41	24.24	3.07	3.19	ns	-3.18	9.33	0.12
	20 weeks	42	51.33	25.97	57	44.25	23.15	4.58	3.03	ns	-1.36	10.52	0.18
WHQ sleep problems	Baseline	44	34.09	25.66	60	37.78	26.01						
	6 weeks	44	46.97	27.91	60	37.22	26.10	12.75	3.22	0.001	6.45	19.06	0.49
	20 weeks	42	48.41	21.72	56	40.77	30.47	12.39	3.79	0.001	4.96	19.82	0.48
MRQ negative impact	Baseline	46	2.17	0.73	60	2.27	0.83						
	6 weeks	43	2.13	0.91	60	2.45	0.77	-0.23	0.11	0.05	-0.45	-0.01	0.29
	20 weeks	43	2.09	0.84	59	2.38	0.69	-0.21	0.10	0.05	-0.41	-0.01	0.27
MRQ relief	Baseline	46	2.52	0.82	60	2.37	0.96						
	6 weeks	43	2.64	0.95	60	2.50	0.95	0.03	0.13	ns	-0.22	0.29	0.04
	20 weeks	43	2.70	0.84	59	2.37	1.00	0.25	0.11	0.024	0.03	0.46	0.28

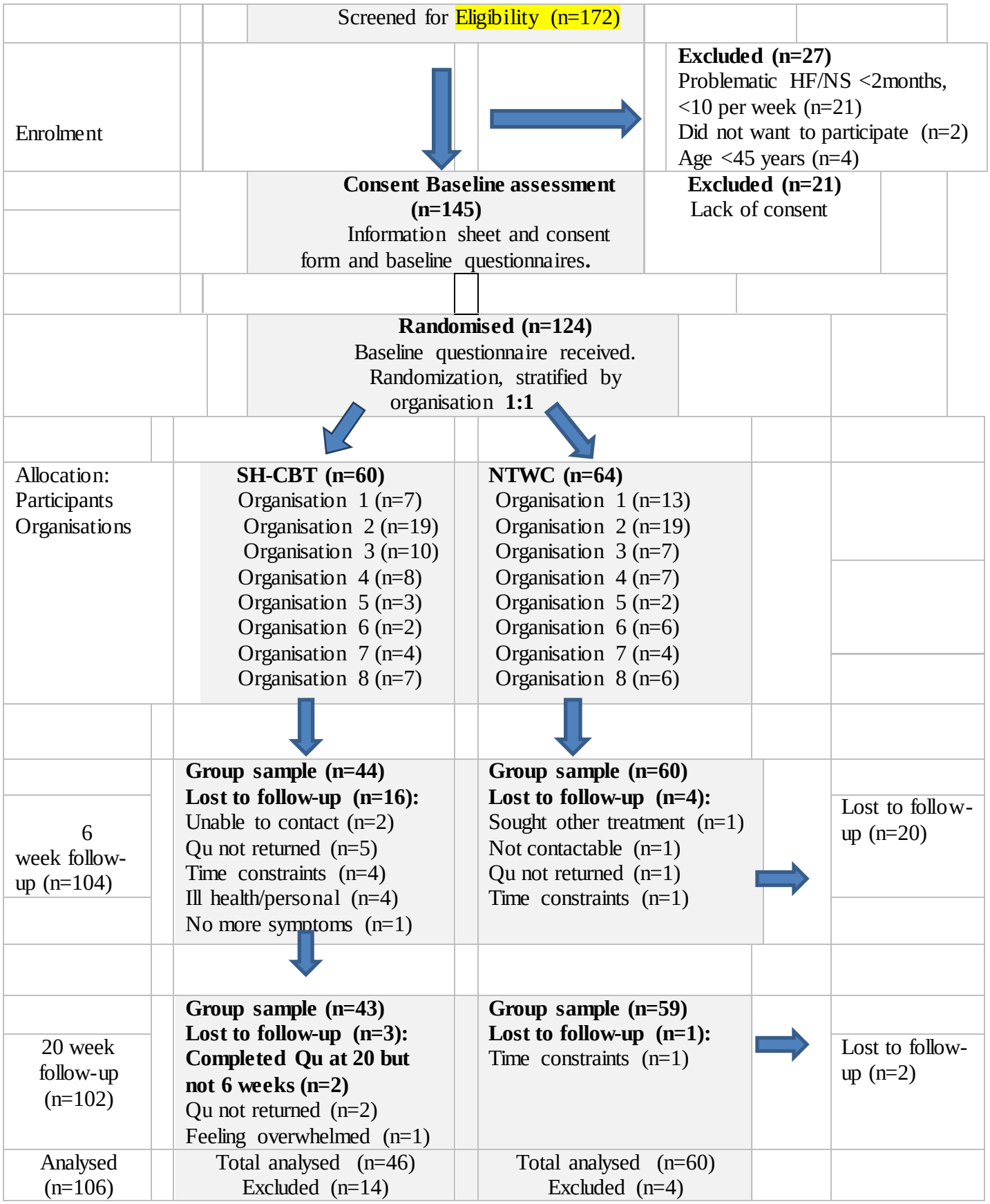
MRQ new phase	Baseline	46	1.72	0.92	60	1.73	0.87						
	6 weeks	43	2.13	0.77	60	1.71	0.91	0.41	0.12	0.001	0.17	0.65	0.46
	20 weeks	43	2.22	0.74	59	1.89	0.76	0.29	0.11	0.01	0.08	0.51	0.33
MRQ control/cure	Baseline	46	2.11	0.63	60	1.94	0.90						
	6 weeks	43	2.82	0.81	60	2.05	0.84	0.64	0.11	0.001	0.43	0.86	0.81
	20 weeks	43	2.88	0.65	59	2.10	0.80	0.66	0.11	0.001	0.44	0.88	0.83
MRQ identity	Baseline	46	17.17	8.28	60	15.80	8.00						
	6 weeks	43	16.35	9.08	60	15.28	7.98	-0.22	1.07	ns	-2.31	1.87	0.03
	20 weeks	43	16.40	7.52	59	15.97	8.61	-0.41	1.08	ns	-2.53	1.71	0.05
HF social beliefs	Baseline	46	2.35	1.67	60	2.30	1.37						
	6 weeks	44	1.59	1.35	60	2.40	1.38	-0.80	0.15	0.001	-1.09	-0.51	0.53
	20 weeks	42	1.55	1.27	57	2.24	1.39	-0.64	0.14	0.001	-0.91	-0.37	0.43
HF coping/control beliefs	Baseline	46	2.26	1.22	60	2.45	1.06						
	6 weeks	44	1.57	1.14	60	2.31	1.17	-0.60	0.16	0.001	-0.91	-0.29	0.53
	20 weeks	42	1.77	1.23	58	2.29	1.20	-0.47	0.18	0.01	-0.83	-0.11	0.42
NS/sleep beliefs	Baseline	46	2.08	1.09	60	2.42	1.33						
	6 weeks	44	1.29	1.09	60	2.36	1.41	-0.90	0.16	0.001	-1.21	-0.58	0.73
	20 weeks	42	1.26	0.90	57	2.08	1.31	-0.64	0.16	0.001	-0.95	-0.33	0.52
HF/NS avoidant behaviours	Baseline	46	0.75	1.03	60	1.19	1.41						
	6 weeks	44	0.65	1.00	60	1.21	1.28	-0.25	0.15	0.05	-0.54	0.04	0.20
	20 weeks	42	0.79	1.03	57	1.25	1.51	-0.16	0.20	ns	-0.55	0.23	0.13
HF/NS positive behaviours	Baseline	46	3.34	1.01	60	3.13	1.19						
	6 weeks	44	3.67	0.86	60	3.11	1.13	0.43	0.14	0.01	0.15	0.71	0.39
	20 weeks	42	3.64	1.07	58	3.13	1.17	0.41	0.18	0.05	0.06	0.75	0.37
Absenteeism (days), 4 weeks	Baseline	46	1.17	3.93	60	2.20	4.25						
	6 weeks	46	0.50	2.25	60	1.13	2.16	-0.54	0.44	ns	-1.40	0.32	0.13

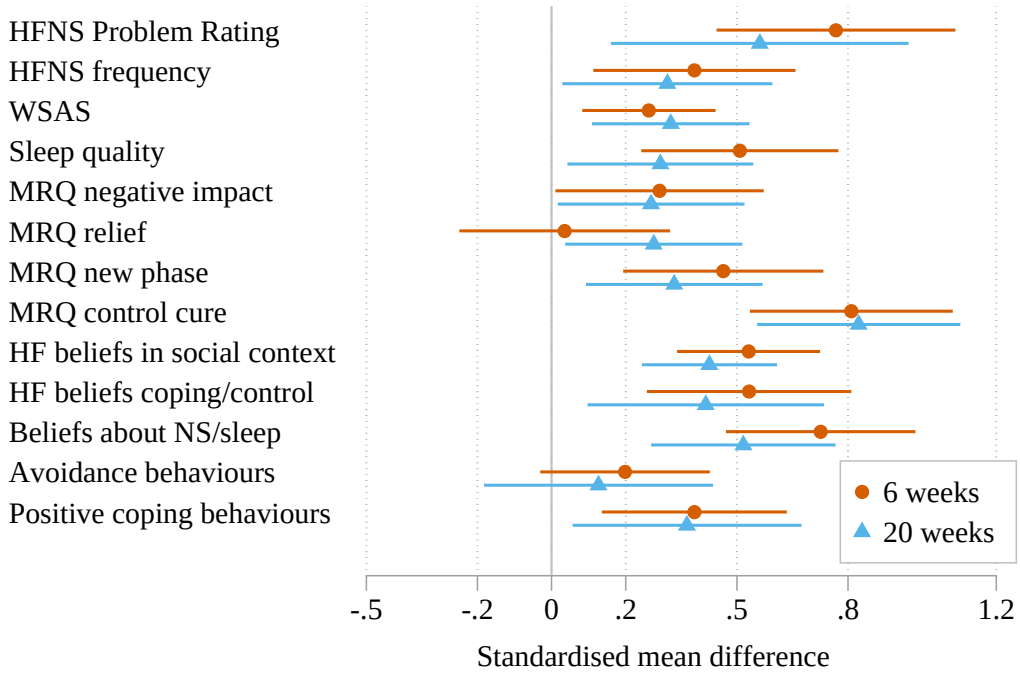
	20 weeks	46	0.70	3.00	60	1.43	3.27	-0.64	0.55	ns	-1.71	0.43	0.16
SPS Presenteeism	Baseline	46	20.24	6.34	60	18.67	6.40						
	6 weeks	43	22.12	7.16	59	19.36	6.93	1.64	0.90	ns	-0.13	3.41	0.26
	20 weeks	43	23.21	5.84	57	18.18	7.18	4.18	0.80	0.001	2.60	5.76	0.65
Turnover intention	Baseline	46	2.43	0.97	60	2.67	0.96						
	6 weeks	43	2.32	1.02	59	2.67	0.90	-0.20	0.12	ns	-0.43	0.03	-0.21
	20 weeks	42	2.48	1.06	58	2.50	0.93	0.09	0.12	ns	0.14	0.31	0.09
Job performance	Baseline	46	4.07	0.83	59	4.07	0.93						
	6 weeks	44	4.20	0.76	60	4.18	0.83	-0.02	0.12	ns	-0.25	0.22	-0.02
	20 weeks	43	4.30	0.71	59	4.10	0.74	0.16	0.12	ns	-0.07	0.40	0.19

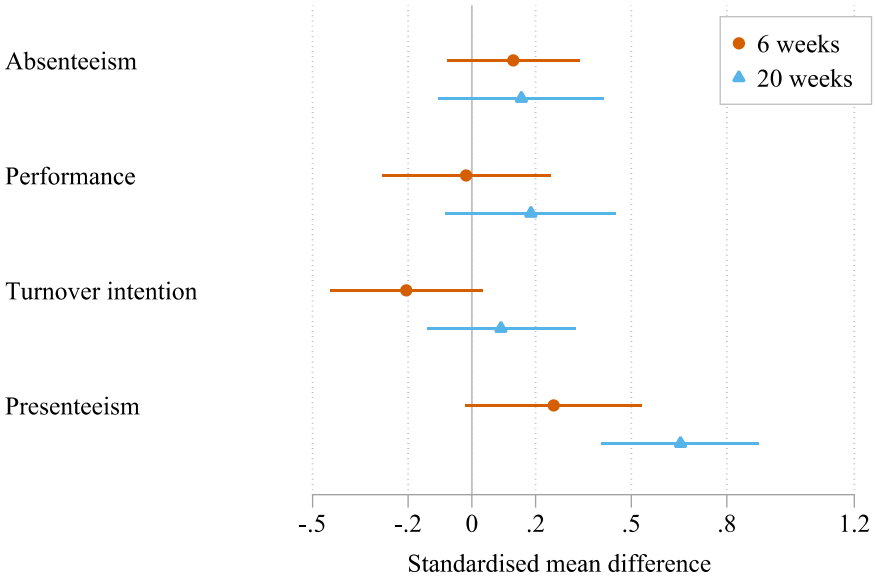
Figure 1. Flow chart of trial

Figure 2. Standard mean differences between SH-CBT vs NTWC groups in HFNS problem rating and frequency, interference (WSAS), sleep quality, menopause appraisals and HFNS beliefs and behaviours. Positive values favour intervention.

Figure 3. Standard mean differences between SH-CBT vs NTWC groups in work related variables. Positive values favour intervention.


Screened for Eligibility (n=172)
Enrolment
Excluded (n=27)
Problematic HF/NS <2months, <10 per week (n=21)
Did not want to participate (n=2)
Age <45 years (n=4)
Consent Baseline assessment (n=145)
Information sheet and consent form and baseline questionnaires.
Excluded (n=21)
Lack of consent
Randomised (n=124)
Baseline questionnaire received. Randomization, stratified by organisation 1:1
Allocation: Participants Organisations
SH-CBT (n=60)
Organisation 1 (n=7)
Organisation 2 (n=19)
Organisation 3 (n=10)
Organisation 4 (n=8)
Organisation 5 (n=3)
Organisation 6 (n=2)
Organisation 7 (n=4)
Organisation 8 (n=7)
NTWC (n=64)
Organisation 1 (n=13)
Organisation 2 (n=19)
Organisation 3 (n=7)
Organisation 4 (n=7)
Organisation 5 (n=2)
Organisation 6 (n=6)
Organisation 7 (n=4)
Organisation 8 (n=6)
6 week follow-up (n=104)
Group sample (n=44)
Lost to follow-up (n=16):
Unable to contact (n=2)
Qu not returned (n=5)
Time constraints (n=4)
Ill health/personal (n=4)
No more symptoms (n=1)
Group sample (n=60)
Lost to follow-up (n=4):
Sought other treatment (n=1)
Not contactable (n=1)
Qu not returned (n=1)
Time constraints (n=1)
Lost to follow-up (n=20)
20 week follow-up (n=102)
Group sample (n=43)
Lost to follow-up (n=3):
Completed Qu at 20 but not 6 weeks (n=2)
Qu not returned (n=2)
Feeling overwhelmed (n=1)
Group sample (n=59)
Lost to follow-up (n=1):
Time constraints (n=1)
Lost to follow-up (n=2)
Analysed (n=106)
Total analysed (n=46)
Excluded (n=14)
Total analysed (n=60)
Excluded (n=4)


HFNS Problem Rating
HFNS frequency
WSAS
Sleep quality
MRQ negative impact
MRQ relief
MRQ new phase
MRQ control cure
HF beliefs in social context
HF beliefs coping/control
Beliefs about NS/sleep
Avoidance behaviours
Positive coping behaviours
6 weeks
20 weeks
-.5
-.2
0
.2
.5
.8
1.2
Standardised mean difference


Absenteeism
Performance
Turnover intention
Presenteeism
6 weeks
20 weeks
-.5
-.2
0
.2
.5
.8
1.2
Standardised mean difference