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Telephone-guided Self-Help Cognitive Behavioural Therapy for menopausal symptoms

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ABSTRACT

Objectives: Group and Self-Help forms of Cognitive Behavioural Therapy (CBT) are effective treatment options for women with problematic menopausal hot flushes and night sweats (HF/NS). However, some women are unable to attend face-to-face sessions. This study investigates whether Self-Help CBT for HF/NS is as effective when rolled out to women living at a distance with minimal telephone guidance.
Study design: Forty-seven women completed a Self-Help CBT intervention (booklet and relaxation/paced breathing CD) during a 4-week period. They also received one 'guiding' telephone call from a clinical psychologist two weeks into treatment to provide support and discuss individual treatment goals. Questionnaires were collected at baseline, 6 weeks (post-treatment) and 3 months (follow-up) after the end of the intervention.
Main outcome measures: HF/NS problem rating. Secondary outcome measures: HF/NS frequency, HF/NS beliefs and behaviours, sleep, anxiety and depressed mood.
Results: There was a significant reduction in HF/NS problem-rating following the intervention which was maintained at follow-up. Moreover, women reported less frequent HF/NS along with further improvements in sleep quality, mood and HF/NS beliefs and behaviours.
Conclusions: Telephone-guided Self-Help interventions might provide an effective way of widening access to CBT treatment for HF/NS.

1. Introduction

Cognitive Behavioural Therapy (CBT) has been found to reduce the impact of hot flushes and night sweats (HF/NS) in recent randomised controlled trials (MENOS 1 and MENOS 2) with well women and breast cancer patients [1,2]. HF/NS are the cardinal symptoms of the menopause transition and can negatively impact on sleep, mood and quality of life [3,4]. Guided Self-Help CBT was found to be as effective as Group CBT in reducing HF/NS problem-rating or interference [1] and may be offered in order to widen access to treatment for women experiencing troublesome symptoms. Indeed, use of Self-Help formats has been found to be a cost-effective method of delivering treatments for anxiety and depression [5]. The UK National Health Service (NHS) also recognises that Self-Help CBT and other self-management interventions play an important role in addressing health inequalities in chronic symptom management [5,6].

Typically, guided Self-Help consists of a psychological intervention involving the patient taking home a standardised psychological manual in a written format (e.g. in a booklet, downloadable pdf etc.) and working through it in an independent manner [7,8]. Using step-by-step instructions, patients can learn how to apply a generally accepted psychological treatment to address their own needs; moreover, minimal time is required by a therapist, whose role is primarily supportive in helping the patient to work through the treatment her/himself. Therapist input tends to be maintained at a fairly minimal level by brief face-to-face contact, telephone, email or other communication methods [5].

However, guided Self-Help interventions often come in many forms and with different levels and types of therapist input, which may have significant implications for the costs of the treatments or their effectiveness [9]. For instance, although strong associations between higher levels of therapist input and better health-related outcomes have been reported [9], a recent meta-analysis suggested comparable outcomes between guided Self-Help and face-to-face interventions for anxiety and mood disorders; consequently, the authors argued that it may not be so much the intensity of therapist input (e.g. type, number or length of sessions) that makes a difference, but rather having contact between the two people in itself [5].

A CBT treatment for menopause-related HF/NS was developed based on a theoretical model of HF/NS, which outlines specific components (e.g. biological, psychological and social factors) and how these might influence women's experiences of HF/NS [10,11]. In

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the MENOS 2 trial [1], women received CBT in a Self-Help format (i.e. booklet and relaxation/paced breathing CD) and had two contacts with a therapist: one face-to-face session during which the CBT approach was explained and a guiding phone call 2 weeks into treatment. Women reported significantly less problematic HF/NS compared to no-treatment controls at the end of intervention, which remained significant at 6 months follow-up [1]. During qualitative interviews carried out after the end of follow-up assessments, women reported finding the Self-Help approach beneficial [12]. Nevertheless, some women were unable to participate or attend face-to-face sessions due to travelling distance.

This study investigates whether a guided Self-Help CBT intervention for HF/NS can be as effective as MENOS 2 Self Help CBT [1] when rolled out to women living at a distance with minimal telephone guidance. Findings are therefore discussed in relation to MENOS 2 data. HF/NS problem rating at post-treatment was selected as the most appropriate primary outcome measure because it is associated with reduced quality of life [4,13,14]. Secondary outcome measures included HF/NS frequency, beliefs and behavioural reactions towards HF/NS, sleep, anxiety and depressed mood.

2. Methods

2.1. Participants

Women with variable menstrual cycles (menopause transition) or who were more than one year from their last menstrual period (post-menopause) with problematic HF/NS were recruited from websites and newspaper advertisements.

Inclusion criteria: English speaking women, 18 years old or older, having problematic HF/NS (score > 2 on the Hot Flush Rating Scale (HFRS)) [11] for at least 1 month and minimum frequency of 10 flushes per week) and unable to attend for face-to-face interviews (e.g. living outside London) [1]. Exclusion criteria: non English speaking women and/or with history of medical or psychiatric conditions that would affect their ability to participate.

2.2. Procedure

Potential participants were initially contacted by telephone for a screening assessment, which included an eligibility check and an explanation of the research procedure. If eligible and interested, they were sent information together with a consent form and assessment questionnaires, which they completed and returned to the research team using a freepost envelope. On receipt of the questionnaires and signed consent forms, the intervention was sent out. Another set of questionnaires was sent out at 6 weeks (post-treatment) and again at 3 months (follow-up) after the end of the intervention.

Ethical approval was obtained from Kings College London Research Ethics Committee (Psychiatry, Nursing and Midwifery Research Ethics Subcommittee, reference: PNM/08/09-42). All participants gave written informed consent before taking part.

2.3. Intervention

The intervention included psychoeducation, paced breathing and relaxation, and CBT to help women to manage HF/NS [1,15]. The intervention has been shown to be acceptable to women and has shown effectiveness in randomised clinical trials of Self-Help and group CBT [1,2]. It is based on a cognitive behavioural model of HF/NS that describes how a range of psychological factors might influence the physiological mechanisms as well as women's perception and appraisal of HF/NS [10]. The model includes four stages of HF/NS experience: physiological processes, symptom perception, cognitive appraisal and behavioural reactions to symptoms. Research examining the cognitive appraisals of HF/NS suggests that negative thoughts and beliefs about HF/NS are associated with problematic HF/NS, whereas calm thoughts, accepting the symptoms and not over-reacting, are associated with less problematic symptoms [10,16]. Negative attitudes to menopause have been found to be correlated with negative beliefs about HFNS [16], and depressed mood and anxiety have been found to be associated with more problematic HFNS.

Self-Help CBT included a booklet completed over a four-week period. The content of Self-Help CBT was identical to a Group CBT intervention delivered in previous trials [1,2] with participants receiving a relaxation/paced breathing CD for daily practice and completing weekly homework tasks (e.g. daily diaries of their HF/NS so that they could monitor their own progress). The booklet also included interactive exercises with space for participants to write relevant information. The booklet content has been described previously: week 1 introduced participants to the CBT model of HF/NS and stress; week 2 introduced cognitive and behavioural strategies for dealing with HF; week 3 focused on managing NS and sleep and during week 4 participants reviewed individual goals and developed a maintenance plan (for more detailed information see [1,15]).

Telephone guiding consisted of a telephone call from a clinical psychologist 2 weeks into treatment to provide support and discuss individual treatment goals. The psychologist discussed participants' progress in reading through the materials and practising the exercises (e.g. cognitive and behavioural strategies, relaxation and breathing exercises). Possible barriers were identified (e.g. time constraints) and practical strategies to overcome these were considered. Telephone guiding lasted on average 25 min (range 15–35 min). Women were also provided with the contact details of the clinical psychologist in case they wished to gain clarification regarding anything they did not understand.

2.4. Measures

Sociodemographic information, menopausal status, health and lifestyle questions were included with the following standardised questionnaires.

The *Hot Flush Rating Scale* (*HFRS*) [11] is a self-report measure of HF/NS frequency and problem-rating over the past week. Problem-rating is calculated as the mean of the scores on three Likert scales (scores range from 1–10) assessing the extent to which HF/NS are problematic, distressing and causing interference in daily life. Higher scores indicate more problematic HF/NS whereas a 2-point change on the scale is considered clinically significant. The scale has shown good test–retest reliability and concurrent validity.

The *Hot Flush Beliefs Scale* (*HFBS*) [16] is a 27-item questionnaire, which assesses women's beliefs about their HF/NS. It consists of three sub-scales (scores range from 0–5) reflecting negative beliefs about (i) hot flushes in a social context, (ii) coping/control over HF/NS and (iii) coping with night sweats and sleep. Higher scores indicate more negative beliefs. Internal consistency of the subscale items ranged between 0.78 and 0.93 and test–retest reliability ranged between 0.74 and 0.78.

The Hot Flush Behaviour Scale (*HFBehS*) [17] is an 11-item questionnaire that measures behavioural strategies used to deal with HF/NS. It consists of three subscales (scores range from 0–5) assessing (i) behavioural avoidance, (ii) practical cooling behaviours and (iii) positive behavioural strategies. The scale has shown adequate internal consistency and concurrent criterion validity.

The *Women's Health Questionnaire* (WHQ) [18] is a reliable tool in assessing women's perceptions of emotional and physical health