

**EFFECTS OF A COGNITIVE-BEHAVIORAL TREATMENT INTERVENTION ON
MENOPAUSAL VASOMOTOR AND PSYCHOLOGICAL SYMPTOMS.**

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Introduction

- Hot flushes and night sweats are vasomotor symptoms commonly experienced by menopausal women
 - Approximately 80% of all women experience this symptom and for 40% it is the main reason given for seeking medical help during the menopause (Hunter, 1990 & Dennerstein, 1996)
 - Between 10-25% describe the symptom as problematic i.e. due to physical discomfort, sleep disruption and social embarrassment (Hunter, 1995)
 - Hot flushes & night sweats are experienced in those periods of the female life when estrogen levels are low. Hormone replacement therapy (HRT) is thus the first choice of treatment for hot flushes (Hahn et al. 1998; Berendsen, 2000)
- *Hot flush is characterized by a sudden sensation of heat or burning which starts in the head and neck area and then passes, often in waves, over the entire body but particularly marked in the head, neck, upper chest and back. This process is often preceded by a sensation of pressure in the head like a headache (Berendsen, 2000). Recent findings suggest that hot flushes might also be preceded by an increase of core body temperature (Freedman et al 1995 & Freedman et al 1998)*
- *The mechanism that causes nocturnal sweats is most likely the same as the mechanism that induces hot flushes. During sleep dreams occur. These dreams are considered the stress factor to trigger a release of 5-HT that, via activation of the 5-HT_{2A} receptors, results in sweating and/or a hot flush (Berendsen, 2000)*

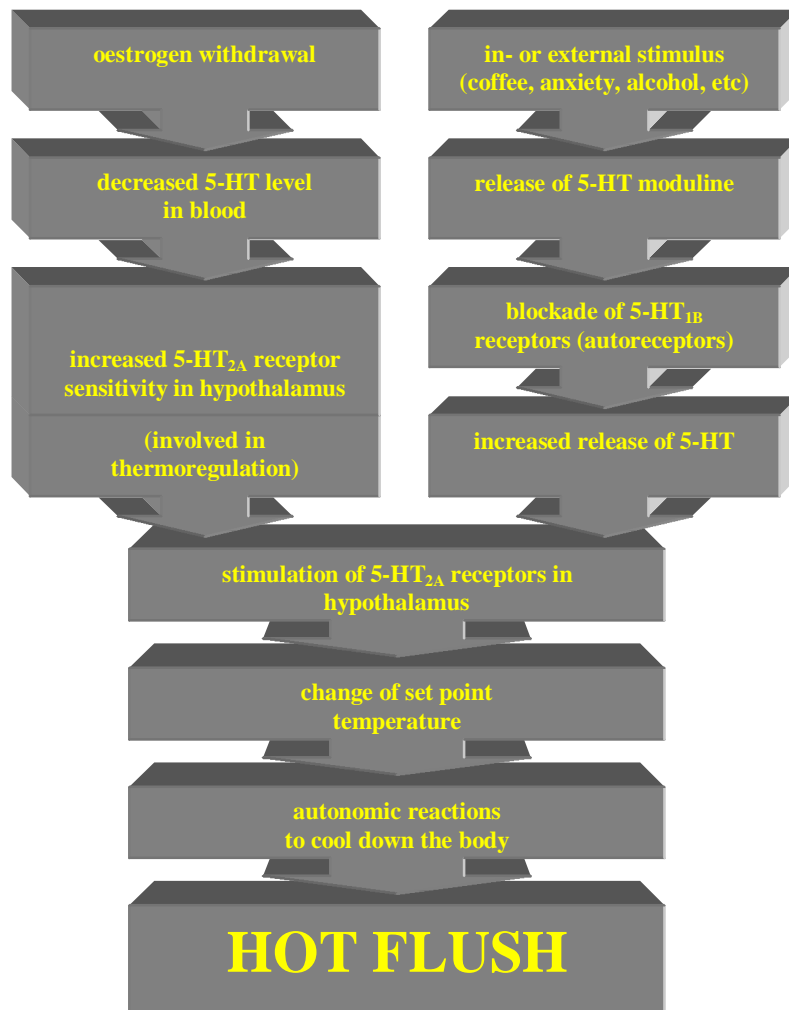


Fig 1. Possible mechanism by which a hot flush is induced as suggested by Berendsen (2000).

Rationale

Taking into consideration

- Low compliance rate of Hormone Replacement therapy (HRT) (Notelovitz, 1994; Hemmie & Berendsen, 2000) *due to*
 - Contraindications (family history for breast or endometrial cancer, impaired liver function etc)
 - Subjective complaints (e.g. fear for undesired resumption of vaginal bleeding and other side effects)
- The few alternative treatments available (e.g. oil of evening primrose – normally not very effective in reducing vasomotor symptoms, Chenoy et al., 1994)
- The possible relationship between hot flush reporting and stress, (Swartzman et al., 1990), *and*
- The positive results obtained by behavioral / Cognitive Behavioral (CBT) treatments in reducing hot flush frequency (Stevenson & Delprato, 1983; Freedman & Woodward, 1992; and Hunter & Liao, 1996)

It was predicted in the current study that:

1. Cognitive-behavioral group intervention would significantly reduce vasomotor symptoms (hot flushes & night sweats)
2. Hormone Replacement therapy (HRT) would significantly reduce vasomotor symptoms (hot flushes & night sweats)
3. Cognitive-behavioral group intervention would additionally significantly reduce negative mood states and improve mood (anxiety; depression; self-efficacy)
4. A delayed treatment control group would not change significantly over time (duration of study)

Methods

Participants

- 27 women who reported vasomotor symptoms (hot flushes or night sweats) 1/week or more frequently were recruited via posters/communication with physician from two general and three gynecological practices in Patras, Greece
- mean age = 50.12 (SD=6.12) years
- 83% currently married or lived with partner
- 78% had 1 or > children
- 62% were currently employed or had been employed in the past
- 95% Greek citizens; 5% non Greek citizens but living in Greece e.g. Albanian

Study design

Patient preference design, (part randomized treatment/control). Completion of interview, provided description of three treatment options: cognitive-behavioral therapy (CBT), Hormone replacement therapy (HRT), No treatment (C). No women chose “No treatment” option therefore those choosing CBT were randomly allocated to treatment (CBT) vs. delayed treatment (C).

- q 7 patients received CBT treatment, (Structured five-session cognitive-behavioral treatment package)
- q 9 patients received HRT, (Physicians provided standard hormonal treatment i.e. oral or transdermal oestradiol plus progestogen for 12-14 days/month)
- q 11 C - delayed treatment control (C group received delayed CBT treatment after 6 weeks wait period)

Statistical analysis

One-way ANOVAS to compare groups at baseline and post-treatment

Paired t-tests to assess within-group changes across pre- to post-test periods

Measures

- q Women’s Health Questionnaire (WHQ) assesses mid-aged women’s perception of their emotional and physical health, including depression and anxiety (Hunter, 1992)
- q Assessment of hot flushes/sweats (1-week estimate of *frequency, duration and problem rating* i.e., extent flushes distressing, interfere daily living, perceived to be a problem)
- q Profile of Mood states (POMS). Consists of six sub-scales measuring several identifiable mood or affective states. *Tension –Anxiety (T), Depression – Dejection (D), Anger – Hostility (A), Vigor – Activity (V), Fatigue-Inertia (F), and Confusion – Bewilderment (C)* (McNair, Lorr, & Droppleman, 1992)

Results

Table 1

Participant characteristics at baseline of the 3 treatment groups (CBT, HRT, C), means and standard deviations

	CBT (n=7)	HRT (n=9)	C-delayed treatment (n=11)
Age	50.57 (7.01)	50.05 (6.80)	52.88 (6.62)
VASOMOTOR SYMPTOMS. (hot flushes/sweats)			
Frequency / weekly	27.06 (20.34)	41.82 (32.26)	22.29 (18.55)
Problem rating	5.87 (2.41)	5.26 (1.78)	5.21 (1.93)
Duration	6.73 (11.72)	1.95 (1.49)	3.62 (4.19)
Chronicity	5.27 (5.07)	5.34 (4.34)	6.05 (7.06)
WHQ			
Depressed mood	0.47 (0.32)	0.44 (0.31)	0.28 (0.22)
Anxiety	0.52 (0.28)	0.56 (0.26)	0.46 (0.32)
Self-esteem	3.68 (1.57)	3.52 (1.34)	3.68 (0.89)
TREATMENT RATINGS			
Keeness	7.39 (1.58)	7.49 (1.35)	-----
Perceived - effectiveness	5.75 (1.63)	8.39 (0.85)*	-----
Self-efficacy	7.34 (1.64)	8.14 (0.90)	-----

- q At baseline (pre-intervention) there were no significant differences between the groups on variables assessed, except *perceived effectiveness* ($p < .01$) i.e. *HRT group believed treatment will be more effective in reduction of hot flushes/sweats* (see table 1)

Table 2

Means and standard deviations for hot flush frequency/sweats and problem ratings for CBT, HRT and C groups from pre to post treatment

	CBT (n=7)	HRT (n=9)	C (n=11)
HOT FLUSH FREQUENCY			
Pre treatment	26.08 (19.04)	40.90 (31.26)	24.29 (19.29)
Post treatment	11.42 (16.52)*	9.50 (13.06)*	22.14 (17.67)
HOT FLUSH PROBLEM RATING			
Pre treatment	5.69 (2.98)	5.26 (1.88)	4.31 (1.73)
Post treatment	3.23 (1.67)*	5.03 (1.29)	3.72 (1.72)

DEPRESSED MOOD (WHQ)			
Pre treatment	0.39 (0.27)	0.42 (0.32)	0.28 (0.23)
Post treatment	0.24 (0.20)**	0.37 (0.31)	0.31 (0.22)
ANXIETY (WHQ)			
Pre-treatment	0.58 (0.29)	0.44 (0.22)	0.43 (0.30)
Post-treatment	0.34 (0.34)**	0.51 (0.30)	0.46 (0.32)

p<.01*

p<.001**

Table 3
Changes from pre to postintervention on Mood for participants in the cognitive behavioral treatment (CBT) condition as measured by the Profile of Mood States

Variable	Pre-Test mean Value	Post-Test mean Value	t-value	p
POMS T	21.2	17.4	- 4.84	<0.01
POMS D	36.7	25.2	- 4.63	<0.01
POMS A	22.6	16.2	- 1.72	<0.05
POMS V	16.7	24.8	2.59	<0.05
POMS F				n.s
POMS C				n.s

- q Within group changes between pre and post- treatment for CBT group were significant for hot flush frequency (p<.01) and problem rating (p<.01) (table 2)
- q For HRT group there was a significant pre to post reduction in hot flush frequency (p<.01) but not for problem rating (table 2)
- q The C Group showed no significant differences between pre-post assessments on vasomotor symptoms
- q There were significant within group differences (reductions) in WHQ depressed mood (p<.001) and anxiety (p<.001) between pre and post treatment for CBT group (table 2)
- q No significant improvement in mood or anxiety for HRT or C group between pre and post treatment
- q Within group changes between pre and post-treatment for CBT group were significant for (POMS) scales T, D (p<.01) and scales A, V (p<.05) (table 2)

- Between group comparison at post – treatment were significant on hot flush problem rating ($p < .02$) post hoc tests revealed significant difference between HRT and CBT groups. Measures of hot flushes/sweats were n.s at post treatment
- Between group differences at post-intervention assessments were also significant on measures of anxiety and self-efficacy ($p < .01$)

Conclusions

- ∅ The CBT treatment group showed significant within group differences on measures of anxiety, mood, self-efficacy and hot flushes on post intervention assessments.
- ∅ The HRT group showed significant within group differences on measures of hot flushes, but anxiety and negative mood states were not significantly reduced.
- ∅ The CBT group showed significant improvements on measures of anxiety, mood and self-efficacy compared to the C and HRT groups.
- ∅ The C group did not show any significant changes compared to the CBT and HRT groups on vasomotor (hot flushes) or psychological symptoms.

∅ The above preliminary results suggest that Cognitive Behavioral interventions may significantly decrease anxiety and negative mood states, as well as increase coping self-efficacy in menopausal women, and possibly decrease vasomotor symptoms (hot flushes/sweats) as effectively as HRT. Therefore, CBT might be an especially useful treatment for menopausal women who seek therapy for both vasomotor and psychological symptoms and those resistant/non compliant to hormonal treatments.

Limitations of the Study

- *Small sample size*
- *Larger trial necessary to effectively evaluate between-group differences*
- *No follow up phase*
- *Clinical significance of CBT especially for vasomotor symptoms needs to be further investigated*

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