Hot flashes and depression among menopausal women: Is acupuncture an effective intervention?

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Forord

Nasjonalt forskningssenter innen komplementær og alternativ medisin (NAFKAM) ved Universitetssykehuset i Nord-Norge gjennomførte i 2006-2007 Acuflash-studien under ledelse av Sameline Grimsgaard. Studien tok for seg akupunktur som behandling av hetetokter hos kvinner i overgangsalderen. I tillegg til flere spørreskjema om psykisk og fysisk helse, data om fysisk aktivitet, helsehistorie, hormonnivåer og mye annet, ble det i studien også samlet inn data om depresjonssymptomer hos deltakerne. Vår veileder Catharina E. A. Wang var involvert i den delen av studien som skulle omhandle depresjon. Vi var raske til å gripe sjansen da hun gav oss muligheten til å gjøre dette til vårt hovedoppgaveprosjekt.

Ideen til å studere depresjon i Acuflash-utvalget ble utarbeidet i samarbeid mellom Catharina E. A. Wang og Sameline Grimsgaard, mens de spesifikke problemstillingene vi belyser har kommet frem i samarbeid mellom Catharina E. A. Wang og oss. En utfordring i dette arbeidet har vært å se et prosjekt som i utgangspunktet var medisinsk forankret med ”psykologiske” øyne. En annen utfordring har vært å håndtere svært mange sett av variabler som var innbyrdes assosierte.

Acuflash var en multisenterstudie som ble gjennomført i Tromsø, Bergen og Oslo. Datainnsamlingen ble ledet fra Tromsø. Stipendiat Einar Kristian Borud var ansvarlig for å tilrettelegge datafilene til dette arbeidet. Fra et relativt omfattende datamateriale, valgte vi selv ut de spørreskjema og variabler som vi ønsket å benytte i vår studie. De deler av data som var spesifikt rettet mot vår studie har vi bearbeidet selv. Vi har også gjennomført alt av analysearbeid selv. Det samme gjelder litteratursøket, litteraturgjennomgangen, og selvsagt selve oppgaveskrivingen. Relevant litteratur ble funnet via databaser som PubMed og Medline, samt via referanselister. Ettersom vi fikk tilgang på et ferdig innsamlet datamateriale, har vi lagt spesiell vekt på en omfattende litteraturgjennomgang og et grundig analysearbeid.

Vi ønsker å takke Samline Grimsgaard som har vært biveileder for oss, for hennes velvillige og energiske tilbakemeldinger, spesielt i forhold til analyser og resultater. Vi ønsker også å takke Einar Kristian Borud som har vært behjelpelig med svar på spørsmål om datamaterialet. En spesiell takk rettes til Catharina E. A. Wang

som har vært vår veileder og som ikke bare har hjulpet oss faglig, men som også har vært til stor inspirasjon og oppmuntring i vårt arbeid.

For begge forfatterne har de siste månedene bydd på store personlige utfordringer. Annbjørg Dørmænen vil gjerne takke sin forlovede David: for hans støtte og tålmodighet, og for at han tok hånd om alt når jeg ikke kunne. Marte Rye Heimdal vil takke sin kjære familie: min lille solstråle Maiken på 7 måneder, og min mann Håvard, som har vært en uvurderlig støtte i skriveprosessen og en fantastisk pappa for Maiken vår.

Sist, men ikke minst, retter vi en stor takk til hverandre! Tross tunge tak, lange arbeidsdager og stor geografisk avstand har vårt samarbeid vært en fornøyelse!

Abstract

Title:	Hot flashes and depression among menopausal women: Is acupuncture an effective intervention?
Authors:	Annbjørg Dørmænen, Stud.psychol. Marte Rye Heimdal, Stud.psychol.
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The aim of this study was to compare the effectiveness of individualized acupuncture and self-care versus self-care only on hot flashes, health related quality of life (HR-QoL) and depression in postmenopausal women, experiencing a high frequency of hot flashes. The study also aimed to shed light on the question about an association between menopause and depression. It was conducted on a subsample from the Acuflash-study (Borud et al., in press) and involved a pragmatic, randomized, controlled trial with two parallel arms. A heightened prevalence of depression, as measured with Beck Depression Inventory, was found, compared to the general population. Both use of acupuncture in addition to self-care, and self-care only, led to significant improvements in hot flash frequency and intensity, improvements in the vasomotor and anxiety/fears dimensions of the Women's Health Questionnaire, and decreased severity of depression from baseline to 12 week follow-up. No significant differences were found between the acupuncture group and the self-care group on these measures, implying the importance of the treatment experience as a whole. A model for the relationship between menopause and depression is proposed, including an intervening cognitive component between the presence of hot flashes and psychological reactions.

Hot flashes and depression among menopausal women: Is acupuncture an effective intervention?

The term *menopause* refers to the physiological event of the cessation of the menses in women in midlife. The *premenopausal* stage signifies the time before menopause begins. This is followed by the *perimenopause* where the menstrual cycles become irregular. After 12 months of amenorrhea, the *postmenopausal* stage has been reached. Women going through the menopausal transition report symptoms such as hot flashes and sweats, depressed mood, sleep disturbances, sexual concerns or problems, cognitive symptoms, vaginal dryness, urinary incontinence and somatic or bodily pain symptoms (Woods & Mitchell, 2005). Hot flashes, in particular, are associated with the menopausal transition, and are experienced by almost two thirds of postmenopausal women (Kronenberg, 1990). The hot flashes cause considerable distress and impairment in quality of life (Sturdee, 2008). Nocturnal hot flashes also contribute to sleep disturbances (e.g. Freedman & Roehrs, 2007; Kravits et al., 2003; Kronenberg, 1990). This symptom pressure could contribute to a view of menopausal women as sweaty, tired and depressed, but is that view correct? The present study seeks to shed light on the question about an association between depression and menopause, and also investigates the effect of acupuncture on menopausal symptoms for women in mid life.

Depression and Menopause

According to the World Health Organization (WHO), depression is ranked as the fourth most contributing disease which leads to disability and mortality (Murray & Lopez, 1997a, 1997b). Depression is also associated with reduced quality of life (Joffe et al., in press). In addition to personal costs, depression has great socioeconomic costs due to for instance loss in productivity and lost tax receipts (London School of Economics and Political Science, 2006), and represents a strong risk factor of disability pension (Mykletun et al., 2006; Overland et al., 2008). Symptoms of depression include lowering of mood, reduction of energy, decrease in activity, disturbed sleep, diminished appetite and reduced self-esteem, self-confidence and capacity for enjoyment (International statistical classification of diseases 10th revision [ICD-10], 2007). Depression is also often comorbid with anxiety disorders (Brown, Campbell, Lehman, Grisham & Mancill, 2001; Zimmerman, Chelminsky & McDermut, 2002). A Norwegian epidemiological study showed that the 12-month prevalence of major depression in females was 9.7%, and

the lifetime prevalence was 24.0%. Females were nearly 2.5 times more likely than males to have a lifetime affective disorder (Kringlen, Torgersen & Cramer, 2001). According to the European Outcome of Depression International Network (ODIN) – study, the prevalence of depressive disorders was about 10.0% in the female population (Ayuoso-Mateos et al., 2001). Another Norwegian study found a two-week prevalence of 4.4% in women aged 40 to 59 years old (Sandanger, Nygård, Ingebrigtsen, Sørensen & Dalgard, 1999). As the menopause is commonly associated with an array of physical and psychological symptoms, several studies have also investigated the relationship between depression and menopause.

There is mixed evidence for an association between the menopause and depression. Most women do not develop depression during the menopausal transition (Schmidt, 2005; Woods, Mariella & Mitchell, 2006). Still, several studies have established that for some women, the menopausal transition period does confer an increased risk for development of mood disorders compared with the premenopausal period (Amore et al., 2007; Avis, Brambilla, McKinlay & Vass, 1994; Bromberger et al., 2001; Cohen, Soares, Vitonis, Otto & Harlow 2006; Freeman et al., 2004; Freeman, Sammel, Lin & Nelson, 2006; Hay, Bancroft & Johnstone, 1994; Hunter, 1992a; Schmidt, Haq & Rubinow, 2004).

In the Penn Ovarian Aging Study, Freeman et al. (2004) found an increased likelihood of depressive symptoms, as measured by the Center for Epidemiologic Studies Depression Scale (CES-D), during the transition to menopause, and a decreased likelihood after menopause. In a follow-up study, high CES-D scores were found to be more than four times more likely to occur during a woman's menopausal transition, compared to when she was premenopausal, in women with no history of depression (Freeman et al., 2006). These results have been supported in the Harvard Study of Moods and Cycles, where the authors found an increased risk for the development of a first episode of depression among women entering the perimenopause (Cohen et al., 2006). Along the same line, a large percentage (35%) of women with past or current depressive illness attending a menopause clinic, reported having experienced their first episode of depression in the perimenopausal period (Hay et al., 1994). The perimenopausal period has also been tied to psychological distress in the Study of Women's Health Across the Nation (SWAN: Bromberger et al., 2001) and in the Massachusetts Women's Health Study (MWHS: Avis et al., 1994).

However, also the postmenopausal stage has been connected to symptoms of depression. The South-East England longitudinal study of peri- and postmenopausal women showed that depressed mood, as measured by the Women's Health Questionnaire (WHQ), increased significantly from pre- to peri-/postmenopause (Hunter, 1992a). Another longitudinal study revealed an increased risk of depression in women during both the late perimenopause and the early postmenopause, compared to the premenopause (Schmidt et al., 2004). Also a cross-sectional study of non-clinical menopausal women, using the WHQ, found that depressive and sexual symptoms presented greater severity in the post-menopausal group compared to the premenopausal group (Amore et al., 2007).

As mentioned earlier, whereas several studies have found an association between psychological symptoms such as depression and menopause, others have disputed such a link, rejecting at least the notion of a simple, direct link between menopause and depression (Dennerstein, 1996; Holte & Mikkelsen, 1991a; Holte, 1992; Mariella, Mitchell & Woods, 2002; Nicol-Smith, 1996). It has further been pointed out that many of the studies that do find an association between depression and menopause are haunted by a number of methodological problems.

Methodological issues. One problem pointed out is that of sampling method. For instance, data gathered from samples drawn from a preselected group, such as women visiting a menopause clinic, cannot easily be generalized to the larger population (Morse et al., 1994). Another issue is the lack of a common definition of both depression and menopause (Gyllstrom, Schreiner & Harlow, 2007). Several different measures of depression are in use, together with differing cut-off scores, making it difficult to interpret the study data. Studies also use different definitions of menopause and the stages of the menopausal transition, again making both interpretation and comparison difficult.

Furthermore, some general limitations present in many areas of research are also of concern in studies of menopausal symptoms. One of them is the use of self-report, which are naturally more vulnerable to biases and lapses in memory than objective measurements. Joffe, Soares and Cohen (2003) suggested that women, who experience hot flashes, may underestimate their frequency or severity, particularly in retrospect. Another potential problem is the use of cross-sectional designs, as opposed to longitudinal designs. The nature of the cross sectional design makes it

difficult to draw conclusions about causality, as has been pointed out by among others Joffe et al. (2002).

Matters of causality were also studied in a review by Nicol-Smith (1996), who carried out an evaluation of the ability of several studies to causally connect depression to menopause. She pointed out that several factors, other than menopausal status, were associated with depression in these studies. This signifies the difficulty in proclaiming a direct effect of menopause on mood.

An important issue for many of the studies in this area is the nature of the possible connection between depressive symptoms and the menopausal transition. Both vulnerability factors, such as earlier depression and cognitive vulnerability, and stress factors, such as hormonal changes, psychosocial factors, vasomotor symptoms and sleep problems, have been suggested to play a role. Some of these hypotheses will be reviewed in the following.

Earlier depression. Some studies have showed an increased risk of onset of first time depression during the menopause, in women without a previous history of depression (e.g., Cohen et al., 2006; Freeman et al., 2006). Still, a history of depression has proven to be one of the strongest predictors of a depressive episode during the menopausal transition in many studies (e.g., Avis et al., 1994; Callegari et al., 2007; Freeman et al., 2004; Hunter, 1992a).

Regression analyses on factors prediciting depressed mood have shown earlier depression to be the factor accounting for the largest part of the variance (Avis et al., 1994; Hunter, 1992a). Furthermore, women with a history of depression have been found significantly more likely to report higher levels of depressive symptoms than women without such history (Callegari et al., 2007; Freeman et al., 2004).

Hormonal changes. Several studies have suggested a contribution of hormonal changes to explain the possible relationship between menopause and depression. A meta-analysis of studies that examined the effectiveness of hormone replacement treatment on menopausal depressed mood, concluded that both progesterone, estrogen and androgens lead to reductions in depressed mood (Zweifel & O'Brien, 1997). Schmidt (2005) reviewed the research literature and pointed to the finding that estrogen has an antidepressant effect in depressed women in perimenopause, but not necessarily in postmenopause, as indicating the significance of fluctuating hormone levels for mood disorders in perimenopausal women. Another

review considered the finding that estrogen seems to be a serotonin agonist, as a possible explanation for its effect on mood in women (Steiner, Dunn & Born, 2003).

Psycho-social factors. Different sociodemographic variables, such as body mass index, smoking, employment and marital status (Freeman et al., 2006), and age and social networks (Holte & Mikkelsen, 1991b) have been related to depression in menopause. In addition, certain psychosocial events could be especially typical for mid life, such as caring for aging parents, parenting adolescents and experiencing the onset of illness. These might act as an extra stressor for women at this particular point in life, making them especially vulnerable to depression.

Several studies have found an influence of negative life events and difficulties on psychological symptoms in menopause (Binfa et al., 2004; Cohen et al., 2006; Hardy & Kuh, 2002). Negative vital events and family dysfunction have also been found to impact psychological complains, but then to a lesser degree than vasomotor symptoms, suggesting a modulating role for psycho-social factors in the expression of psychological symptoms (Blümel et al., 2004). However, the study did not find differences in occurrence of vital events, family dysfunction or social support in the participants most bothered by climacteric symptoms.

The association between physical and psychological health at menopause was described by Callegari et al. (2007) who studied 64 women attending a menopause clinic. Using the Beck Depression Inventory (BDI), they found that 28% of their sample fit the diagnosis of depression. The symptoms checklist (SCL-90) further revealed that the depressed women among other things had higher levels of somatic symptoms, with somatic and depressive clusters as the most frequent. The authors suggest that this may be because physical symptoms that follow from the climacteric can contribute to the worsening of psychological symptoms and vice versa. Similarly, Holte (1992) concluded that his findings of increased social dysfunction following menopause might be explained by increased vasomotor symptoms.

Cognitive vulnerability. There are many potential sources of distress for midlife women, from physical symptoms to adult-developmental issues (Derry, 2004). Like any other stressors, cognitive appraisal processes might play an important role in how women will respond to them. How women experience the menopausal transition, and what meaning they give to it, differs vastly. While some consider it a catastrophic loss of youth, others see it as a profound inner journey, while yet others do not give it any larger meaning at all (Derry, 2004). Experiences

of, and attitudes towards, the menopause are important. Women with negative attitudes toward the menopause and aging are more likely to develop hot flashes or depression (Avis, Crawford, McKinley, 1997). Furthermore, one study showed that depressed mood, anxiety and low self-esteem, but not frequency of hot flashes, discriminated between the women who regarded hot flashes as problematic, and those who did not (Hunter & Liao, 1995). This suggests that besides the presence and gravity of the individual symptoms, there might also be cognitive factors deciding the impact of the menopause on a woman's life, making some women more vulnerable to develop depression.

Vasomotor symptoms. Recent research has shown that vasomotor symptoms (i.e., hot flashes, night sweats) are associated with an increased risk of depression (Joffe et al., 2002; Blümel et al., 2004; Juang, Wang, Lu, Lee & Fuh, 2005; Cohen et al., 2006).

A cross-sectional study of mid aged women seeking primary care, found that perimenopausal women with vasomotor symptoms were more than four times more likely to be depressed, than perimenopausal women without vasomotor symptoms (Joffe et al., 2002). A population-based study of Taiwanese women found that hot flashes both in peri- and postmenopausal women were associated with anxious and depressive symptoms, as measured with the hospital anxiety and depression scale (HADS, Juang et al., 2005). Another cross-sectional study of mid aged women involved the Greene's scale for climacteric symptoms and found that premenopausal women presenting with vasomotor symptoms had higher prevalence of both psychological and somatic symptoms and stress (Blümel et al., 2004). Also Bosworth et al. (2001) found an association between depression and other menopausal symptoms, including hot flashes, night sweats and trouble sleeping.

Sleep disturbances. Sleep disturbances are a common problem both in clinical and general populations. In a Norwegian population aged 40 – 45 years old, 12.2% of the women reported insomnia at least one or more times per week (Ursin, Holsten & Bjorvatn, 2006). In a community-based survey 43% of postmenopausal women reported difficulty sleeping within the last 2 weeks, compared to 31% of premenopausal women. (Kravitz et al., 2003). The relationship between insomnia and depression is strong, with women being more likely to report insomnia than men (Ford & Cooper-Patrick, 2001). Sleep disturbances are in fact considered one of the symptoms of depression according to the ICD-10 (2007). People with sleep-

disturbances have also been found to report greater reductions in quality of life than people without sleep-disturbances (Zammit et al., 1999).

Several studies have pointed out that hot flashes can contribute to sleep disturbances (e.g., Freedman & Roehrs, 2007; Koster, Eplov & Garde, 2002; Kravitz et al., 2003; Kronenberg, 1990). Nocturnal hot flashes can lead to frequent awakenings, sweating and need to change bedclothes, and thereby tiredness and irritability. Sleep disturbances has also been one of the factors of interest when it comes to the possible link between menopause and depression.

Campbell and Whitehead (1977) proposed a domino theory for the relationship between menopause and depression, where the menopause in itself generates certain vasomotor symptoms such as hot flashes and night sweats, which in turn can have a negative effect on sleep with frequent awakenings, which finally can lead to depressed and distressed moods. Findings to support this theory have been reported by among others Avis, Crawford, Stellato and Longcope (2001) in the Massachusetts Women's Health Study. However, a recent study has not lent support to the domino theory (Joffe et al., in press). They found that the type of sleep disturbance specific to the depressed women with vasomotor symptoms did not include the interruptions of sleep that are typically associated with hot flashes, namely frequent awakenings.

A broader perspective on menopausal symptoms. Health related quality of life (HR-QoL) offers a broader perspective on menopausal symptoms and well-being in general, integrating both the psychological and physical aspects in one concept. Different instruments have been developed to assess HR-QoL specifically in women in menopause (e.g., WHQ, Hunter, 1992b; Menopause-Specific Quality of Life [MENQOL], Hilditch et al., 1996; Utian Quality of Life Scale [UQOL], Utian, Janata, Kingsberg, Schluchter & Hamilton, 2002). These instruments have all identified certain factors as aspects of women's experience of menopause. These include psychological symptoms like depression, anxiety and feelings of unattractiveness, and physical factors, such as vasomotor symptoms and difficulty with sleep. Several of the factors included are in turn interrelated, further showing the complexity of the sense of well being in this life stage.

Understanding the complex relationship between menopause and depression is important, because decisions about what treatment will be the correct one are affected by how we understand the causality of the problem. Different treatment

strategies would be indicated if the problem is considered to be caused by hormonal changes, psycho-social factors, cognitive factors, vasomotor complaints, sleep problems or by more complex multifactorial mechanisms.

An Alternative Treatment of Menopausal Symptoms and Depression

Alternative treatment of menopausal symptoms. To cope with the different symptoms of menopause, women have over the last few decades been offered medication in the form of hormone replacement therapy (HRT). Lately however**,** this form of treatment has come under criticism after results linking HRT to an increased risk of breast cancer**,** coronary heart disease and stroke (Collaborative Group on Hormonal Factors in Breast Cancer, 1997; Writing Group for the Women's Health Initiative Investigators, 2002; Million Women Study Collaborators, 2003). This has led women and healthcare workers to search for alternative means of relieving the symptoms connected to menopause.

Acupuncture is one of the most frequently used complementary therapies in Norway, with 10.8% reporting use within the last 12 months (National Information Center for Complementary and Alternative Medicine, Norway, 2007). Acupuncture is a family of treatment techniques within traditional Chinese medicine (TCM). The treatments involve stimulating specific points on the body in order to restore and maintain health. TCM acupuncture includes a thorough medical history and examination of the pulse and tongue, leading to a specific TCM diagnosis. Based on this diagnosis, the treatment is individually tailored and comprises both lifestyle advice and needling in selected acupuncture points.

One of the advantages of acupuncture over many other forms of treatment, in particular treatments including medication, is the relatively low occurrence of negative side effects (Norheim, 1996). The most common reported side effects are tiredness, drowsiness, aggravation of preexisting symptoms, minor bleeding at withdrawal of the needle, and pain upon insertion of the needle (Yamashita, Tsukayama, Hori, Kimura & Tanno, 2000). According to Yamashita et al., all of these reactions were mild and transient, and no medical care was required for them. Most adverse effects seem to be a result of incorrect treatment that can be prevented by adequate acupuncturist education (Norheim, 1996).

Carpenter and Neal (2005) has reviewed the research literature of acupuncture studies for postmenopausal hot flashes and concluded that many of the findings were inconsistent. Controlled studies of acupuncture did not reliably

improve hot flashes, sleep disturbances or mood when compared to nonspecific acupuncture, estrogen therapy or superficial needling. Furthermore, differences in type, technique and timing of acupuncture, together with differences in outcome measures, made comparisons across studies difficult. Given that current data are insufficient to draw conclusions on the effect of acupuncture on hot flashes, further research is needed.

The Acuflash study (Borud et al., in press) is a randomized controlled trial that investigated the effect of acupuncture and self-care advice versus self-care advice only on hot flashes and health related quality of life, as measured with the WHQ, in postmenopausal Norwegian women. They found that both acupuncture and self-care, and self-care only contributed to a reduction in hot flashes, but the reduction was significantly greater for those receiving both acupuncture and self-care. Fifty percent of the participants in the acupuncture group experienced 50% or greater reduction in hot flash frequency from baseline to 12 week follow-up, compared with 16% in the control group who only received self-care advice. The perceived severity of hot flashes also decreased, while the mean hours of sleep increased significantly more from baseline to 12 week follow-up in the acupuncture group, than in the self-care only group. Borud el al. also found that the acupuncture group experienced significant improvements in the vasomotor, sleep and somatic symptoms dimensions of the WHQ, compared to the self-care only group.

In a qualitative study of patient experiences in the Acuflash-study, a variety of positive health changes following acupuncture treatment for postmenopausal hot flashes were reported (Alraek & Malterud, 2009). Many of the women receiving acupuncture reported substantial impact from the treatment with respect to a reduction in frequency and intensity of hot flashes both night and day, and changes related to improved sleep patterns. These positive changes in turn made an impact on the women's social life. Women also reported different bodily and mental changes following the treatment, like feeling in a good mood, not always tired and having more energy. One aspect of the study that should be considered, as also pointed out by Alraek and Malterud, is the casual effect following acupuncture treatment. Some of the results may reflect the patient-therapeutic relationship or the "whole treatment-package", rather than being a specific acupuncture effect.

Alternative treatment of depression. A meta-analysis of eight randomized controlled trials, published between the years 1998 and 2006, comparing acupuncture

with sham acupuncture, concluded that acupuncture could significantly reduce the severity of depression (Wang et al., 2008). More specifically they found that half of the included studies showed a significant effect of acupuncture on symptom relief, compared to placebo acupuncture. The rest of the included studies could not find such a difference between experimental and control groups. Wang et al. pointed out that the results from this meta-analysis should be interpreted with caution because of several differences between the compared studies. Among other things the studies differed in their designs of sham acupuncture, type of acupuncture (e.g., manual or electric stimulation), treatment schedule (e.g., number of acupuncture points and length of treatment) and the severity of the depressive conditions.

Another review examined the results of randomized controled trials of the effect of acupuncture on depression (Leo & Ligot, 2007). The results were found to suggest some utility for acupuncture in the treatment of depression, where acupuncture could even be as effective as antidepressants. One example of this is Röschke et al. (2000), where 70 patients presenting with a major depressive episode were randomized to verum acupuncture, placebo acupuncture and a control group. All patients were in addition treated with the same antidepressant medication. The results showed that acupuncture improved the course of depression more than medical treatment alone. However, they could not find a significant difference between placebo acupuncture (i.e., needling at points unspecific to acupuncture and at less than recommended depth) and verum acupuncture. This was also the case in many of the other studies reported in the review by Leo and Ligot. In their review, they too cited a number of other limitations such as small sample sizes, imprecise enrollment criteria, problems of randomization and lack of longitudinal follow-up. These limitations led them to conclude that the evidence thus far is inconclusive.

In medical treatment of depression as much as 32% of patients have been found to discontinue antidepressant medication within 6 weeks (Maddox, Levi & Thompson, 1994). The two main reasons given for stopping medication were side effects and feeling better. Among the side effects reported from newer antidepressants are sexual dysfunction, insomnia, agitation and weight gain (Dording et al., 2002). Considering the relatively benign nature and low occurrence of side effects found in standard acupuncture, acupuncture could be a safe and important supplement to more traditional treatments.

Purposes of the Present Study

The purpose of this study was to replicate the Acuflash study (Borud et al., in press), and in addition get a better understanding of depression in a subsample of postmenopausal Norwegian women from the Acuflash study. First, we wanted to 1) compare the effectiveness of individualized acupuncture and self-care versus self-care only on hot flashes and health related quality of life. Second, we wanted to 2) investigate the prevalence of depression in the sample, as measured by the Beck Depression Inventory, and to 3) examine what factors that may be related to severity of depression in postmenopausal women (i.e., sociodemographic factors, frequency and intensity of hot flashes, sleep, and health related quality of life, as measured by the Women's Health Questionnaire, including factors of depressed mood, somatic symptoms, memory/concentration, vasomotor symptoms, anxiety/fears, sleep problems and attractiveness). Finally, we wanted to 4) investigate whether the intervention against menopausal hot flashes could also affect severity of depression, and to 5) explore what factors accounted for by the intervention that may have influenced that severity (i.e., the acupuncture, the reduction of hot flash frequency and intensity, more hours sleep and better sleep quality, or the intervention as a whole).

Method

The Acuflash study is a multicenter (Tromsø, Bergen and Oslo), pragmatic, randomized, controlled trial with two parallel arms, conducted from 2006 to 2007 (Borud, Alraek, White, Fonnebo & Grimsgaard, 2007). It is approved by the Regional Committee for Medical Research Ethics, the Norwegian Data Inspectorate and the Norwegian Biobank Registry (Appendix A).

Participants and Procedure

The participants were recruited by newspaper advertisements and media coverage. Women who wanted to participate phoned the study coordinator, received some information about the study and were briefly screened for eligibility for participation. Potential participants received a diary in which they recorded frequency and severity of hot flashes and amount of sleep at night for 14 days. Women who returned the diary and fulfilled the inclusion criteria were sent an informed consent form and the baseline questionnaires by mail. Baseline assessment included sociodemographic data, medical history, previous experience with acupuncture, previous use of other interventions to relieve menopausal complaints,

current use of medication and dietary supplements, level of physical activity, smoking status and alcohol consumption. The women brought the completed questionnaires and informed consent to the local study coordinator, who double-checked the inclusion criteria.

The inclusion criteria were postmenopausal status (>1 year past last menstruation), willingness to receive acupuncture and a mean of 7 or more hot flashes per 24 hours during a time period of 7 days. Exclusion criteria were surgical menopause, history of cancer within the past five years including use of tamoxifen, use of anticoagulant drugs, heart valve disease, poorly controlled hypertension, poorly controlled hypothyroidism, hyperthyroidism, poorly controlled diabetes mellitus, organ transplant, psychological illness, overt drug or alcohol dependency, inability to complete study forms, use of HRT (wash out period: 8 weeks for systemic and 4 weeks for local use), use of SSRI (wash out period: 8 weeks). Participants were directly questioned about these conditions, and no standardized instruments were used.

A total of 535 women were screened for eligibility by phone, 428 women received the baseline diary, 399 women completed and returned it, and after final screening 267 women were deemed eligible and consented to participate (Figure 1, flow chart, Borud et al., in press).

After enrollment, the local coordinator obtained group allocation from the central randomization unit at the University Hospital of North Norway (UNN). Randomization lists were computer generated (block randomization, random block size), and stratified by center. The participants met with the local coordinators again at the end of the study period. They then received 400 kroner (US $70) to cover their expenses associated with participation.

Of the 82 participants who were recruited from Tromsø, all were administrated the BDI-II at baseline and at 12 weeks. Of these women 41 were randomized to the experimental group and 41 to the control group. 36 women from each group provided data at both baseline and post-test at 12 weeks, leaving the present study with a final number of participants of 72 (Figure 2, Flow chart). The mean age was 53.25 years (SD = 4.45) in the experimental group and 53.75 years (SD = 3.46) in the control group. Further description of demographic variables will be presented in the results.

Figure 1. Flow chart (Borud et al., in press).

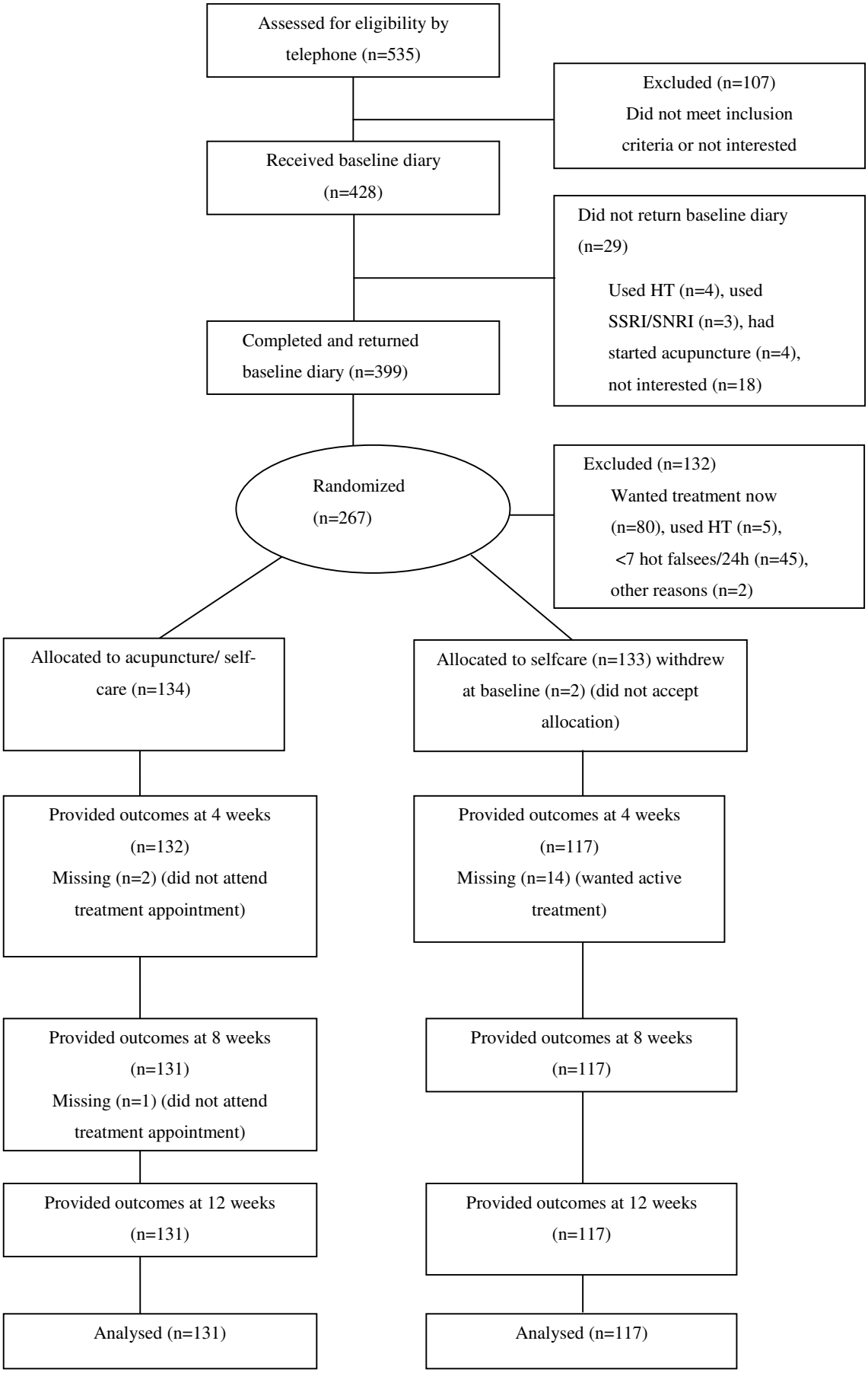
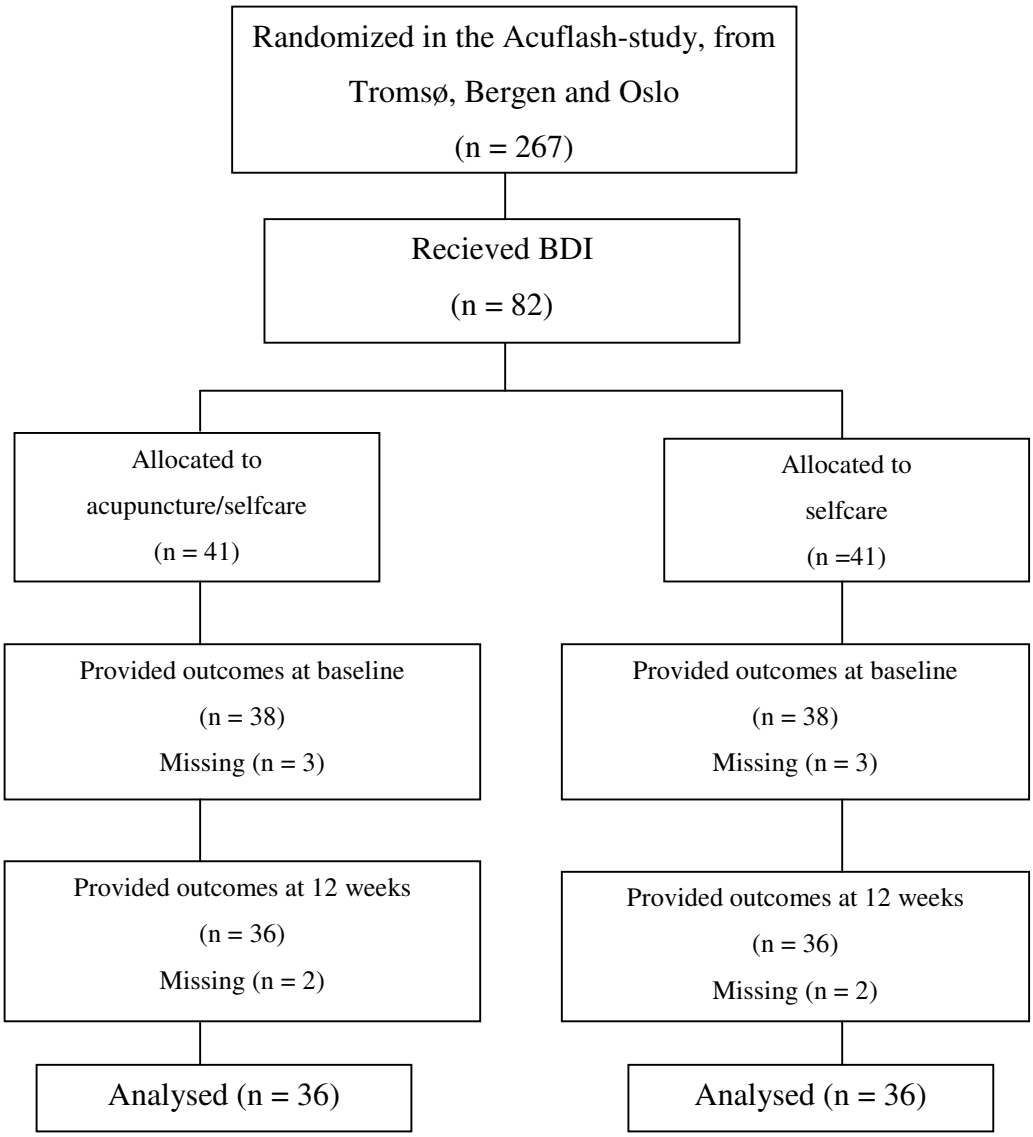


Figure 2. Flow chart



Intervention. Participants were randomized to an experimental- or a control group, respectively receiving both acupuncture and self-care advice (acupuncture group), or self-care advice only (self-care group). The participants in both groups were thus given a one-page intervention leaflet on available self provided care for menopausal symptoms (e.g. soy, herbs, physical activity and relaxation techniques), which was prepared for the study by the project team. The information leaflet was based on a book about the climacteric (Rud, Moen & Seeberg, 2003) and best current advice (The North American Menopause Society, 2004). All the participants also received telephone reminders at 4, 8 and 12 weeks, to start registering hot flashes in the hot flash diary, to insure highest possible compliance with the study.

Acupuncture group. The study acupuncturists had at least 3 years of experience from practice and met the membership criteria of the Norwegian Acupuncture Society (NAFO). Before the study started the acupuncturist from the different cities met and discussed the expected Traditional Chinese Medicine (TCM) diagnoses and the recommended selection of acupuncture points.

The acupuncturists performed a diagnostic evaluation of the participants, according to the principles of TCM. They were free to diagnose, select acupuncture points, and individualize the treatment for each participant. Point location was not standardized, but was left to the acupuncturists to decide. The evaluation first and foremost concerned the TCM syndromes associated with menopausal hot flashes, but the acupuncturists were also free to add additional individualized points to treat other menopause-related symptoms, such as depression and insomnia. Moxibustion (i.e., warmed needles) could also be included upon indication. The experimental group received up to 10 treatment sessions over 12 weeks. The treatment period could be extended by two weeks if needed. The minimum number of treatment sessions was six.

Self-care group. Guided by the information leaflet on self-provided care for menopausal symptoms, the participants were free to use any over-the-counter medication and self-provided non-pharmaceutical interventions. No medical treatment for menopausal symptoms was prescribed to them within the study.

Blinding. All project researchers remained blinded throughout the duration of the study. Hot flash data was entered by a person blinded to group allocation.

Measures

The *Acuflash questionnaire* is a baseline questionnaire developed for the Acuflash study (Borud et al., in press) (Appendix B). This questionnaire was distributed to all participants at baseline and addressed sociodemographic variables, medical history, self-reported current health, previous use of healthcare services, medications and dietary supplements to relieve menopausal complaints, previous use of acupuncture treatment, physical activity, smoking and alcohol consumption. Items covering medical history and alcohol use were used in the screening process at inclusion.

In the present study, the decision about which items to use was guided by present research about which variables usually are related to depression, and preliminary correlation analyses to decide which of the items were related to severity

of depression, as measured with the BDI-II. Accordingly, the items addressing age at menopause, level of education, having children and living with spouse were included because such sociodemographic factors have been found to be related to depression in previous research. In addition, the following variables were included because preliminary correlation analysis showed them to be related to depression: the health variables hypothyroidism and self-reported current health (”how is your health?”), the sleep related variables insomnia (”how often have you been bothered by insomnia?”), and insomnia affecting work (”have you over the last year been bothered by insomnia to an extent that has effected your ability to work?”).

A *hot flash diary* was kept over two weeks before the intervention period and then for one week after week 4, 8 and 12 of the intervention period (Appendix B). In the diary the participants recorded the number of hot flashes, the mean daily hot flash intensity and the hours of sleep per night. Hot flash intensity was scored on a visual analog scale of 0 to 10 were 0 represented “no bother at all” and 10 represented “worst possible intensity of flashes.” Baseline values were calculated on the data from the last seven days of the two weeks before the intervention period.

The *Beck Depression Inventory, second version* (BDI-II, Beck, Steer & Brown, 1996) (Appendix B) is a self report questionnaire consisting of 21 items, measuring severity of depression. The BDI-II items are rated along a four-point scale ranging from 0 to 3, based on the severity of each item. A total scale score is computed by adding up the individual item scores. According to Beck et al. (1996), BDI-II scores are classified as follows: 0-13 minimal range; 14-19 mild; 20-28 moderate and 29-63 severe range. For some of the analyses in the present study we divided our sample into two groups “depressed” and “non-depressed”, with a cut-off at 14 in the BDI-II total score. The BDI-II was administered at baseline and at 12 weeks. In the BDI-II manual, Beck et al. (1996) report a coefficient alpha of 0.93 based on a non-clinical sample of college students. In the present study, the Cronbach’s alpha for the BDI-II total scores at the two different assessments were .92 and .89 respectively.

The *Women’s Health Questionnaire* (WHQ, Hunter, 1992b; Norwegian translation by the MAPI Research Institute) (Appendix B) is a self-report questionnaire addressing health-related quality of life (HR-QoL). It was developed specifically to measure subjective reports of emotional and physical well-being of women in mid life, and has been standardized on a sample of women aging between

45 and 65 years old. The questionnaire consists of 36 items. Each item is scored on a four-point scale with the points signifying “yes, definitely”, “yes, sometimes”, “no, not much” and “no, not at all”. The WHQ covers the following dimensions: depressed mood, somatic symptoms, anxiety/fear, vasomotor symptoms, sleep problems, sexual behavior, menstrual symptoms, memory/concentration and attractiveness. Its content is thus especially directed towards symptoms related to the menopause (Girod, Abetz & de la Loge, 2004), making it a very relevant tool for investigating whether changes following the intervention were due to changes in HR-QoL.

For analyses an average score is calculated. The four-point scale is reduced to a binary option so the average score lies between 0 (good health status) and 1 (poor health status) (Girod et al., 2004). In the present study the WHQ was administered at baseline and at 12 weeks. The menstrual symptoms dimension was excluded from the study because all participants were postmenopausal. Items related to the sexual behavior dimension were also excluded due to a preponderance of missing values. The full scale included in the present study therefore consisted of a total of 29 items. The Cronbach’s alpha for the WHQ dimensions at baseline and twelve weeks, respectively, were for depressed mood, .73 and .71, for somatic symptoms, .68 and .74, for anxiety/fear, .61 and .59, for sleep problems, .53 and .63, for memory/concentration, .68 and .57, and for attractiveness, .65 and .50. The alpha for the vasomotor symptoms dimension could not be calculated at baseline, as it consists of only two items, one of which addresses the presence of hot flashes. This item has no variance at baseline, as all participants had hot flashes. At 12 weeks the alpha for this dimension was .71. The alphas for the full scale, except the menstrual symptoms and sexual behavior domain, were for both baseline and 12 weeks .88.

Statistical Analysis

All analyses were performed on SPSS, version 15.0 (SPSS Inc, Chicago, IL). The rate of missing data was 0.5% for the BDI-data, 0.3% for the WHQ-data, and for the hot flash data it was 1.5% for the entire Acuflash-sample. Missing values in the hot flash data at 12 weeks were substituted with the mean value of the entries in the diary, if data had been recorded over at least 3 days. Missing values in the BDI-data were replaced with the mean of the BDI-items that had been answered. One participant was excluded from the analysis involving BDI-II at 12 weeks, due to an excess of missing values. Finally, missing WHQ-data were replaced with the mean

of the subscale to which the unanswered item belonged. For the attractiveness subscale such replacement was not possible according to the recommendations of the WHQ manual (Girod et al., 2004) and the missing values in this subscale were thus left open.

Changes in frequency and intensity of hot flashes and hours of sleep per night were calculated as mean value at 12 week minus mean value during the last 7 days of the qualifying period. Changes in score on the WHQ dimensions and the BDI-II were calculated as mean value at 12 weeks minus mean value at baseline. Differences in change between groups were assessed with independent samples t-tests. Differences from baseline to 12 weeks within the two groups, respectively, were evaluated with paired-samples t-tests. Eta squared effect sizes were calculated to assess the magnitude of the significant differences between groups. Effect sizes above .01 were interpreted as a small effect, .06 a moderate effect and .14 a large effect (Cohen, 1988). Bivariate correlation analyses were conducted to investigate the association between different variables and severity of depression at baseline, and between different variables and changes in severity of depression over the time of the intervention. A hierarchical regression analysis was performed to investigate factors predicting severity of depression at baseline. Variables with bivariate correlations with the BDI-II stronger than .55 were included in the regression model. However, the WHQ total score was not included due to high intercorrelation with the other independent variables, and also the WHQ depressed mood scale was not included due to its high intercorrelation with the WHQ anxiety/fear scale.

The BDI-II total scores and all the WHQ-dimensions at baseline and 12 weeks, except the WHQ somatic symptoms dimension were not normally distributed. The BDI-II variables were therefore transformed using squared root transformation and analyses involving between-group comparison were run on the transformed scores. For the WHQ-dimensions, transformation could not yield satisfactory normal distribution, and findings were additionally checked using non-parametric Mann-Whitney U Tests and Wilcoxon Signed Rank Tests. However, as no differences in results were obtained with the transformed scores, or the non-parametric tests, as compared to the untransformed scores, only the results based on the untransformed scores are reported here. This to ease the comparison with other studies and the interpretation of our findings.

Results

Table 1 gives an overview of the baseline characteristics from the Acuflash questionnaire of the total sample, the acupuncture group and the self-care group. Upon inspection the acupuncture group and the self-care group were well balanced with respect to background characteristics.

Table 1. Baseline characteristics from the Acuflash questionnaire of the study participants in the total sample, the acupuncture group and self-care group[a]

Characteristics	Total sample (n = 72)	Acupuncture group (n = 36)	Self-care group (n = 36)
Age at randomization, y	53.5 ± 4.0	53.3 ± 4.4	53.8 ± 3.5
Age at menopause, y (n=64)	48.2 ± 5.0	48.4 ± 5.1	47.9 ± 5.0
Having children	67 (93.1)	33 (91.7)	34 (94.4)
Living with spouse	57 (79.2)	28 (77.8)	29 (80.6)
Missing	12 (16.7)	7 (19.4)	5 (13.9)
Years of education			
≤10	18 (25.0)	7 (19.4)	11 (30.6)
11-13	26 (36.1)	14 (38.9)	12 (33.4)
14-17	9 (12.5)	5 (13.9)	4 (11.1)
>17	19 (26.4)	10 (27.8)	9 (25.0)
Hypothyroidism	9 (12.5)	5 (13.9)	4 (11.1)
Self-reported health			
Very bad	2 (2.8)	1 (2.8)	1 (2.8)
Bad	25 (34.7)	12 (33.3)	13 (36.1)
Good	37 (51.4)	17 (47.2)	20 (55.6)
Excellent	7 (9.7)	5 (13.9)	2 (5.6)
Missing	1 (1.4)	1 (2.8)	0

Characteristics	Total sample (n = 72)	Acupuncture group (n = 36)	Self-care group (n = 36)
Insomnia			
Never	23 (31.9)	12 (33.3)	11 (30.6)
One to three nights per month	9 (12.5)	3 (8.3)	6 (16.7)
Once a week	7 (9.7)	4 (11.1)	3 (8.3)
>Once a week	33 (45.8)	17 (47.2)	16 (44.4)
Insomnia affecting work last year			
Yes	39 (54.2)	19 (52.8)	20 (55.6)
No	32 (44.4)	17 (47.2)	15 (41.7)
Missing	1 (1.4)	0	1 (2.8)

[a]Data are presented as either mean ± SD or n (%), where appropriate.

Acupuncture and Self-care versus Self-care Only's Effect on Hot Flashes and HR-QoL

To answer the first aim of the study, independent-samples t-tests were conducted to assess the effectiveness of acupuncture and self-care versus self-care only on hot flash frequency, hot flash intensity, hours of sleep (i.e., hot flash diary) and the WHQ-dimensions. The results are presented in Table 2 and 4, respectively.

Regarding hot flash diary data, the mean frequency of hot flashes per 24 hours among all participants was 12.9 (range, 5.7-27.7) at baseline. At 12 weeks, the mean reduction in hot flash frequency per 24 hours was 5.6 in the acupuncture group and 4.6 in the self-care group, a non-significant difference of 1.0. (95% CI, 1.3-3.3; p=.38). Mean hot flash intensity among all participants was 7.0 (range, 2.1-10 on a 1-10 scale) at baseline. At 12 weeks, mean reduction in hot flash intensity was 3.1 units in the acupuncture group and 2.6 units in the self-care group, a non-significant difference of 0.5 units (95% CI, 0.9-1.7; p=.52). Among all participants, mean hours of sleep per night was 6.1 (range, 3.5-8.3) at baseline. At 12 weeks mean hours of sleep increased by 0.39 hours in the acupuncture group and 0.07 hours in the self-care group, a non-significant difference of .32 hours (95% CI, 0.17-0.80; p=.20).

Table 2. Frequency of hot flashes, intensity of hot flashes and hours of sleep at baseline, and mean change in scores at 12 week[a]

	Acupuncture group (n = 36)	Self-care group (n = 36)	P[b]
Hot flash frequency per 24 h	n = 36	n = 36	
Baseline	13.1 (5.0)	12.6 (4.6)	
Difference from baseline at 12 wk	-5.6 (5.0)	-4.6. (4.8)	.38
Hot flash intensity (0-10)	n = 30	n = 30	
Baseline	6.8 (1.8)	7.1. (2.0)	
Difference from baseline at 12 wk	-3.1 (2.6)	-2.6 (2.5)	.52
Hours of sleep/night	n = 36	n = 34	
Baseline	5.9 (1.3)	6.2 (1.1)	
Difference from baseline at 12 wk	.39 (1.06)	.07 (.96)	.20

[a]Data are presented as mean (SD). [b]Results from independent-samples t-tests, acupuncture group versus self-care group.

Using paired-samples t-tests, the effect of the intervention within the acupuncture group and the self-care group were assessed separately. In the acupuncture group, there were statistically significant decreases in both hot flash frequency and hot flash intensity, and a statistically significant increase in hours of sleep from baseline to 12 weeks, with $t(35) = 6.65$, $p < .0005$ (two-tailed), $t(29) = 6.37$, $p = <.0005$ (two-tailed) and $t(35) = -2.21$, $p < .03$ (two-tailed), respectively. The eta squared statistics indicated large effect sizes, with eta squared (.56), (.58) and (.12), respectively. In the self-care group, there were statistically significant decreases in frequency and intensity of hot flashes, with $t(35) = 5.72$, $p < .0005$ (two-tailed) and $t(29) = 5.83$, $p < .0005$ (two-tailed), respectively. The eta squared statistics indicated large effect sizes, (.48) and (.54). There was no significant increase in hours of sleep per night in the self-care group, $t(33) = -.45$, p =.60.

As presented in Table 3, 47.2% of the women in the acupuncture group experienced 50% or greater reduction in hot flash frequency from baseline to 12 weeks, compared with 22.2% in the self-care group (n.s.).

Table 3. Reduction in hot flash frequency at 12 weeks for acupuncture and self-care group

	Acupuncture group (n=36)			Self-care group (n=36)		
Hot flash reduction, as % of baseline	No. of participants	%	Cumulative %	No. of participants	%	Cumulative %
100	1	2.8	2.8	0	0	0
75-99	7	19.6	22.2	4	11.2	11.1
50-74	9	25.2	47.2	4	11.2	22.2
26-49	7	19.6	67.7	16	44.8	66.7
0-25	10	28.6	94.4	7	19.6	86.1
<0	2	5.6	100	5	14	100

Regarding HR-QoL at baseline, the participants in our study reported better results on the WHQ dimensions depressed mood and attractiveness, and poorer results on the WHQ dimensions somatic health, memory/concentration and sleep problems, compared with a European reference population of postmenopausal women (Girod et al., 2004). In our sample, mean vasomotor score was .99, compared with .47 in the reference population. Independent-samples t-tests showed no significant difference in the mean reduction scores between the acupuncture group and the self-care group on any of the 7 WHQ-dimensions (Table 4).

Using paired-samples t-tests, the effect of the intervention within the acupuncture group and the self-care group were assessed separately. Both in the acupuncture group and the self-care group, there were statistically significant improvements in the vasomotor symptoms dimension, $t(35) = 3.25$, $p = .003$ (two-tailed), eta squared = .23, and $t(35) = 2.50$, $p = .02$ (two-tailed), eta squared = .15 respectively, and in the anxiety/fear dimension, $t(35) = 2.79$, $p = .008$ (two-tailed), eta squared = .18, and $t(35) = 2.36$, $p = .02$ (two-tailed), eta squared = .14, respectively. In the self-care group, there were also significant improvements in the somatic symptoms dimension, $t(35) = 2.11$, $p = .04$ (two-tailed), eta squared = .11, and in the attractiveness dimension, $t(31) = 2.48$, $p = .02$ (two-tailed), eta squared = .17.

Table 4. WHQ scores at baseline and mean change in scores at 12 week[a]

WHQ dimensions	Acupuncture mean (SD)	Self-care Mean (SD)	p[b]	Reference values[c] mean (SD)
Depressed mood				
Baseline (n=72)	.20 (.25)	.23 (.23)		.30 (.26) n=4,484
Mean change from baseline to 12 wk (n=72)	-.04 (.17)	-.08 (.27)	.46	
Somatic symptoms				
Baseline (n=72)	.46 (.30)	.60 (.23)		.38 (.28) n=4,468
Mean change from baseline to 12 wk (n=72)	-.04 (.20)	-.07 (.20)	.51	
Memory/concentration				
Baseline (n=72)	.50 (.38)	.53 (.39)		.37 (.37) n=4,461
Mean change from baseline to 12 wk (n=72)	-.01 (.22)	-.04 (.30)	.65	
Vasomotor symptoms				
Baseline (n=72)	1.00 (.00)	.97 (.12)		.47 (.45) n=4,429
Mean change from baseline to 12 wk (n=71)	-.21 (.38)	-.10 (.23)	.14	
Anxiety/fears				
Baseline (n=71)	.26 (.29)	.32 (.26)		.30 (.32) n=4,502
Mean change from baseline to 12 wk (n=72)	-.08 (.18)	-.11 (.28)	.62	
Sleep problems				
Baseline (n=72)	.54 (.36)	.58 (.32)		.46 (.37) n=4,549
Mean change from baseline to 12 wk (n=71)	-.08 (.31)	-.06 (.29)	.79	
Attractiveness				
Baseline (n=70)	.32 (.42)	.35 (.40)		.58 (.38) n=4,193
Mean change from baseline to 12 wk (n=67)	-.01 (.28)	-.17 (.39)	.07	

[a]The values of the scores vary between 0 and 1, where 0 is an indicator of "good health status" and 1 is an indicator of "poor health status. [b]Results from independent t-tests, acupuncture group versus control group. [c]Reference values are taken from the IQOL WHQ Database, postmenopausal women. (Girod et al., 2004).

Prevalence of Depression

To answer the second aim of the study regarding the prevalence of depression in postmenopausal women, 30.6% (22) of the women met the criteria for depression at baseline (BDI-II ≥ 14). The distribution of total BDI-II scores in the total sample, the acupuncture group and the self-care group are presented in Table 5. An independent-samples t-test on the BDI-II total score showed no significant difference

in the depression scores for the acupuncture group (mean = 10.69, SD = 8.61) and the self-care group, (mean = 10.67, SD = 7.12); $t(70) = .02$, $p = .99$ (two-tailed). Mean and standard deviations for the total sample, the acupuncture group and the self-care group on the BDI-II, WHQ and hot flash diary data at baseline are presented in Table 6.

Table 5. Distribution of total BDI-II scores based on BDI-II classification (Beck et al. 1996) in the total sample, acupuncture group and self-care group

	Total sample	Acupuncture group	Self-care group
BDI-II total score	n (%)	n (%)	n (%)
0-13: minimal range	50 (69.4)	25 (69.4)	25 (69.4)
14-19: mild range	9 (12.5)	4 (11.1)	5 (13.9)
20-28: moderate range	10 (13.9)	4 (11.1)	6 (16.7)
29-63: severe range	3 (3.5)	3 (8.3)	0 (0.0)

Table 6. Mean and standard deviations for the total sample, the acupuncture group and the self-care group on the BDI-II, WHQ and hot flash diary data at baseline

Variable	Total sample (N = 72)		Acupuncture group (N = 36)		Self-care group (N = 36)	
	Mean	SD	Mean	SD	Mean	SD
BDI-II total score	10.68	7.85	10.69	6.61	10.67	7.12
WHQ-dimensions						
Depressed mood	.22	.24	.20	.25	.23	.23
Somatic symptoms	.53	.27	.46	.30	.60	.23
Memory/concentration	.52	.38	.50	.38	.53	.39
Vasomotor symptoms	.99	.08	1.00	.00	.97	.12
Anxiety/fear	.29	.28	.26	.29	.32	.26
Sleep problem	.56	.34	.54	.36	.58	.32
Attractiveness	.34	.41	.32	.42	.35	.40
Hot Flash Diary						
Hot Flash frequency per 24 h	12.86	4.79	13.10	5.01	12.62	4.63
Hot flash intensity (1-10)	6.96	1.94	6.80	1.84	7.12	2.04
Hours of sleep/night	6.06	1.17	5.95	1.27	6.19	1.05

Factors Related to Severity of Depression in Postmenopausal Women

To answer the third aim of the study, the relationship between the BDI-II total score at baseline and sociodemographic, health and sleep variables from the Acuflash questionnaire, the WHQ-dimensions and hot flash diary data were assessed by Pearson's correlation coefficient. The results are presented in Table 7-9.

The factor most strongly correlated with the BDI-II scores was the WHQ total score (r = .83, n = 70, p < .000). There were strong correlations between the BDI-II scores and insomnia (r = .50, n = 72, p < .000), and insomnia affecting work (r = -.54, n = 71, p < .000) from the Acuflash questionnaire. A strong correlation was also found between the BDI-II scores and the WHQ sleep problem dimension, (r = .59, n = 72, p < .000), and there was a moderate, negative correlation between the BDI-II total score and hours of sleep, (r = -.36, n = 70, p = .002).

There were moderate, negative correlations between BDI-II scores and hypothyroidism (*r=-.33, n= 71, p = .005*), and self-reported health (r = -.43, n = 71, p < .000) from the Acuflash questionnaire. There was also a strong positive correlation between level of depression and the somatic symptoms dimension of the WHQ (r = .56, n = 72, p < .000).

A strong, positive correlation was found between the BDI-II scores and the WHQ depressed mood dimension (r = .74, n = 72, p < .000). Another three dimensions of the WHQ were also positively correlated with the BDI-II: the memory and concentration dimension (r = .48, n = 72, p < .000), the anxiety/fear dimension (r = .68, n = 72, p < .000) and the attractiveness dimension (r = .55, n = 70, p < .000). The only WHQ dimension not significantly related to the BDI-II was the vasomotor symptoms dimension. Neither were there any significant correlations between BDI-II total scores and frequency and intensity of hot flashes, as measured by the hot flash diary. Finally, none of the correlations between depression and the sociodemographic variables having children, living with spouse and level of education were significant.

Table 7. Intercorrelations between BDI-II scores at baseline, sosiodemographic variables, sleep- and health variables from the Acuflash questionnaire

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
1. BDI-II total score	--									
2. Age	-.08	--								
	n=72									
3. Age at menopause	-.03	.28*	--							
	n=64	n=64								
4. Education	-.06	.02	.35**	--						
	n=72	n=72	n=64							
5. Children	-.04	-.09	.17	.10	--					
	n=72	n=72	n=64	n=72						
6. Living with spouse	.01	-.09	-.16	.06	-.04	--				
	n=60	n=60	n=53	n=60	n=60					
7. Hypothyroidism	-.33**	.03	-.10	-.12	.11	.08	--			
	n=71	n=71	n=64	n=71	n=71	n=59				
8. Self-reported health	-.43***	.02	-.19	.34**	-.04	.23	.27*	--		
	n=71	n=71	n=63	n=71	n=71	n=59	n=70			
9. Insomnia	.50***	.12	.02	-.16	.02	.05	-.13	-.27*	--	
	n=72	n=72	n=64	n=72	n=72	n=60	n=71	n=71		
10. Insomnia	-.54***	-.09	.10	.23	.08	-.05	.27**	.32**	-.61***	--
affecting work	n=71	n=71	n=63	n=71	n=71	n=59	n=70	n=70	n=71	

*Note. *p < .05. **p < .01. ***p < .001.*

Table 8. Intercorrelations between BDI-II scores at baseline and WHQ dimensions

	1.	2.	3.	4.	5.	6.	7.	8.	9.
1. BDI-II total score	--								
WHQ dimensions									
2. Depressed mood	.74***	--							
	n=72								
3. Somatic symptoms	.56***	.47***	--						
	n=72	n=72							
4. Memory/concentration	.48***	.47***	.29**	--					
	n=72	n=72	n=72						
5. Vasomotor symtoms	.13	.10	-.07	.08	--				
	n=72	n=72	n=72	n=72					
6. Anxiety/fears	.68***	.74***	.51***	.52***	.03	--			
	n=72	n=72	n=72	n=72	n=72				

	1.	2.	3.	4.	5.	6.	7.	8.	9.
7. Sleep problems	.59***	.47***	.47***	.27*	.20	.56***	--		
	n=72	n=72	n=72	n=72	n=72	n=72			
8. Attractiveness	.55***	.49***	.41***	.25*	-.28*	.42***	.14	--	
	n=70	n=70	n=70	n=70	n=70	n=70	n=70		
9. WHQ total score	.83***	.85***	.76***	.63***	.06	.85***	.66***	.57***	--
	n=70	n=70	n=70	n=70	n=70	n=70	n=70	n=70	

Note. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 9. Intercorrelations between BDI-II scores at baseline and hot flash diary data

	1.	2.	3	4.
1. BDI-II total score	--			
2. Hot flash frequency per 24 h	.17	--		
	n=72			
3. Hot flash intensity (1-10)	.12	.46***	--	
	n=60	n=60		
4. Hours of sleep/night	-.36**	-.26*	-.42***	--
	n=70	n=70	n=60	

Note. **$p < .01$. ***$p < .001$.

The relationship between the WHQ and hot flash diary data were also assessed by Pearson's correlation coefficient (Table 10). There were no significant correlations between the frequency and intensity of hot flashes, and any of the WHQ dimensions. The hours of sleep measure showed a moderate negative correlation with the WHQ total score (r = -.31, n = 69, p = .009) and the sleep problems dimension (r = -.49, n = 72, p < .000), and small negative correlations with the depressed mood dimension (r = -.29, n = 70, p = .016) and the anxiety/fear dimension (r = -.24, n = 70, p = .048).

Table 10. Intercorrelations between WHQ and hot flash diary data

	Hot flash frequency per 24 h	Hot flash intensity (1-10)	Hours of sleep per night
WHQ total score	.09	.11	.31**
	n=70	n=60	n=69
WHQ depressed mood	.13	.13	-.29*
	n=72	n=60	n=70
WHQ somatic symptoms	.10	.13	-.22
	n=72	n=60	n=70
WHQ memory/concentration	.06	.01	-.04
	n=72	n=60	n=70
WHQ vasomotor symptoms	.14	.18	-.12
	n=72	n=60	n=70
WHQ anxiety/fears	.03	.13	-.24*
	n=72	n=60	n=70
WHQ sleep problems	.06	.20	-.49***
	n=72	n=60	n=72
WHQ attractiveness	.02	-.21	-.07
	n=70	n=60	n=69

Note. *$p < .05$. **$p < .01$. ***$p < .001$.

Hierarchical multiple regression analyses were then performed to assess different variables' ability to predict level of depression (i.e., BDI-II). Preliminary analyses showed no violations of the assumptions of normality, linearity, multicollinearity or homoscedasticity. The results of the hierarchical multiple regressions are presented in Table 11.

The WHQ attractiveness dimension was entered in step 1, explaining 30.4% of the variance in severity of depression, which was a statistically significant contribution. The WHQ somatic symptoms dimension was entered in step 2, explaining an additional statistically significant 13.8% of the variance in depression. The WHQ sleep problems dimension was entered in step 3, explaining an additional 15.6% of the variance in depression, also this a statistically significant contribution. After entry of the WHQ anxiety/fear dimension in step 4, the total variance explained by the model as a whole was 64.6%, $F(4, 65) = 29.63$, $p < .0005$. In the final model,

all the predictor variables were statistically significant, except the WHQ somatic symptoms dimension. The final beta values of the remaining predictor variables were of equal size, although the WHQ attractiveness dimension obtained the highest beta value (beta =.33, p <.000), followed by the WHQ sleep problem dimension (beta =.32, p =.001), and the WHQ anxiety/fear dimension (beta =.30, p =.004).

Table 11. Hierarchical regression analysis with WHQ dimension predicting depression

	Level of depression			
Step and predictor variables	R^2	ΔR^2	$\beta^{1)}$	Final $\beta^{2)}$
Step 1				
WHQ attractiveness dimension	.30	.30***	.55	.33***
Step 2:		.		
WHQ somatic symptoms dimension	.44	.14***	.41	.13
Step 2:				
WHQ sleep problem dimension	.60	.16***	.45	.32***
Step 3:				
WHQ anxiety/fear dimension	.65	.05**	.30	.30**

*Note. *p < .05.**p < .01. ***p < .001.*

[1)]Beta when first entered. [2)]Beta in last step.

Acupuncture and Self-care versus Self-care Only's Effect on Severity of Depression

At week 12, 14.1% (10) of the women met the criteria for depression. The distribution of BDI-II total scores at 12 week in the total sample, the acupuncture group and the self-care group are presented in Table 12.

Table 12. Distribution of total BDI-II scores at 12 week based on BDI-II classification (Beck et al., 1996) in the total sample, acupuncture group and self-care group

BDI-II total score	Total sample n (%)	Acupuncture group n (%)	Self-care group n (%)
0-13: minimal range	61 (84.7)	29 (80.6)	32 (88.9)
14-19: mild range	7 (9.7)	4 (11.1)	3 (8.3)
20-28: moderate range	3 (4.2)	2 (5.6)	1 (2.8)
29-63: severe range	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (1.4)	1 (2.8)	

To answer the fourth aim of the study, paired-samples t-tests were first conducted to evaluate the impact of the intervention on depression. In the acupuncture group, there was a statistically significant decrease in depression scores from baseline (M = 10.40, SD = 8.55) to 12 weeks (M = 5.91, SD = 6.36), $t(34) = 5.08$, $p<.0005$ (two-tailed). The mean decrease in depression scores was 4.49 with a 95% confidence interval ranging from 2.69 to 6.28. The eta squared statistics (.43) indicated a large effect size. In the self-care group, there was also a statistically significant decrease in depression scores from baseline (M = 10.67, SD = 7.12) to 12 weeks (M = 6.36, SD = 5.05), $t(35) = 4.56$, $p<.0005$ (two-tailed). The mean decrease in depression scores was 4.31 with a 95% confidence interval ranging from 2.39 to 6.22. The eta squared statistics (.37) indicated a large effect size. Independent samples t-test showed no significant difference in the mean reduction scores between the acupuncture group and the self-care group, $t(69) = -.14$, $p=.89$ (two-tailed).

Independent samples t-tests were then conducted to assess mean change in BDI-II scores from baseline to 12 weeks for women with BDI-II scores within the symptomatic range (BDI-II≥14) as opposed to outside the symptomatic range (BDI-II<14). The test was run for the acupuncture and self-care groups, separately. For the acupuncture group there was a significant difference in mean reduction scores for those with BDI-II ≥14 (Mean = -7.5, SD = 7.25), compared to those with BDI-II<14 (Mean = -3.28, SD = 3.70), $t(33) = 2.29$, $p=.03$ (two-tailed). The group with higher levels of depression presented the largest reduction. The magnitude of the difference in the means (mean difference = 4.22, 95% CI: .47 to 7.97) was large (eta squared = .14). Also in the self-care group there was a significant difference in mean reduction

scores for those with BDI-II ≥14 (Mean = -8.55, SD = 7.39), compared to those with BDI-II<14 (Mean = -2.44, SD = 3.50), $t(12.02) = 2.61$, p=.02 (two-tailed). Also here the group with higher levels of depression presented the largest reduction. The magnitude of the difference in the means (mean difference = 6.11, 95% CI: 1.02 to 11.20) was large (eta squared = .17).

Factors Accounted for by the Intervention Contributing to a Decline in Depression

To answer the fifth aim of the study, factors associated with the change in BDI-II scores from baseline to 12 weeks were assessed by Pearson's correlation coefficient. The results are presented in Table 13-16.

At first, correlations between baseline factors and change in BDI-II scores were run. The factor most strongly correlated with change in BDI-II scores at 12 weeks was the level of depression as measured by the BDI-II at baseline. It showed a strong, negative correlation (r = -.66, n = 71, p < .000).

Significant negative correlations were found between change in BDI-II scores and the WHQ depressed mood dimension (r = -.40, n = 71, p = .001), sleep problem dimension (r = -.42, n = 71, p < .000) and somatic symptoms dimension (r = -.32, n = 71, p = .007). The WHQ total score was similarly correlated (r = -.39, n = 70, p < .000). There was also a small correlation between change in BDI-II score and self-reported health from the Acuflash questionnaire (r = .28, n = 70, p = .02).

Hours of sleep at baseline measured by the hot flash diary showed a small, positive correlation with change in BDI-II scores (r = .29, n = 69, p = .02). There were also significant correlations between change in BDI-II scores and insomnia (r = -33, n = 71, p = .005) and insomnia affecting work (r = .30, n = 70, p = .01).

No significant correlations were found between frequency and intensity of hot flashes at baseline, as measured by the hot flash diary, and change in BDI-II scores. Neither was there any significant correlation with the vasomotor symptoms dimension of the WHQ. None of the correlations between change in BDI-II scores and the sociodemographic variables having children, living with spouse and level of education were significant.

Secondly, correlations were run between the change in BDI-II scores and change in other variables also retested at 12 weeks. There was a moderate positive correlation with change in the WHQ depressed mood dimension (r = .44, n = 71, p < .000), and small positive correlations with change in the WHQ somatic symptoms dimension (r = .26, n = 71, p = .03), and WHQ anxiety/fear dimension (r = .25, n =

71, $p = .04$). There was also a moderate positive correlation between change in BDI-II scores and change in the WHQ total score ($r = .37$, $n = 66$, $p = .003$).

There were no significant correlations between changes in frequency and intensity of hot flashes over time, as measured by the hot flash diary, and change in BDI-II scores. On the same note, change in the vasomotor symptoms dimension of the WHQ was not significantly correlated with change in BDI-II scores. Finally there was no significant correlation between change in hours of sleep as measured by the hot flash diary and change in BDI-II scores.

Table 13. Intercorrelations between BDI-II difference from baseline to 12 weeks, BDI-II total score baseline and sosiodemographic, sleep- and health variables from the Acuflash questionnaire

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
1. BDI-II, change from baseline at 12 week	--										
2. BDI-II total score at baseline	-.66*** n=71	--									
3. Age	.07 n=71	-.08 n=72	--								
4. Age at menopause	.19 n=63	-.03 n=64	.28* n=64	--							
5. Education	-.04 n=71	-.06 n=72	.02 n=72	.35** n=64	--						
6. Children	-.07 n=71	-.04 n=72	-.09 n=72	.17 n=64	.10 n=72	--					
7. Living with spouse	-.05 n=59	.01 n=60	-.09 n=60	-.16 n=53	-.06 n=60	-.04 n=60	--				
8. Hypothyroidism	.22 n=70	-.33** n=71	.03 n=71	-.10 n=64	-.12 n=71	.11 n=71	.08 n=59	--			
9. Self-reported health	.28* n=70	-.43*** n=71	.02 n=71	-.19 n=63	.34** n=71	-.04 n=71	.23 n=59	.27* n=70	--		
10. Insomnia	-.33** n=71	.50*** n=72	.12 n=72	.02 n=64	-.16 n=72	.02 n=72	.05 n=60	-.13 n=71	-.27* n=71	--	
11. Insomnia affecting work	.30* n=70	-.54*** n=71	-.09 n=71	.10 n=63	.23 n=71	.08 n=71	-.05 n=59	.27* n=70	.32** n=70	-.61*** n=71	--

*Note. *p < .05. **p < .01. ***p < .001.*

Table 14. Intercorrelations between BDI-II difference from baseline to 12 weeks and WHQ dimensions

	1.	2.	3.	4.	5.	6.	7.	8.	9.
1. BDI-II, change from baseline at 12 week	--								
WHQ dimensions									
2. Depressed mood	-.40** n=71	--							
3. Somatic symptoms	-.32** n=71	.47*** n=72	--						
4. Memory/concentration	-.11 n=71	.47*** n=72	.29** n=72	--					
5. Vasomotor symtoms	-.06 n=71	.10 n=72	-.07 n=72	.08 n=72	--				
6. Anxiety/fears	-.21 n=71	.74*** n=72	.51*** n=72	.52*** n=72	.03 n=72	--			
7. Sleep problems	-.42*** n=71	.47*** n=72	.47*** n=72	.27* n=72	.20 n=72	.56*** n=72	--		
8. Attractiveness	-.18 n=69	.49*** n=70	.41** n=70	.25* n=70	-.28* n=70	.42*** n=70	.14 n=70	--	
9. WHQ total score	-.39*** n=70	.85*** n=70	.76*** n=70	.63*** n=70	.06 n=70	.85*** n=70	.66*** n=70	.57*** n=70	--

Note. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 15. Intercorrelations between BDI-II difference from baseline to 12 weeks and WHQ dimensions for difference from baseline to 12 week

	1.	2.	3.	4.	5.	6.	7.	8.	9.
1. BDI-II, change from baseline to 12 week	--								
WHQ dimensions, change from baseline to 12 week									
2. Depressed mood	.44*** n=71	--							
3. Somatic symptoms	.26* n=71	.27* n=72	--						
4. Memory/concentration	-.12 n=71	.17 n=72	.04 n=72	--					
5. Vasomotor symtoms	.02 n=71	-.06 n=72	.12 n=72	-.16 n=72	--				

	1.	2.	3.	4.	5.	6.	7.	8.	9.
6. Anxiety/fears	.25*	.58***	.38***	.04	-.06	--			
	n=71	n=72	n=72	n=72	n=72				
7. Sleep problems	-.13	.09	.28*	.29*	.20	.01	--		
	n=71	n=72	n=72	n=72	n=72	n=72			
8. Attractiveness	.09	.44***	.05	.24	-.13	.09	.12	--	
	n=66	n=67	n=67	n=67	n=67	n=67	n=67		
9. WHQ total score, change	.37**	.77***	.66***	.38***	.15	.66***	.43***	.45***	--
from baseline to 12 week	n=66	n=67	n=67	n=67	n=67	n=67	n=67	n=67	

Note. *$p < .05$. **$p < .01$. ***$p < .001$.

Table 16. Intercorrelations between BDI-II difference from baseline to 12 weeks, hot flash diary data at baseline and hot flash diary data for difference from baseline to 12 week

	1.	2.	3	4.	5.	6.	7.
1. BDI-II total score, change	--						
from baseline to 12 weeks							
2. Hot flash frequency per 24 h	-.08	--					
	n=71						
3. Hot flash intensity (1-10)	-.14	.46***	--				
	n=60	n=60					
4. Hours of sleep/night	.29*	-.26*	-.41**	--			
	n=69	n=70	n=60				
5. Hot flash frequency per 24 h,	.07	-.43***	-.31*	.20	--		
change from baseline to 12 week	n=71	n=71	n=60	n=69			
6. Hot flash intensity (1-10),	.12	-.16	-.46***	.25	.75***	--	
change from baseline to 12 week	n=60	n=60	n=60	n=60	n=60		
7. Hours of sleep/night,	-.11	.20	.22	-.53***	-.36**	-38**	--
change from baseline to 12 week	n=69	n=69	n=60	n=69	n=60	n=60	

Note. **$p < .01$. ***$p < .001$.

The relationship between the change in the WHQ dimensions from baseline to 12 weeks, and the change in the hot flash diary data from baseline to 12 weeks was also assessed by Pearson's correlation coefficient. The results are presented in Table 17. There were significant correlations between change in the WHQ vasomotor symptoms dimension and change in both frequency ($r = .54$, $n = 72$, $p < .000$) and intensity ($r = .35$, $n = 60$, $p = .006$) of hot flashes, and change in hours of sleep ($r = -.27$, $n = 70$, $p = .023$). There was also a moderate correlation between

change in hot flash intensity and the WHQ sleep problems dimension (r = .46, n = 60, p < .000). Finally, there was a small correlation between change in the hours of sleep and change in the sleep problems dimension of the WHQ (r = -.24, n = 70, p = .046).

Table 17. Intercorrelations between WHQ dimensions for difference from baseline to 12 week and hot flash diary data for difference from baseline to 12 week

	Hot flash frequency per 24 h	Hot flash intensity (1-10)	Hours of sleep per night
WHQ total score, change from baseline to 12 weeks	.14 n=67	.21 n=57	-.16 n=66
WHQ dimensions, change from baseline to 12 weeks			
Depressed mood	.05 n=72	.04 n=60	-.10 n=70
Somatic symptoms	.05 n=72	.12 n=60	-.04 n=70
Memory/concentration	-.08 n=72	-.08 n=60	-.06 n=70
Vasomotor symptoms	.54*** n=72	.35** n=60	-.27* n=70
Anxiety/fears	.00 n=72	.03 n=60	-.04 n=70
Sleep problems	.20 n=72	.46*** n=60	-.24* n=70
Attractiveness	-.14 n=67	.01 n=66	.01 n=66

Note. *p < .05. **p < .01. ***p < .001.

Discussion

The present study sought to replicate the Acuflash-study (Borud et al., in press), that is to investigate the effect of acupuncture on menopausal hot flashes and health related quality of life (HR-QoL) in a subsample of the Acuflash-sample. Furthermore the study aimed to shed light on the prevalence of, and factors related to

depression in this sample, and the question about an association between depression and menopause. And finally, the aim was to investigate whether the acupuncture treatment for menopausal hot flashes could also help alleviate depression in mid life women.

The main findings of this study were firstly, an elevated prevalence of depression in our sample of postmenopausal women with a high level of hot flashes, as compared to women in the general population. Secondly, our findings point to the particular effect of attractiveness, sleep problems and anxiety in explaining severity of depression in postmenopausal women. Thirdly, we found that both use of acupuncture in addition to self-care, and self-care only, contributed to clinically relevant reductions in hot flashes, improvements on certain dimensions of HR-QoL and decreased levels of depression. We propose that several factors, in addition to a specific acupuncture effect, can have a positive effect on hot flashes, HR-QoL and depressed mood in postmenopausal women.

Acupuncture and Self-care versus Self-care Only's Effect on Hot Flashes, Sleep and HR-QoL

In the present study, no significant differences were found from baseline to 12 week between the acupuncture and self-care group and the self-care only group on either frequency of hot flashes, intensity of hot flashes or hours of sleep per night. However, in both the acupuncture group and self-care group, separately, statistically significant decreases in frequency and intensity of hot flashes were observed. In the acupuncture group, there was also a statistically significant increase in hours of sleep per night.

Furthermore, there was no significant difference between the acupuncture group and the self-care group in HR-QoL, as measured by the WHQ. However, both in the acupuncture group and the self-care group, there were statistically significant improvements in the vasomotor and anxiety/fear dimension of the WHQ.

The present study involves a subsample of 72 postmenopausal women from the Acuflash study (Borud et al., in press). Borud et al. found a significant difference in mean frequency of hot flashes, intensity of hot flashes and hours of sleep from baseline to 12 weeks between the acupuncture group and the self-care group. The frequency and intensity of hot flashes were found to decrease more in the acupuncture group than in the self-care group, while hours of sleep was found to increase more in the acupuncture group than in the self-care group. The discrepancy

between the findings in the present study and the findings of Borud et al. might be due to the smaller sample size in our study. However, in the present study nearly half of the women in the acupuncture group achieved a 50% or more reduction in hot flashes, compared with only about one fourth of the women in the self-care group. This could indicate that the women in our study showed the same tendencies as those in Borud et al.

Prevalence of Depression

In our sample, the prevalence of depression (BDI≥14) was 30.6% at baseline, as measured with the BDI-II. This is higher than results from epidemiological studies of depression in the general female population, with prevalence estimates ranging from about 4.4 to 10% (Ayuoso-Mateos et al., 2001; Sandanger et al., 1999). Taking into account only those reporting moderate to severe depression (BDI≥20), the prevalence of depression was 17.4%, also this high compared with figures from the general female population. Although most women in the present study did not show clinical levels of depression, our findings suggest that for some women, the menopause might be a vulnerable period in life with increased risk of developing depression, as is also indicated by several other studies (Amore et al., 2007; Avis, Brambilla, McKinlay & Vass, 1994; Bromberger et al., 2001; Cohen, Soares, Vitonis, Otto & Harlow 2006; Freeman et al., 2004; Freeman, Sammel, Lin & Nelson, 2006; Hay, Bancroft & Johnstone, 1994; Hunter, 1992a; Schmidt, Haq & Rubinow, 2004).

Factors Related to Severity of Depression in Postmenopausal Women

To investigate which factors that might be related to severity of depression in the sample, bivariate correlation analyses were run. These revealed moderate to strong correlations between the BDI-II total score and all of the sleep- and health related variables from the Acuflash questionnaire and between BDI-II total score and hours of sleep from the hot flash diary. All of these correlations indicated that experiencing problems with sleep and health was associated with higher levels of depression. This is in accordance with studies showing the connection between depression and physical health (Callegari et al., 2007), and depression and sleep (Ford & Cooper-Patrick, 2001). Furthermore, the WHQ total score and all the WHQ-dimensions, except the WHQ vasomotor symptoms dimension, showed significant correlations with BDI-II total score. This indicates that low HR-QoL was associated with higher severity of depression in postmenopausal women, as is consistent with

findings of Joffe et al. (in press). None of the sociodemographic variables showed significant correlations with the BDI-II total score, as did neither frequency nor intensity of hot flashes from the hot flash diary.

The fact that the WHQ vasomotor symptoms dimension did not show any significant correlations with neither the BDI-II total score, nor any other baseline measurement, is likely to be explained by the lack of variance in this variable. As all the participants in the present study had a high degree of vasomotor complaints, the variance in the WHQ vasomotor symptom dimension became nearly zero, which has also been pointed out by Borud, Martinussen, Eggen and Grimsgaard (2009). However, the fact that frequency and intensity of hot flashes, as measured by the hot flash diary, also showed no significant correlation with the BDI-II total score is all the more interesting, in the light of earlier findings linking vasomotor symptoms and depression (Blümel et al., 2004; Bosworth et al., 2001; Cohen et al., 2006; Joffe et al., 2002; Juang et al., 2005). This could suggest that in our sample, vasomotor symptoms had little direct association with severity of depression.

Also the finding of no correlation between sociodemographic variables and BDI-II total score is interesting. Depression has been linked to various sociodemographic variables (e.g., Freeman et al., 2006). The lack of such an association in our sample of postmenopausal women with a high degree of vasomotor complaints could suggest that other variables associated with menopause were of greater relevance than variables normally associated with depression. Another possible explanation is that our sample was relatively equal in many sociodemographic matters, leaving little variance in these variables. For example the women were of relatively equal age, only 5 reported not having children, and only 3 reported not living with a spouse. In addition the process of self-recruiting to the study may have led to a preselecting of fairly resourceful women.

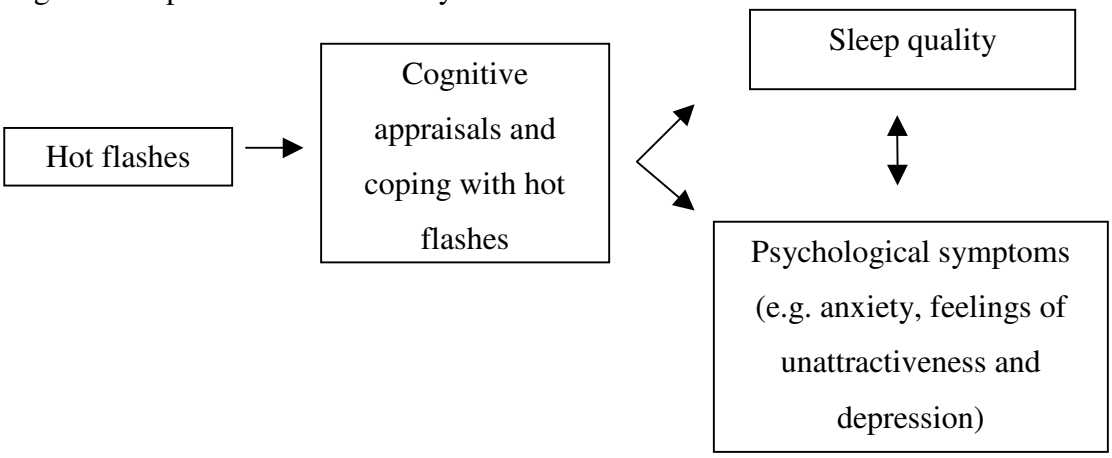
A multiple regression analysis was run to further study the relationship between the factors most correlated with depression (i.e., attractiveness, somatic symptoms, sleep problems and anxiety). The results from this analysis showed that the WHQ attractiveness dimension, followed by the sleep dimension and the anxiety/fear dimension of the WHQ were important predictors of severity of depression. The somatic symptoms factor did not contribute significantly to the prediction of depression after all other factors were controlled for. The fact that anxiety predicates depression in not surprising, considering that anxiety and

depression often are comorbid conditions (Brown et al., 2001; Zimmerman et al., 2002). Sleep problems, lowered self-esteem and thereby also a lowered feeling of attractiveness are also common features of depression.

As an explanation of these findings it would be reasonable to believe that a high prevalence of vasomotor symptoms, by increasing anxiety, increasing feelings of unattractiveness and decreasing quality of sleep, indirectly affects severity of depression. For example, the concern of having hot flashes could lead to anxieties related to social interaction, the features of hot flashes, such as sweating, could lead to feelings of unattractiveness, and night sweats could cause disturbances in sleep. However, when we inspect the intercorrelations between frequency and intensity of hot flashes, and the dimensions of the WHQ, including the somatic symptoms, anxiety/fear, attractiveness and sleep problems dimensions, we find that hot flashes do not correlate significantly with any of these dimensions. This leads us to suggest that vasomotor symptoms are not in and of themselves the basis for the relationship between these factors and depression.

As an extension of these findings, we suggest an expanded domino theory that also includes a cognitive component (Figure 3). The original domino theory suggested that hot flashes led to disturbed sleep that in turn led to depression (Campbell & Whitehead, 1977). We propose that how women appraise and subsequently cope with their hot flashes acts as an intervening variable between the presence of hot flashes and the psychological reactions to them. That is, if the hot flashes are interpreted as loss of control over one's body and the individual does not feel able to cope with the flashes, this could lead to worrying and anxiety, lowered sleep quality and over time reduced self-esteem and feelings of unattractiveness. Meanwhile, if the woman feels able to cope with the flashes and considers them a controllable and tolerable part of life, they could be present in the same amounts, but might not lead to psychological symptoms. Such a model would be in accordance with the findings of Hunter and Liao (1995).

Figure 3. Expanded domino theory



Acupuncture and Self-care versus Self-care Onlys's Effect on Severity of Depression

As with the efficiency of acupuncture and self-care versus self-care only on hot flashes and hours of sleep, there was no statistically significant difference between the two groups on severity of depression from baseline to 12 weeks. However, both within the acupuncture group and the self-care group, statistically significant decreases were found in severity of depression from baseline to 12 week. At 12 weeks, 14.1% of the women met the criteria for depression (BDI-II≥14), as opposed to 30.6% at baseline. In the total sample, 4.2% reported moderate to severe depression at 12 week (BDI≥20), compared to 17.4 % at baseline. This implies that after the intervention, the prevalence of depression in our sample is more in accordance with the prevalence in the general population. In both groups, those with higher levels of depression (BDI-II≥14) also presented the largest reduction in mean score from baseline to 12 weeks.

Factors Accounted for by the Intervention Contributing to a Decline in Depression

Bivariate correlations showed that the factor most strongly correlated with change in depression from baseline to 12 weeks, was the baseline level of depression. More specifically, the larger the severity of depression at baseline, the larger the improvement over the time of the intervention. This could indicate a certain effect of regression to the mean, where extreme measures at baseline show a tendency of reapproaching the mean at post-test. The same pattern was seen with the WHQ depressed mood dimension, health- and sleep related variables from the Acuflash questionnaire, hours of sleep per night and the WHQ total scale, as measured at baseline. That is, the more depression, somatic symptoms, sleep problems and general poor HR-QoL the women showed at baseline, the more they improved on the

BDI-II over the intervention. However several other factors as well were related to the decline in depression.

Not surprisingly, there were moderate correlations between decline in depression as measured by the BDI-II, and improvements in both the WHQ depressed mood dimension and the WHQ total score over time. In addition to these two, the anxiety/fear dimension and the somatic symptoms dimension of the WHQ were the only of the variables signifying change over the intervention, that were significantly related to decline in severity of depression from baseline to 12 weeks. With that in mind, it is interesting to note that like at baseline, there was no significant correlation between changes in frequency and intensity of hot flashes and the decline in BDI-II score. This leads us again to suggest that the presence of vasomotor symptoms did not directly influence the severity of depression in the present sample. In the expanded domino theory presented previously, we have suggested that the way women appraise and cope with their hot flashes might be more important than the actual frequency of hot flashes, and that this might play an important role in the development of psychological symptoms. The finding of a relationship between improvement in anxiety and improvement in depression, we further interpret to indicate the complex interplay between cognitive and psychological reactions.

The fact that significant improvements in severity of depression were found both in the acupuncture group and the self-care group is interesting. This leads us to the question of what factors accounted for by the interventions that have led to these improvements. It is reasonable to believe that the intervention in itself might have led to decreased levels of anxiety and thereby also decreased levels of depression. This is supported by the finding of significant improvements in the WHQ anxiety/fear dimension, in addition to the relationship between improvements in the anxiety/fear dimension and depression. We propose that in addition to the specific effects of the interventions of acupuncture or self-care, the treatment experience as a whole has an effect. Being part of the Acuflash study would for all participants have entailed a special attention being paid to them and their hassles. All participants received information leaflets on available self-provided care, and they also received telephone reminders before each week of registering hot flashes. All in all, this could have contributed to a sense of calmness and control about their symptoms, reducing the

anxiety arousing effect of the stresses of the menopause, which, in accordance with the expanded domino theory, could lead to decreases in depression.

Limitations

Some limitations should be mentioned. Firstly, the women in our sample were selected based on a relatively high level of hot flashes (more than 7 hot flashes per 24 hours in a one-week period). This selection yields a good opportunity to study the consequences of a high menopausal symptom pressure. It could, however, also contribute to difficulties in generalizing the findings to women not thus selected.

Secondly, in studying acupuncture, different researchers have pointed to the challenges of obtaining a good control condition (Leo & Ligot, 2007; Wang et al. 2008). One limitation of the present study is the lack of a control group also receiving some form of needling treatment. On the other hand, the use of more stringent acupuncture designs will often also lead to a more fixed treatment in the experimental group. One of the great strengths of the present study is the individualized treatment given to all the women in the acupuncture group, making it similar to the treatment given in general practice.

Thirdly, the small sample size could have contributed to a too small power to obtain significant results. For instance, this might be the case for the lack of significant differences between the groups in terms of hot flash reduction over the time of the intervention. Such differences were found by Borud et al. (in press) in the larger Acuflash-sample. It is possible that an effect would have been found with a larger sample size.

When it comes to the WHQ, some weaknesses have been observed in a psychometric evaluation of the Norwegian version, when applied to a sample of women with a high prevalence of hot flashes (Borud et al., 2009). Among these are low factor structure, with the original factor structure replicated only to a limited extent, and low alpha values in some of the dimensions. This was especially true for the vasomotor symptoms dimension, were the Cronbach's alpha was .12, partly explained by the low number of items included in the dimension. In addition, low alpha values were found in the sleep problem dimension, the attractiveness dimension and the anxiety/fear dimension. In the present study, the alpha value for vasomotor symptoms at baseline could not be calculated at all, and also several dimensions showed low Cronbach’s alphas. This means that care should be taken in the interpretation of the dimensions of the WHQ. Future research might consider

using the revised 23-item version of the WHQ (Girod et al., 2006), where some of the psychometric problems from the original 36-item WHQ have been addressed.

Finally, the present study was not specifically designed to study depression. Therefore several factors that have been related to depression in previous research were not included in the measures. Among these is a measure of previous depression, which probably would have shown itself related to severity of depression (Avis et al., 1994; Callegari et al., 2007; Freeman et al., 2004; Hunter, 1992a). Another such factor is negative life events. It is likely that stressors affecting the women's life would also affect their level of depression (Binfa et al., 2004; Blümel et al., 2004; Hardy & Kuh, 2002). Further measures of psychological variables to gain an insight into the cognitive appraisals and attitudes of these women concerning the menopause, would also have shed an interesting light on the severity of depression. We have proposed that not only factors related to the menopause in itself, but also such personal psychological mechanisms are of importance in the development of depressive symptoms in menopause. Future studies should include measures of these psychological factors.

Clinical implications

The results from the present study yields useful information regarding treatment practice for menopausal problems. First of all, the present study finds an elevated prevalence of depression in our sample of postmenopausal women with a high frequency of hot flashes. By adding a cognitive component as an intervening variable between the presence of hot flashes and psychological reactions to them, it is reasonable to believe that some menopausal women might be extra vulnerable to develop depression, regardless of their menopausal status. Thus, we propose that our findings can be generalized also to pre- and perimenopausal women with vasomotor symptoms. Considering the large amount of women experiencing hot flashes (Kronenberg, 1990), and given the personal and socioeconomic burden of depression (London School of Economics and Political Science, 2006), finding appropriate treatment solutions is important.

Second, the finding of improvement in severity of depression and in dimensions of the WHQ, both in the acupuncture group and in the self-care group, suggests that the treatment experience as a whole had an effect. We have proposed that reducing the anxiety arousing effects of the menopausal symptoms by providing information and means to cope with these symptoms, may have led to a decrease in

depression severity. Considering the recent findings of health risks associated with hormone replacement therapy (Collaborative Group on Hormonal Factors in Breast Cancer, 1997; Writing Group for the Women's Health Initiative Investigators, 2002; Million Women Study Collaborators, 2003), the finding of a lacking association between presence of hot flashes and severity of depression leads us to suggest that menopausal women might benefit from a change in focus from medical to psychological and/or alternative treatments.

Based on our findings we suggest that with relatively little resources, much can be done to alleviate depression and to improve the overall quality of life of menopausal women. Counseling supplied by low threshold services might be effective. Such services should focus on information on common symptoms associated with menopause, and giving advice on how to cope with these, thereby giving women a sense of control over their menopausal symptoms. Group-counseling could provide important social support and make such services especially cost efficient. Considering the personal and societal costs of depression, such preventive measures would be highly recommendable.

Conclusion

We conclude that both use of acupuncture in addition to self-care, and self-care only, led to significant improvements in hot flash frequency and intensity, improvements in the vasomotor and anxiety/fears dimension of the WHQ and decreased levels of depression. This implies the importance of the treatment experience as a whole. We also suggest an expanded domino theory in explaining depression in menopause, including a cognitive component as an intervening variable between the presence of hot flashes and psychological reactions to them.

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APPENDIX A

A-1: Approval from the Regional Committee for Medical Research Ethics

A-2: Approval from the Norwegian Data Inspectorate

A-3: Approval from the Norwegian Biobank Registry

A-1

Sameline Grimsgaard
UNN, Klinisk Forskningssenter
9038 TROMSØ

Deres ref.: 5.2005.2587 Vår ref.: 200507687-4/IAY/400 Dato: 28.12.2005

P REK NORD 102/2005 - EFFEKT AV AKUPUNKTUR MOT HETETOKTER HOS POSTMENOPAUSLAE KVINNER - SLUTTVURDERING - KOMITEEN HAR INGEN INNVENDINGER MOT AT PROSJEKTET GJENNOMFØRES

Prosjektet ble lagt fram for Regional komité for medisinsk forskningsetikk, Nord-Norge (REK NORD) i møtet 15.12.2005. I referatet heter det:

Formålet med hovedstudien er å undersøke effekten av akupunkturbehandling på forekomst av hetetokter og helserelatert livskvalitet hos postmenopausale kvinner som har 7 eller flere hetetokter pr 24 timer, sammenlignet med det kvinner kan gjøre på egenhånd for å lindre plagene. Kvinnene som inkluderes randomiseres til 10 akupunkturbehandlinger eller egenomsorg (kontroll) i 12 uker. 286 kvinner inkluderes.
Formålet med delstudien er å kartlegge mulige mekanismer for en eventuell effekt av akupunktur ved å måle biologiske variabler hos en subgruppe av kvinne i hovedstudien. Delstudien omfatter 70 kvinner (35 i hver behandlingsarm) før og etter intervensjonsperioden.
Komiteen klassifiserer prosjektet som terapeutisk, klinisk anvendt forskning på friske kvinner.

Komiteen har følgende merknader til prosjektet:
Dokumentene inneholder uoverensstemmende informasjon om hvilket beløp som skal utbetales til deltakerne (kr 400 og kr 500).

Vedtak:
Regional komité for medisinsk forskningsetikk, Nord-Norge (REK Nord) har ingen innvendinger mot at prosjektet gjennomføres.

Det forutsettes at prosjektet er godkjent av aktuelle formelle instanser før det settes i gang. Det forutsettes at prosjektet forelegges komiteen på nytt, dersom det under gjennomføringen skjer komplikasjoner eller endringer i de forutsetninger som komiteen har basert sin avgjørelse på. Komiteen ber om å få melding dersom prosjektet ikke blir sluttført.

Vennlig hilsen
for
Ingunn Ytrehus
førstekonsulent

May Liss Paulsen
konsulent

REGIONAL KOMITÉ FOR MEDISINSK FORSKNINGSETIKK, NORD-NORGE
Regional komité for medisinsk forskningsetikk, Nord
Universitetet i Tromsø, No-9037 Tromsø, tlf 77 64 40 00, e-post postmottak@uit.no, http://uit.no
førstekonsulent Ingunn Ytrehus, tlf 77 64 48 76, faks 77 64 53 00, e-post rek-nord@fagmed.uit.no

A-2

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

NSD

Harald Hårfagres gate 29
N-5007 Bergen
Norway
Tel: +47-55 58 21 17
Fax: +47-55 58 96 50
nsd@nsd.uib.no
www.nsd.uib.no
Org.nr. 985 321 884

Sameline Grimsgaard
Klinisk forskningssenter
Universitetssykehuset Nord-Norge HF
Boks 78
9038 TROMSØ

Vår dato: 26.01.2006 Vår ref: 13939/SS Deres dato: Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 05.01.2006. All nødvendig informasjon om prosjektet forelå i sin helhet 26.01.2006. Meldingen gjelder prosjektet:

13939	*Effectiveness of acupuncture-care for treatment of hot flushes among postmenopausal women*
Behandlingsansvarlig	*Universitetssykehuset Nord-Norge HF, ved institusjonens overste leder*
Daglig ansvarlig	*Sameline Grimsgaard*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/endringsskjema. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/register/

Personvernombudet vil ved prosjektets avslutning, 31.12.2007 rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Bjørn Henrichsen Synnøve Serigstad

Kontaktperson: Synnøve Serigstad tlf: 55 58 35 42

Vedlegg: Prosjektvurdering

Personvernombudet for forskning, NSD

Prosjektvurdering - Kommentar

13939

Personvernombudet finner deltakerinformasjonen tilfredsstillende, etter at den er revidert etter ombudets anbefalinger. Ombudet vil presisere at anonymisering 31.12.2007 innebærer at koplingsnøkkelen makuleres, slik at det ikke lenger er mulig å knytte opplysningene i datamaterialet til enkeltpersoner.

Personvernombudet forutsetter at forskningsbiobanken er godkjent av regional komité for medisinsk forskningsetikk.

A-3

Sosial- og helsedirektoratet

Sameline Grimsgaard
UNN
Klinisk Forskningssenter
9038 TROMSØ

Deres ref:
Saksbehandler: jte
Vår ref: 06/110
Arkivkode:
Dato: 25.1.2006

Melding om opprettelse av forskningsbiobank: Effekt av akupunkturbehandling mot hetetokter hos postmenopausale kvinner

Vi viser til brev vedrørende ovennevnte. Sosial- og helsedirektoratet er delegert å vurdere meldinger om opprettelse av forskningsbiobanker i henhold til biobankloven § 4.

Direktoratet har ingen innsigelser til at forskningsbiobanken opprettes i henhold til biobankloven.

Direktoratet forutsetter at opprettelsen av den planlagte forskningsbiobanken oppfyller nødvendige krav til godkjenning, konsesjon m.v. i henhold til annet relevant regelverk, herunder bioteknologiloven, helseregisterloven og legemiddelloven.

Deres søknad om utførsel vil bli besvart i separat brev.

Meldingen om forskningsbiobanken vil bli sendt til Nasjonalt folkehelseinstitutt som har fått ansvaret for å føre et offentlig tilgjengelig register over landets biobanker, jf. biobankloven § 6.

Med vennlig hilsen

Ragnhild Castberg e.f.
seniorrådgiver

Jill Terserus
rådgiver

Kopi:
Leder Bjørn Odvar Eriksen, Klinisk Forskningssenter, UNN, 9038 TROMSØ
REK Nord 200507687-4/IAY/400
Biobankregisteret

Sosial- og helsedirektoratet
Avdeling for spesialisthelsetjenester

Postadr: Pb 7000 St Olavs plass, 0130 Oslo • Besøksadr: Universitetsgaten 2, Oslo
Tel: 810 20 326 • Faks: 24 16 30 08 • Org.nr.: 983 544 622 • postmottak@shdir.no • www.shdir.no/ts

APPENDIX B

”Measures”

B-1: Acuflash Questionnaire

B-2: Hot flash diary

B-3: The Beck Depression Inventory, second version

B-4: The Women’s Health Questionnaire, Norwegian translation by the MAPI Research Institute

B-1

Deltaker: _____

Dato: _____

Randnr.: _____

ACUFLASH SPØRRESKJEMA

UTDANNING, ARBEID OG BOFORHOLD

Hvilken utdanning er den høyeste du har fullført?

- ☐ Mindre enn 7 år grunnskole
- ☐ Grunnskole 7-10 år, framhaldsskole, folkehøyskole
- ☐ Realskole, middelskole, yrkesskole, 1-2 årig vid. skole
- ☐ Artium, øk. gymnas, allmennfaglig retning i vid. skole
- ☐ Høgskole, universitet, mindre enn 4 år
- ☐ Høgskole, universitet, 4 år eller mer

Hvor mange hele års skolegang har du gjennomført?
(Ta med alle år du har gått på skole eller studert)

Antall år: _____

Er du i lønnet arbeid ☐ Ja ☐ Nei

Hvis ja, hvor høy er bruttoinntekten i husholdet pr. år?

- ☐ Under 150.000
- ☐ 151.000-300.000
- ☐ 301.000-450.000
- ☐ 451.000-600.000
- ☐ 601.000-750.000
- ☐ 751.000-1 million
- ☐ over 1 million

Bor du sammen med noen? ☐ Ja ☐ Nei

Hvis ja,

Ektefelle/samboer ☐ Ja ☐ Nei

Andre personer, 18 år og eldre ☐ Ja ☐ Nei Ant. _____

Personer under 18 år ☐ Ja ☐ Nei Ant. _____

MENSTRUASJON

Hvor gammel var du da du fikk menstruasjon første gang?

_____ år

Hvor mange år tok det før menstruasjonen ble regelmessig?

Ett år eller mindre	Mer enn ett år	Aldri	Husker ikke
☐	☐	☐	☐

Da du hadde menstruasjon, hadde du noen av disse plagene?
(Sett ett kryss for hvert spørsmål)

Var du nedtrykt (deprimert) eller irritabel?

Nei	Ubetydelig	Merkbart	Plagsomt
☐	☐	☐	☐

Hadde du smertefulle bryst?

Nei	Ubetydelig	Merkbart	Plagsomt
☐	☐	☐	☐

Hadde du hovne hender/fetter, vektøkning eller følelse av å ese ut?

Nei	Ubetydelig	Merkbart	Plagsomt
☐	☐	☐	☐

Hvordan stoppet menstruasjonen?

- ☐ Av seg selv
- ☐ Operert vekk eggstokkene
- ☐ Operert vekk livmoren
- ☐ Usikker, har brukt hormontilskudd som gav regelmessige blødninger
- ☐ Annet

Alder da menstruasjonen opphørte _____ år

GRAVIDITET, FØDSLER OG PREVENSJON

Har du barn? ☐ Ja ☐ Nei

Egne barn ☐ Ja ☐ Nei Ant. _____

Adoptivbarn ☐ Ja ☐ Nei Ant. _____

Angi fødselsår for hvert barn du har født om (også dødfødte eller barn som døde senere). Dersom du ikke har født barn fortsett til neste spørsmål.

Barn 1 Fødselsår _____ Barn 4 Fødselsår _____

Barn 2 Fødselsår _____ Barn 5 Fødselsår _____

Barn 3 Fødselsår _____ Barn 6 Fødselsår _____

Har du hatt svangerskap som varte i mindre enn 6 mnd., dvs spontanabort eller selvbestemt abort?

☐ Ja ☐ Nei

Hvis ja, hvor mange aborter har du hatt i alt? Ant. _____

Har du noen gang brukt p-piller, minipiller inkludert?

☐ Ja ☐ Nei

Hvis ja, hvor lenge har du brukt p-piller i alt? _____ år

Hvor gammel var du første gang du brukte p-piller? _____ år

BRUK AV HORMONPREP. I OVERGANGSALDEREN

Har du noen gang brukt hormontabletter/-plaster?

☐ Ja ☐ Nei

Hvis JA, hvor lenge har du brukt hormontabletter/-plaster i alt?

_____ ant. år _____ ant. mnd

Hvor gammel var du første gang du brukte hormontabl./plaster?

_____ år

Hvorfor begynte du å bruke hormontabletter/-plaster?

☐ Lindre plager i overgangsalderen (hetetokter, underlivsplager mm.

☐ Forebygge beinskjørhet

☐ Forebygge hjerte-/karsykdommer

☐ Annet

Når sluttet du å bruke hormontabletter/-plaster?

_____ mnd _____ årstall

Bruker du østrogenpreparat i skjeden nå? (krem/stikkpiller/vaginaltabletter/vaginalinnlegg)

☐ Ja ☐ Nei

Hvis ja, hvor lenge har du brukt det? _____ år _____ mnd

Bruker du hormonspiral nå? ☐ Ja ☐ Nei

HELSE OG BRUK AV HELSETJENESTER, MEDISINER OG KOSTTILSKUDD

Hvor høy er du? _____ cm

Hvor mye veier du i dag? _____ kg

Hvordan er helsen din nå? (Sett bare ett kryss)

☐ Dårlig

☐ Ikke helt god

☐ God

☐ Svært god

Har du eller har du hatt?	Ja	Nei	Alder første gang
Høyt blodtrykk	☐	☐	_____
Stoffskiftesykdom	☐	☐	_____
Diabetes (sukkersyke) (ikke svangerskapsdiabetes)	☐	☐	_____

Hvor ofte er du plaget av søvnløshet?

☐ Aldri, eller noen få ganger i året

☐ 1-3 ganger i måneden

☐ Omtrent 1 gang i uken

☐ Mer enn en gang i uken

Har du siste året vært plaget av søvnløshet som har gått ut over arbeidsevnen?

☐ Ja ☐ Nei

Med tanke på egen helse eller sykdom siste år, hvor mange ganger har du vært: (Sett 0 hvis du ikke har hatt slik kontakt)

	Ant. ganger siste år
Innlagt i sykehus	_____
Hos psykolog eller lege (allemannslege/legevakt/spesialist)	_____
Hos fysioterapeut eller kiropraktor	_____
Hos utøver av alternativ behandling (homeopat/akupunktør/soneterapeut/naturmedisiner	_____

Har du noen gang fått akupunkturbehandling?

☐ Ja ☐ Nei

Hvis JA, angi sykdom/plage som du har brukt akupunkturbehandling for og effekt av behandlingen:

Sykdom/plage	Forverring	Ingen effekt	Lite effekt	God effekt
_____	☐	☐	☐	☐
_____	☐	☐	☐	☐
_____	☐	☐	☐	☐
_____	☐	☐	☐	☐

Tror du akupunkturbehandling kan ha effekt (generelt)?

☐ Ja

☐ Nei

☐ Vet ikke

☐ Andre kommentarer _____

Har du noen gang brukt alternativ behandling mot plager i forb. med overgangsalderen? (enten ved å oppsøke utøver eller som egenbehandling)

☐ Ja ☐ Nei

Hvis JA, hvilken type behandling har du fått

Angi behandlingsform	Egenbehandling	Hos utøverbehandler
_____	☐	☐
_____	☐	☐
_____	☐	☐
_____	☐	☐

Tror du at plagene du har i forbindelse med overgangsalderen kan lindres av akupunktur?

☐ Ja

☐ Nei

☐ Vet ikke

☐ Andre kommentarer _____

BRUK AV MEDISINER OG KOSTTILSKUDD

Har du i løpet av de siste 4 ukene brukt legemidler eller kosttilskudd (herunder reseptbelagte og reseptfrie legemidler, naturmidler, kosttilskudd)?

☐ Ja ☐ Nei

Hvilke preparater har du brukt og hvor ofte?

Angi preparat	Daglig	Hver uke men ikke daglig	Sjeldnere enn hver uke	Grunn til at du har brukt dem
_____	☐	☐	☐	_____
_____	☐	☐	☐	_____
_____	☐	☐	☐	_____
_____	☐	☐	☐	_____

	Ja, daglig	Ikke	Nei
Bruker du tran, trankapsler, fiskeoljekapsler?	☐	☐	☐

FYSISK AKTIVITET I FRITID OG ARBEID

Fritid siste året.
Hva slags aktivitet har du utført i din fritid siste året? Dersom aktiviteten varierer mye, for eks. mellom sommer og vinter, så tenk deg et gjennomsnitt (sett ett kryss i den ruten som passer best)

☐ Leser, ser på TV eller annen stillesittende aktivitet

☐ Spaserer, sykler eller beveger deg på annen måte minst 4 timer i uka (her kan du også regne med gang eller sykling til arbeidssted, søndagsturer mm.)

☐ Driver du med mosjonsidrett, tyngre hagearbeid eller lignende? (merk at aktiviteten skal vare minst fire timer i uken)

☐ Trener hardt eller driver konkurranseidrett regelmessig og flere ganger i uken

Arbeidsaktivitet siste året.
Hva slags aktivitet har du vanligvis i arbeidet ditt?

☐ For det meste stillesittende arbeid (eks. kontorarbeid)

☐ Arbeid som krever at du går mye (du blir ikke svett og hjertet slår ikke fortere, eks. ekspeditør, lærer, frisør)

☐ Arbeid der du går mye og løfter mye (du svetter litt og hjertet slår raskere, eks. syke-/hjelpepleier, postbetjent)

☐ Tungt kroppsarbeid (du svetter en del og hjertet slår raskt, tunge løft, jordbruk, tungt omsorgsarbeid)

Har du vært yrkesaktiv de siste 12 mnd.? ☐ Ja ☐ Nei

Hvor stor stillingsprosent har du? _____ %

FYSISK AKTIVITET SISTE 3 MND

Angi i skjemaet nedenfor de fritidsaktiviteter du har deltatt i siste tre måneder. Oppgi hvor ofte og hvor lenge pr. gang du holdt på. Angi aktivitetsnivået (se nedenfor) på en skala fra 1 (lavt) til 4 (høyt)

A. Lese bøker/TV-titting
B. Gå til/spasere
C. Gå i skogen/på fjellet/jakte
D. Jogge/løpe
E. Sykle (også trimsykkel)
F. Svømme
G. Tennis/badminton/squash
H. Golf/bowling
I. Gymnastikk/aerobic/trim/turgåing/dans/ballett
J. Styrketrening/vekttrening
K. Husarbeid
L. Ski (langrenn), turgåing/konkurranse
M. Kjøre slalåm/telemark
N. Ake/sparke, gå på skøyter (også rulleskøyter)
O. Ro/padle/seile
P. Plukke bær/sopp/fiske
Q. Annet

Aktivitetsnivå for fritidsaktiviteter

1. = Overveiende stillesittende
2. = Lett trening. Du blir ikke svett og hjertet slår ikke fortere
3. = Middels hard trening. Du svetter litt og hjertet slår litt fortere
4. Hard trening. Du svetter mye og hjertet slår fort.

Aktivitet	Gj.snitt tid pr.g. (min)	Gj.snitt Ant. pr. mnd	Aktivitetsnivå			
			1	2	3	4
Eks. A	*35*	*12*	*x*			

TRANSPORT TIL OG FRA ARBEID

Spørsmålene gjelder transport mellom hjem og arbeidsplass siste 3 måneder

Hvordan kommer du deg vanligvis til/fra arbeid?

Ta et gjennomsnitt for en måned. (Angi antall ganger du bruker de forskjellige transportmidlene).

	Ant. ganger pr. mnd
Bil/buss/trikk/tog/båt	_____
Sykkel	_____
Til fots	_____

Hvor lang tid tar vanligvis transporten til/fra arbeid?
(Du kan fylle ut flere kategorier)

Bil/buss/trikk/tog/båt	_____ min.
Sykkel	_____ min.
Til fots	_____ min.

LEVEVANER

Er du vegetarianer? ☐ Ja ☐ Nei

Har du røykt/røyker du?

Ja, daglig	Ja, men ikke daglig	Ja, tidligere	Nei, har aldri røykt
☐	☐	☐	☐

Hvor mange kopper kaffe og te drikker du daglig?

Koffeinholdig kaffe	_____ kopper
Koffeinfri kaffe	_____ kopper
Te	_____ kopper

Er du totalavholdskvinne? ☐ Ja ☐ Nei

Hvis nei, hvor ofte og hvor mye drakk du i gj.snitt siste år?

	Aldri, gjelden	1 pr.mnd	2-3 pr. mnd	1 pr. uke	2-4 pr. uke	5-6. pr. uke	1+ pr. dag
Øl (1/2 l)	☐	☐	☐	☐	☐	☐	☐
Vin (glass)	☐	☐	☐	☐	☐	☐	☐
Brennevin (drinker)	☐	☐	☐	☐	☐	☐	☐

Mange takk for hjelpen!

B-2

Registrering nr. 1 (uke 4): _____

Randnr.: _____

Deltaker intialer: _____

SKJEMA FOR REGISTRERING AV HETETOKTER

Utfylling: Oppgi antall hetetokter i løpet av dagen og siste natt. Velg et tall fra 0 *(ikke i det hele tatt)* til 10 *(svært mye)* for å angi gjennomsnittlig hvor mye hetetoktene har plaget deg. Noter hvor mange timer du sov siste natt. Skriv ned svaret ditt hver kveld før du legger deg.

0	1	2	3	4	5	6	7	8	9	10
Ikke i det hele tatt										Svært mye

	Dag/dato	Dag/dato	Dag/dato	Dag/dato	Dag/dato	Dag/dato	Dag/dato
	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall
DAG Antall svette- eller hetetokter i løpet av dagen							
NATT Antall svette- eller hetetokter i løpet av siste natt							
Tall for hvor mye svette- eller hete-toktene plaget meg siste døgn							
Antall timer med søvn siste natt							

Registrering nr. 2 (uke 8): _____

Randnr.: _____

Deltaker intialer: _____

SKJEMA FOR REGISTRERING AV HETETOKTER

Utfylling: Oppgi antall hetetokter i løpet av dagen og siste natt. Velg et tall fra 0 *(ikke i det hele tatt)* til 10 *(svært mye)* for å angi gjennomsnittlig hvor mye hetetoktene har plaget deg. Noter hvor mange timer du sov siste natt. Skriv ned svaret ditt hver kveld før du legger deg.

0 Ikke i det hele tatt 1 2 3 4 5 6 7 8 9 10 Svært mye

	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____
	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall
DAG Antall svette- eller hetetokter i løpet av dagen	_____	_____	_____	_____	_____	_____	_____
NATT Antall svette- eller hetetokter i løpet av siste natt	_____	_____	_____	_____	_____	_____	_____
Tall for hvor mye svette- eller hete-toktene plaget meg siste døgn	_____	_____	_____	_____	_____	_____	_____
Antall timer med søvn siste natt	_____	_____	_____	_____	_____	_____	_____

Registrering nr. 3 (uke 12):_____

Randnr.: _____

Deltaker intialer: _____

SKJEMA FOR REGISTRERING AV HETETOKTER

Utfylling: Oppgi antall hetetokter i løpet av dagen og siste natt. Velg et tall fra 0 *(ikke i det hele tatt)* til 10 (*svært mye)* for å angi gjennomsnittlig hvor mye hetetoktene har plaget deg. Noter hvor mange timer du sov siste natt. Skriv ned svaret ditt hver kveld før du legger deg.

0	1	2	3	4	5	6	7	8	9	10
Ikke i det hele tatt										Svært mye

	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____	Dag/dato _____
	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall	Antall/ tall
DAG Antall svette- eller hetetokter i løpet av dagen	_____	_____	_____	_____	_____	_____	_____
NATT Antall svette- eller hetetokter i løpet av siste natt	_____	_____	_____	_____	_____	_____	_____
Tall for hvor mye svette- eller hete-toktene plaget meg siste døgn	_____	_____	_____	_____	_____	_____	_____
Antall timer med søvn siste natt	_____	_____	_____	_____	_____	_____	_____

B-3

BDI™-II Selvvurderingshefte

Navn _____

Kjønn ☐ Kvinne ☐ Mann Testdato år ☐☐ måned ☐☐ dag ☐☐

Testleder _____

Instruksjon

Dette heftet består av 21 grupper av utsagn. Les nøye gjennom hvert utsagn, og velg det utsagnet i hver gruppe som best beskriver hvordan du har følt deg i løpet av de siste to ukene, medregnet i dag.

Sett en ring rundt tallet foran det utsagnet du velger. Dersom flere utsagn innen en gruppe ser ut til å passe like bra, velger du utsagnet med det høyeste tallet.

Pass på at du bare velger ett av utsagnene i hver gruppe. Dette gjelder også gruppe 16 (Endringer i søvnmønster) og gruppe 18 (Endringer i matlyst).

Assessio
Assessio Norge AS

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All kopiering forbudt!

Trykk: Sandvikens Tryckeri AB, Sandviken 2005
Art.nr: 800-401

1. **Tristhet**
   - 0 Jeg føler meg ikke trist.
   - 1 Jeg føler meg trist store deler av tiden.
   - 2 Jeg føler meg trist hele tiden.
   - 3 Jeg er så trist eller ulykkelig at jeg ikke holder det ut.

2. **Pessimisme**
   - 0 Jeg er ikke motløs med tanke på fremtiden.
   - 1 Jeg er mer motløs med tanke på fremtiden enn jeg var før.
   - 2 Jeg forventer at ting ikke vil gå i orden for meg.
   - 3 Jeg føler at fremtiden min er håpløs, og at alt bare vil bli verre.

3. **Mislykkethet**
   - 0 Jeg føler meg ikke mislykket.
   - 1 Jeg har mislyktes mer enn jeg burde.
   - 2 Når jeg ser tilbake, ser jeg mange nederlag.
   - 3 Jeg føler meg som en fullstendig mislykket person.

4. **Tap av glede**
   - 0 Jeg får like mye glede ut av ting jeg liker som før.
   - 1 Jeg får ikke like mye glede ut av ting som før.
   - 2 Jeg får svært liten glede ut av de tingene som jeg pleide å like.
   - 3 Jeg får ingen glede ut av de tingene som jeg pleide å like.

5. **Skyldfølelse**
   - 0 Jeg føler ikke særlig mye skyld.
   - 1 Jeg føler skyld for mange ting jeg har gjort eller burde gjøre.
   - 2 Jeg føler skyld mesteparten av tiden.
   - 3 Jeg føler skyld hele tiden.

6. **Følelse av å bli straffet**
   - 0 Jeg føler ikke at jeg blir straffet.
   - 1 Jeg føler det som om jeg kan bli straffet.
   - 2 Jeg forventer å bli straffet.
   - 3 Jeg føler det som om jeg blir straffet.

7. **Mislike seg selv**
   - 0 Mitt selvbilde er uforandret.
   - 1 Jeg har fått mindre selvtillit.
   - 2 Jeg er skuffet over meg selv.
   - 3 Jeg misliker meg selv.

8. **Selvkritiskhet**
   - 0 Jeg kritiserer eller bebreider ikke meg selv mer enn vanlig.
   - 1 Jeg kritiserer meg selv mer enn jeg pleide.
   - 2 Jeg kritiserer meg selv for alle mine feil.
   - 3 Jeg klandrer meg selv for alt leit som skjer.

9. Selvmordstanker

0 Jeg har ingen tanker om å ta livet mitt.
1 Jeg har tanker om å ta livet mitt, men har ingen planer om å gjøre det.
2 Jeg ønsker å ta livet mitt.
3 Jeg ville tatt livet mitt dersom jeg fikk mulighet til det.

10. Gråt

0 Jeg gråter ikke mer enn før.
1 Jeg gråter mer enn før.
2 Jeg gråter for hver minste ting.
3 Jeg ønsker å gråte, men klarer det ikke.

11. Rastløshet

0 Jeg er ikke mer rastløs eller urolig enn vanlig.
1 Jeg føler meg mer rastløs eller urolig enn vanlig.
2 Jeg er så rastløs og urolig at det er vanskelig å være i ro.
3 Jeg er så rastløs og urolig at jeg må bevege meg eller gjøre noe hele tiden.

12. Tap av interesse

0 Jeg har ikke mistet interessen for andre mennesker eller aktiviteter.
1 Jeg er mindre interessert i andre mennesker eller ting enn tidligere.
2 Jeg har mistet det meste av min interesse for mennesker eller ting.
3 Det er vanskelig å bli interessert i noe som helst.

13. Ubesluttsomhet

0 Jeg tar beslutninger like lett som før.
1 Jeg synes det er vanskeligere å ta beslutninger nå enn før.
2 Jeg har mye større vanskeligheter med å ta beslutninger nå enn før.
3 Jeg har vanskeligheter med å ta enhver beslutning.

14. Verdiløshet

0 Jeg føler meg ikke verdiløs.
1 Jeg opplever meg ikke like verdifull og nyttig som før.
2 Jeg føler meg mer verdiløs enn andre mennesker.
3 Jeg føler meg fullstendig verdiløs.

15. Tap av energi

0 Jeg har like mye energi som før.
1 Jeg har mindre energi enn jeg pleide.
2 Jeg har ikke nok energi til å gjøre særlig mye.
3 Jeg har ikke nok energi til å gjøre noe som helst.

Snu

S 3

16. Endringer i søvnmønster

0 Jeg har ikke merket noen endringer med søvnen min.
1a Jeg sover litt mer enn vanlig.
1b Jeg sover litt mindre enn vanlig.
2a Jeg sover mye mer enn vanlig.
2b Jeg sover mye mindre enn vanlig.
3a Jeg sover mesteparten av døgnet.
3b Jeg våkner opp 1–2 timer for tidlig, og får ikke sove igjen.

17. Irritabilitet

0 Jeg er ikke mer irritabel enn vanlig.
1 Jeg er mer irritabel enn vanlig.
2 Jeg er mye mer irritabel enn vanlig.
3 Jeg er irritabel hele tiden.

18. Endringer i matlysten

0 Jeg har ikke merket noen endringer i min matlyst.
1a Min matlyst er litt mindre enn vanlig.
1b Min matlyst er litt større enn vanlig.
2a Min matlyst er mye mindre enn vanlig.
2b Min matlyst er mye større enn vanlig.
3a Jeg har ingen matlyst i det hele tatt.
3b Jeg føler trang til å spise hele tiden.

19. Konsentrasjonsvansker

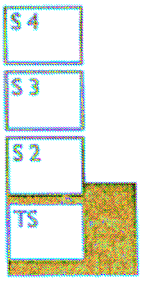
0 Jeg kan konsentrere meg like bra som før.
1 Jeg kan ikke konsentrere meg like godt som vanlig.
2 Det er vanskelig for meg å konsentrere meg om noe som helst særlig lenge.
3 Jeg merker at jeg ikke kan konsentrere meg om noe som helst.

20. Tretthet og utmattelse

0 Jeg er ikke mer trøtt eller utmattet enn jeg pleier.
1 Jeg blir fortere trøtt eller utmattet enn jeg pleier.
2 Jeg er for trøtt eller utmattet til å gjøre mange av de tingene jeg pleide å gjøre.
3 Jeg er for trøtt eller utmattet til å gjøre mesteparten av de tingene jeg pleide å gjøre.

21. Tap av seksuell interesse

0 Jeg har ikke merket noen endring i min interesse for sex i det siste.
1 Jeg er mindre interessert i sex enn jeg pleide å være.
2 Jeg er mye mindre interessert i sex nå.
3 Jeg har mistet all interesse for sex.



B-4

Deltaker: _____

Dato: _____

Randnr.: _____

SPØRRESKJEMA OM HELSE FOR KVINNER

Vennligst oppgi hvorledes du har det nå, eller hvorledes du har hatt det DE SISTE DAGENE, ved å krysse av i den rette ruta som svar på hvert av de følgende utsagnene:

1. Jeg våkner tidlig og sover deretter dårlig resten av natta

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

2. Jeg får anfall av angst eller panikk tilsynelatende uten noen som helst grunn

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

3. Jeg føler meg elendig og trist

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

4. Jeg kjenner meg engstelig når jeg går hjemmefra alene

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

5. Jeg har mistet interessen for saker og ting

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

6. Jeg får hjertebank eller en følelse av "sommerfugler i magen"

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

7. Jeg gleder meg fremdeles over ting jeg har pleid å glede meg over

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

8. Jeg føler at livet ikke er verdt å leve

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

9. Jeg føler meg anspent eller har mye indre spenning

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

10. Jeg har god appetitt

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

11. Jeg er rastløs og kan ikke holde meg i ro

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

12. Jeg er mer irritabel enn vanlig

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

13. Jeg bekymrer meg for å bli gammel

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

14. Jeg har hodepine

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

15. Jeg kjenner meg mer sliten enn vanlig

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

16. Jeg får anfall av svimmelhet

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

17. Brystene mine kjennes ømme eller ubekvemme

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

18. Jeg plages av ryggsmerter eller smerter i armer eller ben

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

19. Jeg får hetetokter

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

20. Jeg er mer klønete enn vanlig

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

21. Jeg kjenner meg ganske livlig og energisk

Ja, helt klart ☐ | Ja, noen ganger ☐ | Nei, ikke så mye ☐ | Nei, ikke i det hele tatt ☐

22. Jeg får kramper eller føler ubehag i underlivet

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

23. Jeg føler meg kvalm

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

24. Jeg har mistet interessen for seksuell aktivitet

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

25. Jeg opplever tilfredshet og velvære

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

26. Jeg får sterke menstruasjonsblødninger
(vennligst hopp over hvis det ikke forekommer menstruasjoner)

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

27. Jeg plages av svettetokter om natta

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

28. Underlivet føles oppblåst

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

29. Jeg har vanskelig for å falle i søvn

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

30. Jeg merker ofte en prikkende følelse i hender og føtter

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

31. Jeg er tilfreds med mitt nåværende seksualliv
(vennligst hopp over hvis ikke seksuelt aktiv)

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

32. Jeg føler meg fysisk tiltrekkende

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

33. Jeg har problemer med å konsentrere meg

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

34. På grunn av tørr skjede har samleie blitt ubehagelig
(vennligst hopp over hvis ikke seksuelt aktiv)

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

35. Jeg må tisse oftere enn vanlig

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

36. Hukommelsen min er dårlig

Ja, helt klart	Ja, noen ganger	Nei, ikke så mye	Nei, ikke i det hele tatt
☐	☐	☐	☐

37. Er det svært vanskelig for deg å klare å leve med eller mestre ett eller flere av de symptomene som er nevnt ovenfor?

☐ Ja ☐ Nei

Hvis ja, hvilke(t): _____