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Dietary sodium and the premenstrual syndrome.

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DIETARY SODIUM AND THE PREMENSTRUAL SYNDROME

A Dissertation Presented

By

JUDITH NISSENBAUM

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ABSTRACT

Dietary Sodium and the Premenstrual Syndrome

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The present study was a double-blind placebo-controlled investigation of the effect of reduced dietary salt on premenstrual syndrome. Dependent measures included subjects' self-reports of moods and water retention during four phases each of six monthly cycles. Subjects' weight and blood pressure were measured three times during each cycle. After two baseline cycles, all subjects started a reduced sodium diet. In addition, half the subjects took 4 grams of salt per day in capsule form, thereby approximately replacing the salt they removed from their diet (placebo condition). The rest of the subjects took identical capsules containing an inert substance (reduced salt treatment condition). After two months the cross over took place: subjects in the placebo condition began the treatment condition by having their salt capsules replaced by inert capsules, and vice versa. Thus all subjects underwent two cycles each of baseline, placebo, and treatment.

During baseline subjective water retention was the only consistent premenstrual change observed. Self-report mood symptoms and physiological symptoms either did not show the expected menstrual cycle pattern or were not consistent over the two months. Treatment effects were therefore inconclusive, especially in view of the small number of subjects completing the study. No significant premenstrual differences between baseline, placebo, or treatment conditions were observed. When measures were averaged across each cycle, however, MAACL anxiety was significantly lower during treatment than during baseline. Excluding an extreme weight loss subject from analyses, weight during treatment was significantly lower than baseline, and a decrease in systolic blood pressure during treatment approached significance.

Extreme variability in baseline measures raises questions of methodology for this type of research. A longer time for both baseline and treatment conditions may be required before valid premenstrual data will emerge. Other factors, such as environmental stress and dietary factors, must be taken into account in studying the premenstrual syndrome. The fact that reduced dietary sodium had an effect on overall anxiety level and on blood pressure in a normotensive population may have

important implications for preventive aspects of research on hypertension.

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INTRODUCTION

Fluctuations in physical and psychological states have long been associated with women's monthly hormonal cycling. While the effects of menstrual cycle changes have for ages variously influenced women in their lives and legends, not until this century has scientific documentation of those phenomena begun to accumulate. Recent reviews have cited evidence for increased incidence of numerous problems for women during the premenstruum. While these seem to be quite minor for most women, some of the more pronounced negative reactions include depression, anxiety, suicidal behavior, psychiatric hospital admissions, epileptic seizures, allergic reactions, accidents, and criminal behavior (Smith, 1975; Reid and Yen, 1981). Although for many women premenstrual symptoms do not require professional interventions, epidemiological evidence suggests that from 70% to 90% of all women report recurrent premenstrual symptoms, and 20% to 40% of women experience some degree of temporary mental or physical dysfunction premenstrually (Reid and Yen, 1981).

Current popular women's literature abounds with polemical discussions of premenstrual syndrome. On the one hand, it is argued that, contrary to tradition, women

do not become less functional or capable as a result of monthly cycling, and that they should therefore not be treated differently on account of the phases of their cycles. (Research shows, in fact, that premenstrual or menstrual symptoms do not generally interfere with actual task or job performance [Sommer, 1973]). On the other hand, some have argued that menstrual cycle effects are a biological reality and must be taken seriously and not be patronized or dismissed. This view is exemplified in its extreme by recent highly publicized court cases where premenstrual syndrome has been used in the defense of women who have committed violent acts.

Political controversy aside, it can be asserted that menstrual cycle changes do have both biological and psychosocial reality for women. Serious and rigorous research in the area must continue for the purpose of clarifying the nature of those realities. Research is also essential in order to help make available the informed choices necessary for women to be able to maximize their own potential for physical and mental well-being. For example, some traditional treatments, such as progesterone injections, are being shown in controlled research either to be ineffectual, or to be effective for only a small subgroup of women who experience menstrual cycle symptoms. More refined and well-controlled research can identify specific sub-groups of women who might respond to

particular treatments, and also can test and develop alternative, less invasive treatments, such as changes in activity levels and diet. Investigating the effects of dietary sodium changes is an important step in this direction, since sodium and fluid retention are common premenstrual complaints.

Description of the Premenstrual Syndrome

The descriptive terminology used with reference to menstrual cycle symptoms is often unclear and imprecise. "Dysmenorrhea" may or may not refer to "premenstrual syndrome," which may or may not include "premenstrual tension." This confusion may be partly because premenstrual and menstrual symptoms are in fact not always clearly separable. While there may be some overlap of symptoms between the premenstrual and menstrual phases of the cycle, however, recent research strongly suggests that those two cycle phases are generally characterized by two different types of symptoms. The two syndromes are not mutually exclusive as some previous investigators have suggested (Chesney and Tasto, 1975); that is, women can experience either, neither, or both menstrual and premenstrual symptoms.

The symptoms most usually associated with the menstrual phase of the cycle include cramps or spasms of pain, nausea, and dull, continuous pain. Premenstrual

symptoms tend to be more variable both in their nature and the time of their occurrence, which may be any time from ten days to two weeks prior to menstruation to just a day or two before the onset of menstruation. Physical symptoms may include headache, backache, fatigue, and skin problems. Among the most common physical symptoms are swelling and tenderness of breast or abdominal tissues, bloating, and changes in appetite and food intake--notably cravings and increased consumption of sweet and salty foods. Psychological symptoms can include depression, irritability, anxiety, poor concentration, sadness, emotional lability, and lethargy (Reid and Yen, 1981; Smith, 1975). Different women may experience various combinations of symptoms at different levels of severity. Even the same women may sometimes experience different levels and types of symptoms from one cycle to another. Moos (1977) has factor analyzed data obtained from more than 800 women, and has identified six major symptom clusters which seemed to differentiate the premenstrual phase from the intermenstrual phase. He labeled these clusters pain, concentration, behavior change, autonomic reactions, water retention, and negative affect. In addition, Moos and Liederman (1977) computed cluster analyses of data gathered from more than 500 subjects and identified a variety of symptom patterns. Yet, as Moos and others have pointed out (e.g., Clare, 1979; Smith, 1975), much of the menstrual cycle research that has been

done has assumed a single premenstrual syndrome. The results of this large body of research, even from the small percentage of studies that have been well controlled, are contradictory and inconclusive. Attempts to identify a single cause or a universally effective treatment have not succeeded simply because it is likely that there are a variety of possible causes and therefore a variety of potentially effective treatments for different premenstrual syndromes.

Etiologies of PMS

Early theories, and even some more recent opinion, have often attributed premenstrual symptoms to women's negative attitudes toward menstruation, sex, or sex roles. Socio-cultural attitudes were said to affect women's expectations about premenstrual symptoms such that these expectations actually led to women's experiencing of premenstrual symptomatology. Negative attitudes toward menstruation as acquired by some kinds of religious training or other sources of early attitude development have been seen to be related to severity of menstrual cycle symptoms. According to this view, women learn that they are expected to be ashamed, embarrassed, and dysfunctional at certain times during their cycle, and they interpret their own experiences and feelings in concordance with those socio-cultural expectations.

Since many of the symptoms of premenstrual syndrome involve subjective psychological phenomena such as mood states, problems of measurement become particularly relevant to these kinds of studies. Responses to self-report symptom checklists can be as much a product of subjects' expectations as of their hormone balance. For this reason, it is especially important that premenstrual syndrome studies involve blind, placebo controlled research designs. Placebo effects tend to abate over time, while treatment effects are not as likely to lessen.

Environmental stresses also play an essential role in premenstrual syndrome, since one of its characteristics may be that a woman's vulnerability to stress is more acute premenstrually than at other times during her cycle. This factor is an important contributor to high intra- and intersubject variability of reported symptomatology. In addition, some investigators, notably those with a psychoanalytic orientation, have attempted to associate certain personality types or individual neurotic tendencies with menstrual cycle problems (e.g., Coppen and Kessel, 1963; Rees, 1953). While it is not likely that such factors account for all menstrual cycle symptomatology, it stands to reason that they would affect women's perceptions and reports of their symptoms. Most recent thinkers in the area of menstrual cycle research acknowledge that biological, social, and psychological factors

are interacting contributors to women's experiences of premenstrual symptoms (Ruble, Brooks-Gunn, and Clark, 1980).

The importance of social and psychological factors notwithstanding, the majority of premenstrual syndrome studies have attempted to isolate biological factors as causes of the problems. Fluctuating levels of estrogen and progesterone through the menstrual cycle have until recently been the primary focus for researchers investigating its biological aspects. Frank (1931) was the earliest worker to suggest that excessive estrogen caused premenstrual symptoms. Israel (1941) elaborated by proposing that it was excessive estrogen in relation to progesterone, or unopposed estrogen, which caused symptoms. Subsequently a number of authors have reported evidence supporting the unopposed estrogen theory (Morton, 1950; Widholm, Frisk, Tenhunen, and Hartling, 1967; Cullberg, 1972; Backstrom and Mattsson, 1975). Others, however, have questioned these findings. Munday (1977), for example, reported that premenstrual symptoms often preceded the shift in the estrogen/progesterone ratio, and that in any case only 30% of patients with severe symptoms showed the low progesterone concentrations. O'Brien, Selby, and Symonds (1980) demonstrated that changes in progesterone levels did not coincide with the appearance of significant premenstrual symptoms.

A number of reports have presented evidence that pre-

menstrual syndrome is a progresterone withdrawal phenomenon (e.g., Greene and Dalton, 1953) or an allergic response to endogenous hormones (Zondek and Bromberg, 1945). Although these reports have not been substantiated, research findings in the area of endocrine allergies continue to accumulate (Mabray, 1983).

Other homones besides estrogen and progesterone have been implicated in premenstrual syndrome. In particular, recent evidence about the possible regulatory role of prolactin is of interest. Carroll and Steiner (1978) have suggested that excessive prolactin may interact with estrogen and progesterone levels to produce various mood symptoms, and with renal hormones to affect fluid and sodium retention. Andersch, Hahn, and Isaksson (1978) and Halbreich, Ben-David, Assail, and Borstein (1976) have published similar reports. Some evidence has been noted wherein large doses of vitamin B_6 have reduced prolactin levels and alleviated premenstrual symptoms (Delitala, Masala, Alagna, and Devilla, 1976). Contradictory evidence with regard to the role of prolactin in the premenstrual syndrome have been reviewed in O'Brien, Selby, and Symonds (1980) and in Reid and Yen (1981).

Vitamin B_6 has also been implicated in premenstrual syndrome by other theorists. Rose (1978) has suggested that excessive estrogen leads to a vitamin B_6 deficiency. Since vitamin B_6 is important in the synthesis of dopamine

and serotonin, a diminution of these substances could result when estrogen levels are excessive. The role of vitamins, especially the B vitamins, in the synthesis of these and other neurotransmitters is complex, and not yet clearly understood. There is growing evidence that catecholamines play a role in regulating the hormones vasopressin, renin, and angiotensin that interact to control sodium and fluid balance. Research in this area continues to associate additional brain, pituitary, and renal substances in the cycling of sodium and fluid regulating processes as well as in other menstrual cycle manifestations. Reid and Yen (1981) have summarized the possible interactions of dopamine, beta-endorphins and other neuropeptides, and prostaglandins--all biochemical substances that may contribute to menstrual cycle symptomatology.

Other metabolic processes may be implicated in menstrual cycle problems. Some investigators have suggested that cyclic changes in glucose tolerance may lead to premenstrual symptoms (e.g., DePirro, Fusco, Bertoli, Greco, and Lauro, 1978). Reid and Yen (1981), however, have reviewed evidence suggesting that while cyclic shifts in glucose metabolism may account for some cyclic appetite changes, they are not related to other premenstrual symptoms. Moreover, appetite changes seem to be too widespread a premenstrual phenomenon to be explained by what is probably only a small percentage of individuals with

abnormal glucose tolerance levels. In addition, there is evidence that cyclic changes in sodium appetite are at least as significant as other appetite changes (Weizenbaum, Benson, Solomon, and Brehony, 1979; Dillon, 1983). Very little research has been done in the area of sodium appetite, in spite of the well-established phenomenon of premenstrual water and sodium retention.

Although its relationship to sodium appetite has not been investigated, fluid retention itself has been a major focus of attention in studies of the premenstrual syndrome. Fluid build-up premenstrually has been assumed to be related to increased premenstrual sodium retention, but the underlying mechanism for these changes is not clear. Some investigators have reported that premenstrual fluid retention is not in itself a clear-cut phenomenon. Taggart (1962) and Michelakis, Stant, and Brill (1971) have published evidence that women do not typically show premenstrual weight gain. Others have reported average weight gain of one to three pounds premenstrually (Watson and Robinson, 1965). Preece, Richards, Owen, and Hughes (1975) have noted that localized premenstrual swelling (e.g., of the breast tissues) can occur even though there may be no overall weight gain. Still other investigators (e.g., Janowsky and Berens, 1973) have noted a correlation between premenstrual weight gain and severity of premenstrual negative mood symptoms. Others have failed

to show such a relationship (Golub, Menduke, and Conley, 1965).

Fluid and electrolyte balance are regulated by the renin-angiotensin-aldosterone system. Both estrogen (Preedy and Aitkin, 1956) and progesterone (Oelkers, Schoneshofer, and Blumel, 1974) have been implicated in increasing levels of plasma renin substrate and aldosterone, leading to sodium and fluid retention. Reid and Yen (1981) have pointed out that, while accumulated research evidence suggests that sodium and fluid retention as well as other aspects of premenstrual syndrome are related to a dysfunction along the hypothalamic-pituitary-ovarian axis, the actual mechanisms of the dysfunction or dysfunctions remain elusive.

Treatments for PMS

Even though a clear understanding of the causes of premenstrual syndrome has not yet been achieved, many treatments have been developed, with varying degrees of reported success. A number of psychotherapeutic approaches have been brought to bear on the problem, ranging from psychoanalysis to relaxation and desensitization therapies. Reports of their success have been largely anecdotal (see the review in Tasto and Insel, 1977), but Chesney and Tasto (1975) showed in a controlled study that a muscular relaxation training program was effective

in alleviating menstrual (or what the authors called spasmodic) discomfort but not premenstrual (congestive) symptoms. A variety of psychoactive drugs have also been tried as treatments for premenstrual syndrome. Pennington (1957) reported 78 percent success with Meprobamate (Miltown). Lithium was reported to relieve a number of premenstrual symptoms in eight women in an uncontrolled study (Sletton and Gershon, 1966). A later investigation tested lithium in a double-blind placebo controlled study and found no differences between placebo and lithium (Singer, Chang, and Shore, 1974). It could well be that psychotherapy or the use of psychoactive medications may have benefits for some women suffering from premenstrual symptoms. Indeed, psychological interventions often provide useful adjunctive treatment for individuals who experience any of a variety of chronic physical problems.

Given the widespread interest in the role of progesterone/estrogen balance in premenstrual syndrome, it is not surprising that oral contraceptives have been used in its treatment. Smith (1975) has reviewed the literature on this topic, which has showed mixed results. Culberg (1972) and Moos (1969) in studies of large numbers of users and non-users of oral contraceptives concluded that fewer premenstrual symptoms were experienced by women using various types of oral contraceptive pills. Given the powerful effects of oral contraceptives on natural hormone

balance and function, as well as potential discomfort and danger from side effects of this treatment, it is questionable whether larger numbers of women would or should elect to use oral contraceptives solely for the purpose of alleviating premenstrual syndrome.

The same caveat should apply to the use of progesterone and to synthetic progesterones, which have been even more popular as treatments for premenstrual syndrome. Dalton (1964, 1977) has perhaps been the most active proponent of the use of progesterone as the treatment of choice for premenstrual syndrome. Yet she has only published evidence from uncontrolled clinical trials of progesterone. Sampson (1979) has reported a double-blind placebo controlled trial of progesterone in which progesterone did not differ from placebo in its effectiveness.

Investigators studying the role of prolactin in mediating estrogen/progesterone balance in premenstrual syndrome have claimed that bromocriptine, known to reduce prolactin levels, is an effective treatment for premenstrual syndrome (Carroll and Steiner, 1978). Other researchers, however, show negative results for the same treatment, using controlled studies (Ghose and Coppen, 1977; Graham, Harding, Wise, and Barriman, 1978).

Following the discoveries of the roles of some vitamins in the synthesis and metabolism of various neurotransmitters and hormones, vitamin treatments of premenstrual syndrome

gained considerable popularity, but no well controlled studies have been done to adequately test their efficacy. Some evidence from a controlled study exists suggesting that vitamin B_6 is an effective treatment for depression occurring as a side effect of some oral contraceptives (Adams, Rose, Folkard, Wynn, Seed, and Strong, 1973). Stokes and Mendels (1972), however, looking directly at the effect of vitamin B_6 on premenstrual syndrome, found generally negative, though mixed, results. Other vitamins, especially A, and some minerals have been reported to be effective, but these reports have not been from controlled studies. Reid and Yen (1981) have reviewed the vitamin treatment literature.

Recent interest in the role of prostaglandins in the menstrual cycle have given rise to the development of new treatments. Some investigators hold that an excess of prostaglandins cause premenstrual symptoms. In a double-blind study, Wood and Jakubowicz (1980) found that mefenamic acid (an antiprostaglandin) was highly effective in alleviating a number of premenstrual symptoms, especially negative mood symptoms. On the other hand, some theorists have claimed that premenstrual syndrome is related to prostaglandin deficiency, which can be treated with gammalinoleic acid (Hoes, 1980). While this substance (found in oil of evening primrose) has been reported effective in clinical trials, no controlled studies have

been published to date.

Fluid retention, along with its various manifestations, has been seen as one of the target symptom groups for many treatments, even though its relationship to other premenstrual symptoms has remained unclear. Treatments of premenstrual fluid retention have focused on the use of diuretics. As with other treatments, much of the research reported using diuretics has been uncontrolled or poorly controlled. Some investigators have reported diuretics to be effective in relieving specific symptoms. Greene and Dalton (1953) and Thomas (1933), for example, reported that premenstrual headaches were relieved by diuretics. Reid and Yen (1981) have reviewed and critiqued a number of poorly controlled studies using diuretics. Mattsson and Schoultz (1974) and Andersch, Hahn, and Isaacson (1978) found that both diuretics and placebo were effective in double-blind studies. These studies failed to encompass a time period sufficient for placebo effects to abate so that possible lasting effects of the treatment could be observed. In another controlled study (Jordheim, 1972), diuretics were used in conjunction with other substances, making it impossible to draw conclusions about the effects of specific substances.

Indeed, diuretics may not be an appropriate treatment for premenstrual fluid retention. Like other chemical interventions, diuretics may pose a risk of unwanted side

effects. Huapaya and Ananth (1980) have suggested that one side effect of diuretics may be depression--one of the major symptoms associated with premenstrual syndrome. Another reason diuretics have failed to provide consistent relief for premenstrual symptoms may be that these medications have a superficial and short-term effect of relieving some fluid retention, without altering a more fundamental electrolyte imbalance that could be related to the excessive dietary salt intake which is pervasive in this culture (Dillon, 1976; Tuthill and Calabrese, 1981b). The need for salt in human beings has been shown to be between one and two grams per day, yet the daily median salt intake for individuals in this country ranges between three and ten times that amount (Tuthill and Calabrese, 1981b). Furthermore, Dalvit (1981) has reported strong evidence that females significantly increase their total food intake premenstrually. She followed eight females trained in nutritional record-keeping for two menstrual cycles in a double-blind study. She found that for all sixteen cycles the mean caloric intake for ten postovulation days (premenstrual) was on average 500 calories greater than the mean intake for ten preovulatory days. In this study, subjects also recorded their weight, which showed no significant fluctuations associated with menstrual cycle phase. Although Dalvit did not investigate changes in specific foods consumed, Weizenbaum, Benson,

Solomon, and Brehony (1979) have shown that for at least some women there is a tendency to increase intake of sweet foods and especially of salty foods premenstrually. If this is the case, the already high level of dietary sodium may be even higher for some women during the premenstrual phase of their cycles. No research on the connection between dietary sodium intake and premenstrual syndrome has been reported to date.

Statement of the Problem and Hypotheses

The present study will attempt to answer a number of questions. Does the level of dietary sodium intake increase premenstrually? If the overall dietary sodium level is reduced, how are specific premenstrual symptoms affected; especially weight gain, subjective experience of fluid retention, anxious mood, and depressed mood? Is there a placebo effect on premenstrual symptoms if women believe they are reducing their salt intake and receiving dietary supplements?

In order to address these questions the present study will assess changes in dietary sodium intake over a two-cycle baseline period. Other menstrual cycle changes will be assessed as well, with a focus on the specific premenstrual levels of fluid retention, depression, and anxiety. Dietary levels of sodium will then be altered, and changes in symptom patterns assessed.

The following hypotheses will be tested:

1. Subjects will show less premenstrual fluid retention, as measured both subjectively and objectively when their overall dietary sodium intake is reduced.

2. Subjects will show lower levels of premenstrual depression when their overall dietary sodium intake is reduced.

3. Subjects will show lower levels of premenstrual anxiety when their overall dietary sodium is reduced.

CHAPTER II

METHOD

Design

A placebo controlled double-blind crossover procedure was used in this study to test the effect of a moderate low sodium diet on specific aspects of premenstrual disturbances. All subjects kept regular records of physical symptoms, moods, diet, activity, and stress levels for a total of six monthly cycles. Three times per month subjects brought their records to the experimenter's laboratory office and had their weight and blood pressure checked. For the first two cycles (baseline period) subjects made no dietary change. At the beginning of the third cycle all subjects were given detailed instructions for going on a moderate low sodium diet; i.e., they were given lists of specific foods to avoid or cut down on (see Appendix A). At the same time half the subjects were given a supply of one-half-gram capsules of salt, with instructions to take eight per day (placebo phase). It was estimated that this amount of salt per day (four grams) would approximately replace the amount of salt eliminated by the dietary change, thereby making this group the "no dietary change" group, but at the same time keeping them

(and the research assistants working with them) blind to their condition. The other half of the subjects were given capsules identical in taste and appearance to the salt capsules, but containing one-half-gram of dextrose instead of salt (treatment phase). These subjects were also instructed to take eight capsules per day; this group was the experimental group actually on the low sodium diet. After two complete cycles (cycles three and four) came the crossover phase: subjects who had completed the two month placebo phase were given inert capsules for their treatment phase (cycles five and six), and subjects who had completed their treatment phase were given salt capsules for their final two-month placebo phase (see Tuthill and Calabrese, 1981a, from whom this method of altering dietary sodium intake was adapted). Subjects' self-reported premenstrual symptoms for baseline, placebo and treatment phases were tested for differences and for any order effect. In addition, office measures of weight and blood pressure were tested for changes between experimental phases.

Researchers

Two female graduate students in Clinical Psychology were in charge of the overall administration of the study. One of these two graduate students trained and supervised the five female undergraduate psychology majors who functioned as research assistants. The research

assistants conducted the initial and ongoing interviews with subjects, collated and coded data, and prepared and distributed individualized feedback for subjects after the study was finished.

The other graduate student researcher, the author of this dissertation, also worked with the research assistants, and was in charge of coding, scheduling, and distributing the capsules according to the crossover design. Researchers who met with subjects were aware of the nature and purpose of the study, but after the baseline period they were blind to the condition of the subjects at any given time.

All researchers and research assistants were female, since it was expected that subjects might feel more comfortable discussing their menstrual cycles with females rather than with males.

Subject Selection

Telephone screening. A number of criteria were used to screen subjects for participation in this study. An advertisement was placed in local newspapers and posted in a variety of public places requesting volunteers:

> TROUBLED BY
> PREMENSTRUAL TENSION/DEPRESSION?
>
> Volunteers needed for a study of premenstrual distress being conducted at the University of Massachusetts, Amherst, in the Psychology department.

> Women who experience psychological and/or physical discomfort prior to their menstrual periods are invited to participate.
>
> Volunteers must be willing to keep regular records, and report in regularly for up to seven months.
>
> [A phone number was listed here for interested subjects to call to obtain further information.]

When interested women called in to enquire about the study, trained research assistants gave the following brief description of the study:

> We are looking at the effects of certain dietary changes on premenstrual symptoms. We'll be asking you to keep records at home, which consist of filling out a number of daily check-lists for several days during each menstrual cycle. In addition, we'll be asking you to come into our office three times each month to have your weight and blood pressure taken, and to bring us your completed checklists and pick up new checklists. This home record-keeping and office visit routine will proceed for the entire duration of the study, which will be six monthly cycles. For the first two monthly cycles, we won't ask you to make any dietary changes; this is our baseline period, which will be a time for you to get used to the record-keeping procedures. At the end of the first two cycles we'll be asking you to cut down on the amount of salt in your diet. This will mean that you won't be adding salt to your food, also that you'll be eliminating or cutting down on certain foods that contain a lot of salt. We'll give you detailed instructions for this moderately low-salt diet when the time comes. At the same time you start this dietary change, we'll be giving you some capsules to take every day. Although we

> can't tell you what the capsules contain until you have completed the study, we can assure you that they contain nothing that is a drug or that could be harmful. They will contain either a normal quantity of a dietary supplement, such as a vitamin or mineral, that you could readily purchase, or they might contain a placebo or inert substance. Again, we'll inform you about what you have taken after the study is finished.
>
> After you have completed the entire six-month study, we'll pay you $80, in appreciation for your participation. If you do not complete the entire study, but if you do complete at least four of the six cycles, we'll pay you $25.

During this explanation, the telephone interviewer periodically stopped to ask whether the subject was understanding, and to clarify if there were any questions. If the potential subject continued to be interested after hearing this description, the research assistant asked her to respond to a few qualifying questions before scheduling an initial face-to-face interview. Subjects were not accepted for the study if they 1) were taking, had recently been taking or were planning to take (before the end of the study) oral contraceptives or other hormonal medications; 2) had high blood pressure, kidney disease, or any other disorder that could be affected by change in dietary sodium, 3) were unable to control their own diet (e.g., if they were on a meal plan in a dormitory). In addition, it was explained to subjects that as they would be asked to participate for six monthly cycles, they should not

volunteer if they were planning to move (or become pregnant) within the next half year. Subjects were asked to rule themselves out if they did not have "more-or-less" regular cycles, although it turned out that cycles were extremely variable and unpredictable for many subjects.

It was initially planned that subjects would be screened according to specific premenstrual mood symptoms--specifically, depression or anxiety--so that they could be divided into two groups. Because of the small number of subjects, however, and because of a large proportion of subjects reporting both premenstrual anxiety and depression, this plan was not found to be feasible. In addition, an initial age restriction, intending to include only women over 25, was dropped because of insufficient numbers of subjects volunteering.

Women who qualified according to the criteria described above were scheduled for an initial screening interview with one of the research assistants, where they were to be given a number of questionnaires to fill out and where the details of their participation were to be explained.

Initial interview. The initial interview took from one to one and a half hours. Each subject met with the research assistant to whom she had been assigned in a comfortable, softly lit office. The interviewer chatted

informally with the subject for a few moments to put her at ease, and then described in detail--reiterating and elaborating the information already given on the telephone--what the subject would be required to do to participate in the study. If the subject agreed, she was asked to sign a consent form (see Appendix B).

The research assistant first mapped out the subject's schedule of record keeping and office visits according to her menstrual cycle. This was done with a chart and a sample of a 28-day menstrual cycle (see Appendix C). The research assistant asked the subject to recall the date her last menstrual flow began and to report the average length of her cycle. From this information, the probable starting date of the next cycle was estimated (in this study, as has been customary in menstrual cycle research, the first day of menstruation is designated as day one in a given cycle). The date of ovulation was estimated by figuring ahead to the beginning of the second cycle (after beginning the study) and then moving back exactly 14 days. For example, if a subject with a 31-day cycle expected her period on November 10, the following cycle would begin on December 11. Fourteen days before that is November 27, the day when ovulation would be most likely to occur.

With this projected timetable, a total of twelve packets of daily record-keeping questionnaires were scheduled for the first upcoming menstrual cycle. The

first three packets were to be filled out at the end of each of the first three full days of the cycle. The second group of questionnaire packets were to be filled out at the end of each of a block of three days during the follicular phase (that part of the cycle after menstruation up until ovulation). An office visit was scheduled after this second set of packets, also prior to ovulation. The third set of packets was scheduled to be filled out during the luteal phase--sometime during the week after ovulation. An office visit was scheduled immediately after these packets, also during the post-ovulation week. The fourth and final set of packets was scheduled to be filled out for three days during the last week of the cycle--the premenstrual phase. The third office visit was scheduled for the day after these packets were to be completed, ideally just one or two days before the next cycle was to begin. (The sample 28-day menstrual cycle, Appendix C, shows how the record-keeping and office visits were to be planned.)

When the subject clearly understood her individual schedule, a tentative appointment for the first office visit was made. It was understood that if the subject's cycle started on a different day than expected, the schedule would have to be revised accordingly. Research assistants exchanged phone numbers and available times with their subjects so that reminders and changes in

schedule could be easily communicated.

After the scheduling was completed, the subject had her weight and blood pressure recorded. Weight and blood pressure were taken at the initial interview primarily to familiarize subjects with these procedures, which would be part of the office visit routine. The blood pressure check also afforded direct evidence that subjects did not have high blood pressure. All subjects did in fact show blood pressure levels within normal range. Since subjects did not all undergo the initial interview at the same point during their menstrual cycle, these weight and blood pressure measures were not used for correlational purposes.

Following the weight and blood pressure checks, the subject was given a packet of questionnaires to fill in (Appendices D and F), with the research assistant giving instructions for completing the forms. These questionnaires were given in order to gather some demographic data, as well as some retrospective reports about subjects' menstrual cycle experiences. A number of these initial questionnaires were similar to the questionnaires in the daily packets. These similarities, along with differences in instructions, were explained carefully to the subject.

When the subject had completed all the initial questionnaires, she was given six daily questionnaire packets (for the first two sets of three days of her next cycle) and a copy of her menstrual schedule. The interviewer

went through the home record-keeping packet with the subject, giving detailed instructions for completing the packets. The material contained in these packets was similar to some of the initial interview material just filled out by the subject, so that this material was used as a reference point for the explanation of the home record-keeping packets. After making sure any questions the subject had were answered, the research assistant ended the interview with a promise to call the subject with a reminder to begin the daily record-keeping when her next cycle was to begin.

Office Visits

Three times during each of the menstrual cycles for the duration of their participation in the study, subjects reported to the office for a brief visit. During each of these visits, the research assistant collected weight and blood pressure, using the same doctor's office scale and blood pressure kit each time. In addition to providing the opportunity to collect the home record data and the physiological data, the office visits provided the opportunity for personal contact between the subject and the research assistant. It was expected that this contact would provide motivation for the subjects to follow through with their participation in this lengthy project.

Final Follow-Up Visit

Following the subject's final office visit of their last cycle, a follow-up visit was scheduled. During this visit the subject was debriefed and given detailed feedback as to the nature of the study as well as which cycles she was in the treatment and placebo conditions. Subjects were given checks at this time for the amount of money promised them as payment for their participation.

The Initial Interview Questionnaires

Self-report questionnaire. Some demographic data were collected from subjects in order to look at possible correlations with patterns of premenstrual symptoms (Appendix D). In addition, it was considered important to have this information so that differences between subjects who completed the study and those who dropped out could be examined. Information regarding subjects' age, occupation, marital status, education, income level, and number of children was recorded.

Subjects were asked to rate their "usual" activity level and appetite, on a one to seven scale. These same ratings for specific days were included on the daily record forms. Subjects' self-reports of their "usual" activity and appetite levels would then be compared with changes in these measures over the menstrual cycle.

Subjects' estimates of their daily caffeine intake, as well as their reports of regular medications (dosage and frequency) were also collected during the initial interview. Finally, subjects were asked to report any notable occurrences or events (positive or negative) within the last month which might have a stressful or disruptive effect on them.

MAACL. The Multiple Affect Adjective Check List (Zuckerman and Lubin, 1965), a 132-item check list, yields three affect scale scores: depression, hostility, and anxiety. Normative data, as well as the discriminant validity and high reliability of this instrument have been reported by Zuckerman, Lubin, and Robins (1965) and Pankratz, Glaudin, and Goodmonson (1972). Subjects were asked to check those items that described their overall mood state for the past month.

Menstrual Distress Questionnaire, Form A (retrospective). The Moos Menstrual Distress Questionnaire (Moos, 1977) lists 47 symptoms to be rated on a six-point severity scale (Appendix F). The retrospective (Form A) version of this instrument requires subjects to rate each symptom three times: for the time during the most recent menstrual flow, the time during the week preceding the most recent flow, and for the remaining time of the most recent menstrual cycle. The eight symptom clusters identified

by Moos' (1968) factor analyzed data from 839 subjects are pain, concentration, behavior change, autonomic reactions, water retention, negative affect, arousal, and a control scale which included symptoms not usually specified by women premenstrually. Extensive data on the validity, reliability, and stability of the Menstrual Distress Questionnaire have been reported and reviewed by Moos (1977).

Food frequency list. The food frequency list was devised to assess roughly the amount of sodium in subjects' daily food intake (Appendix G). The list included a wide variety of foods with moderate to high sodium content, as well as a number of filler items so that subjects would not be conscious that the check list was primarily designed to evaluate sodium intake. Subjects were required to give an estimate of how many servings of each item they had consumed during the last month. The lists were scored simply by totaling the number of servings of keyed sodium items.

Health history questionnaire. The final instrument filled out by subjects at the initial interview was a health history questionnaire (Appendix H). Since the data from this questionnaire were not used for this study, it will not be described here.

The Home Record-keeping Questionnaires

Self-report questionnaires. The face sheet of each daily packet required the subject to record ratings of her appetite and activity level for that day, on seven-point scales (Appendix I). Subjects were also asked to report any medications taken that day, including prescription, non-prescription, and recreational substances taken. Caffeine consumption was to be reported. The final question on this questionnaire requested the subject to report any food cravings she had experienced that day, and whether or not she had eaten the foods she craved.

MAACL, short form. The short form of the Multiple Affect Adjective Check List, like the long form, yields three scale scores: depression, anxiety, and hostility, but contains only 63 items (Appendix J). Its validity and reliability, as well as its statistical relationship to the long form, have been reported by Zuckerman, Lubin, and Robins (1965). Subjects were asked to check the items that described their mood for the particular day they were recording.

Menstrual Distress Questionnaire, Form T. Form T of the Moos Menstrual Distress Questionnaire lists the same 47 symptoms contained in Form A, with the same six-point severity scale for each symptom. On Form T, however, each

symptom is rated only once, for the specific day the subject was recording. Moos (1977) has reported and reviewed data regarding the validity, reliability, and stability of this instrument.

Food frequency list. The food frequency list was identical to the one subjects had filled out during the initial interview. The instructions, however, directed subjects to report only foods they had eaten during that single day.

Physiological Measures

Weight. Subjects were weighed with clothing but without their shoes, using a doctor's scale.

Blood pressure. Blood pressure was measured with subjects in a sitting position, using a standard cuff sphygmamometer.

C H A P T E R I I I

RESULTS

Summary

Of 46 subjects who took part in the initial interview screening 33 continued at least long enough to contribute baseline data, and ten completed the entire six-month sodium reduction study. No differences on demographic or initial interview variables were found among these groups.

While the retrospective questionnaire showed expected increases in premenstrual negative moods and subjectively experienced water retention, daily records kept during the two month baseline period showed a consistent premenstrual increase only in experienced water retention, but not in negative mood symptoms.

Given the fact that baseline data did not show expected premenstrual patterns, and considering the small subject sample size and the amount of missing data, it was difficult to interpret effects of the dietary sodium reduction treatment on premenstrual symptoms. When cycle phases were averaged, however, subjects during the low-sodium treatment showed lower overall levels of anxiety than during baseline cycles. In addition, subjects during the low-sodium treatment showed overall cycle weight

decreases and a tendency toward lower systolic blood pressure as compared with baseline.

Subjects

A total of 46 subjects participated in the initial interview and completed all of the initial interview questionnaires. After deciding that the study would be too time consuming, ten women elected not to continue. For a variety of reasons, some personal and some involving specific objections to the study itself, a number of subjects chose to drop out at different points throughout the study. A few women, for example, experienced unexpected family or job crises which made it necessary for them to drop out. When baseline cycles were completed, some women with rigorous dietary principles couldn't continue because of their objections to the capsules: the placebo capsules contained dextrose, and the gelatin casings of the capsules contained animal substances. Three volunteers dropped out before the end of their first baseline cycle. Seven more subjects finished at least one complete baseline cycle, but discontinued their participation before the end of the second cycle. There were twelve subjects who completed two baseline cycles and either discontinued at that point or dropped out prior to the end of the third cycle. Of the remaining 14 subjects, ten agreed to take part in the sodium reduction study and

completed the six full cycles. (Data from the other four subjects, who did not take part in the sodium reduction study, were used for other purposes and are not included in the analyses for the present study.)

In order to see whether there were notable differences between subjects as a function of length of participation in the study, subjects were divided into four groups for comparative purposes (see Figure 1).

The four groups consisted of 1) subjects who took part in the initial interview only, 2) subjects who began the home record-keeping but dropped out before completing both baseline cycles, 3) subjects who completed at least two baseline cycles but did not continue beyond the third cycle, and 4) subjects who completed the entire six cycles of the study. For each group means and standard deviations were computed for the age, weight, number of children, length of menses, day of cycle on which the initial interview was held, the three MAACL mood scales, and water retention, depression, and anxiety for all three phases of the cycle as recalled on the Moos MDQ Form A. A series of *t*-tests showed no significant differences between any groups on any of the variables (see Appendix L for a table of means and standard deviations).

FIGURE 1

Length of Subject Participation

Comparisons of Initial Interview and Baseline Data

Thirty subjects completed at least one baseline cycle. Their ages ranged between 21 and 36 years, with a mean of 28.2 years and a standard deviation of 4.1. Eight of those subjects had children. In spite of prior research evidence that premenstrual syndrome may worsen with childbearing (Moos, 1977), no significant differences were found between groups of women with and without children on any variable.

Recalled menstrual cycle symptoms as assessed in the initial interview on the Moos MDQ Form A showed the predicted patterns (see Table 1). The three scales most relevant to the premenstrual as opposed to the menstrual phase of the cycle were examined: water retention, depression, and anxiety. The water retention scale score was derived by averaging responses to the three symptom items "weight gain," "painful or tender breasts," and "swelling (e.g., abdomen, breasts or ankles)." The depression scale score was the average of the three symptom items "crying," "loneliness," and "depression (feeling sad or blue)." For the anxiety scale score four symptom items were averaged: "anxiety," "restlessness," "irritability," and "tension." T-tests showed all three scale scores to be significantly higher premenstrually than for the rest of the cycle or post-menstrually (see Table 2).

Correlations among the initial interview variables

TABLE 1

Retrospective Menstrual Cycle Symptoms,
Moos Menstrual Distress Questionnaire, Form A

	Menstrual		Post-menstrual		Premenstrual	
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
Water Retention	2.69	1.01	1.39	.83	3.50	1.23
Anxiety	2.92	1.13	2.09	.91	3.45	1.11
Depression	2.75	1.24	1.92	.84	3.11	1.20

TABLE 2

T-tests, Premenstrual versus Post-menstrual Phases, Moos Menstrual Distress Questionnaire, Form A

	t	*df*	*p*
Water Retention	9.54	45	.0001
Anxiety	7.33	45	.0001
Depression	6.91	45	.0001

were computed. Age, children, and day of the cycle on which the interview was conducted showed no significant correlation with any of the MAACL mood scales or the Moos menstrual cycle scales for any phase. Length of menses (the average number of days of menstrual flow as reported by subjects retrospectively), however, was significantly correlated with the Moos retrospective (Form A) menstrual cycle symptoms for some cycle phases (see Table 3). Correlations with premenstrual symptom levels were positive--the longer the menses the worse the symptom--and correlations with post-menstrual phase symptom levels were negative--the longer the menses the more symptom severity subsided post-menstrually. While not all of those correlations with specific phase symptom levels were significant, in all cases correlations with change scores (premenstrual minus post-menstrual) were significant and positive--the longer the menses, the worse the premenstrual symptoms compared to post-menstrual.

Baseline data from the first two cycles of home record-keeping were examined both for comparisons with initial interview variables and for comparisons with treatment and placebo effects. In order to analyze the daily record-keeping data for the baseline period as well as for the four treatment and placebo cycles, certain criteria were established for inclusion of data. Subjects had been instructed to complete four sets of three-day

TABLE 3

Pearson Correlation Coefficients, Reported Average Length of Menses, and the Moos Menstrual Distress Questionnaire, Form A Scales

	Length of Menses	(n=40)
Water Retention		
Premenstrual	r = .32	p < .023
Post-menstrual	r = -.17	p < .240
Change: Premenstrual minus post-menstrual	r = .32	p < .024
Anxiety		
Premenstrual	r = .26	p < .056
Post-menstrual	r = -.22	p < .088
Change: Premenstrual minus post-menstrual	r = .39	p < .006
Depression		
Premenstrual	r = .16	p < .159
Post-menstrual	r = -.38	p < .008
Change: Premenstrual minus post-menstrual	r = .44	p < .002

home record-keeping packets per cycle: one set each during the menstrual phase, follicular (post-menstrual) phase, luteal phase, and premenstrual phase. Because the scheduling of the home record-keeping was based on subjects' estimates of their cycle length, the timing of the actual record-keeping was inaccurate whenever a subject did not begin menstruating on or near the predicted date. Given the fact that the premenstrual phase was the focal part of the cycle in this study, it was the premenstrual record-keeping phase that was used to establish cycle validity for purposes of data analyses. In fact, the accuracy of the premenstrual phase scheduling turned out to be the most variable. The menstrual and post-menstrual (follicular) phases were determined by the actual onset of menstruation, so that their scheduling accuracy was extremely high. The luteal and premenstrual phase schedules, however, were derived by counting back from the predicted onset of the next menses. In order to make sure that only valid premenstrual data were used in data analyses, the following criterion was set: cycle data were included only if a subject began her three-day premenstrual record-keeping packet seven days or less (up to three days) prior to the onset of menstruation. Likewise, physiological data collected from office visits (weight and blood pressure) were included only if the premenstrual visit occurred within a week prior to the

onset of menstruation.

Out of the 33 subjects completing at least one baseline cycle, 23 subjects had valid home record-keeping data for the first baseline cycle, and 17 subjects had valid home record-keeping data for the second baseline cycle. Nineteen subjects had valid office visit data for the first baseline cycle and 14 subjects had valid office visit data for the second baseline cycle. Of these subjects, 12 had valid home record-keeping data for both baseline cycles, and nine subjects had valid office visit data for both baseline cycles.

Comparisons were made of the Moos menstrual cycle symptoms for the two baseline cycles (22 subjects in the first cycle, 16 subjects in the second cycle) with the same symptoms recorded retrospectively in the initial interview. The only symptom scale for which the retrospective and daily measures showed parallel patterns of significant premenstrual change was the water retention scale. The other Moos measures did not show the expected changes for either baseline menstrual cycle (see Table 4).

There were few other consistent menstrual cycle changes observed in either baseline cycle (see Table 5). None of the MAACL mood scales showed significant worsening premenstrually for either cycle. For the first cycle there was a significant weight gain premenstrually, but for the second cycle weight gain was not significant. For the

TABLE 4

T-tests, Premenstrual vs. Post-menstrual Phases, Baseline Cycles
Moos Menstrual Distress Questionnaire, Daily Record-keeping, Form T

	Premenstrual		Post-menstrual				
	$\bar{X}$	SD	$\bar{X}$	SD	t Value	p	df
Cycle 1							
Water Retention	2.81	.95	1.37	.48	6.83	.001	22
Anxiety	2.36	.71	2.20	.79	.79	.436	22
Depression	1.82	.90	1.86	.86	-.20	.843	22
Cycle 2							
Water Retention	2.38	1.09	1.39	.47	3.96	.001	15
Anxiety	2.17	.77	1.98	.51	1.13	.277	15
Depression	1.44	.52	1.69	.84	-1.04	.314	15

TABLE 5

T-tests, Premenstrual vs. Post-menstrual Phases, Baseline Cycles
MAACL Mood Scales, Dietary and Physiological Variables

	Premenstrual		Post-menstrual				
	$\bar{X}$	SD	$\bar{X}$	SD	t Value	p	df
Cycle 1							
MAACL							
Anxiety	1.60	1.09	1.57	.87	.11	.910	22
Depression	6.23	2.20	5.93	2.90	.59	.564	22
Hostility	6.99	1.21	6.28	1.66	1.63	.118	22
Salt Intake	5.53	2.46	5.16	2.95	.65	.522	22
Food Intake	15.93	5.16	16.09	6.01	-.15	.879	22
Blood Pressure							
Systolic	117.9	10.5	114.7	12.0	1.86	.080	17
Diastolic	71.1	6.1	71.7	7.5	-.38	.708	17
Weight	139.8	23.3	138.1	22.1	2.38	.029	17

TABLE 5 (continued)

	Premenstrual		Post-menstrual				
	$\bar{X}$	SD	$\bar{X}$	SD	t Value	p	df
Cycle 2							
MAACL							
Anxiety	1.61	1.16	1.89	1.49	-1.13	.275	15
Depression	5.53	1.62	5.75	2.16	-.33	.748	15
Hostility	6.16	1.48	6.03	1.84	.29	.777	15
Salt Intake	5.71	3.19	5.11	3.61	1.09	.293	15
Food Intake	17.51	7.05	15.02	6.45	1.90	.077	15
Blood Pressure							
Systolic	114.8	9.8	114.9	11.6	-.03	.977	12
Diastolic	74.9	7.7	76.4	8.3	.57	.582	12
Weight	145.1	21.2	144.2	19.6	.96	.354	12

first cycle premenstrual increase in systolic blood pressure approached significance, but showed no change in the second cycle. Subjects' food records showed no cycle change in either salt intake or total food intake for the first cycle, but an increase in premenstrual total food intake approached significance in the second cycle. Pearson correlation coefficients for cycle symptoms in like phases of the retrospective Moos MDQ Form A and the Moos daily MDQ Form T for both the first and second cycles are shown in Appendices M-O. Correlation coefficients for Moos daily MDQ symptoms in like phases of the two baseline cycles are shown in Appendices P-R.

The inconsistency of the symptom patterns reflects the high and varying levels of both between-subject and within-subject variability. Estimates of between- and within-subject variability were calculated for all home record-keeping data and for the physiological data, using the two baseline cycles (see Table 6). For the MAACL mood scales in Table 6, it will be noted that there are blanks for some of the between-subject estimates. These omissions occurred when calculations resulted in standard deviations with negative values. This statistical anomaly indicates that the between-subject variability was very small in relation to the within-subject variability for those particular measures, so that the estimation procedures used in partitioning the variability led to negative estimates

TABLE 6

Comparison of Estimated Between and Within Subject Variability:
Standard Deviations for Baseline Cycles

	Menstrual		Post-menstrual		Premenstrual		Change: Premenstrual minus Post-menstrual		Cycle Average	
	Between	Within	Between	Within	Between	Within	Between	Within	Between	Within
MAACL										
Anxiety	0.742	0.726		1.387	0.642	0.902		1.227	0.467	0.601
Depression	1.397	3.018		2.764		2.197	0.313	2.529	0.667	1.471
Hostility		1.952		1.935	0.185	1.358		2.096	0.458	0.863
Moos MDQ										
Water Retention	0.719	0.788	0.236	0.406	0.744	0.666	0.707	0.731	0.566	0.352
Anxiety	0.535	0.472	0.160	0.556	0.451	0.579	0.212	0.849	0.465	0.207
Depression	0.290	0.893	0.660	0.532	0.368	0.691	0.116	0.923	0.458	0.274
Salt Intake	1.318	2.112	2.236	2.304	2.287	1.541	1.195	2.217	2.050	1.390
Food Intake	2.908	4.460	4.486	4.286	2.725	5.321	1.588	4.880	4.304	2.181
Weight			21.787	1.793	23.124	1.945	1.574	2.952	22.640	0.864
Blood Pressure										
Systolic			10.409	3.964	8.740	3.910	5.817	5.619	8.441	3.300
Diastolic			6.928	3.464	3.823	5.606	5.355	4.957	4.283	3.772

of standard deviations. For the physiological variables no measures were taken for the menstrual phase; therefore those columns have been left blank.

Dietary Sodium Treatment Data

Ten subjects took part in and completed the entire dietary sodium reduction study: two baseline cycles plus two cycles each of treatment (lowered dietary sodium) and placebo (replaced dietary sodium). However, after application of the criteria described above to determine cycle phase validity for the home record-keeping and office visit data, it was found that there was a considerable proportion of invalid or missing data (see Table 7). Because of the amount of missing data and the small number of subjects, cross-over or order effects could not be determined; therefore placebo phases for all subjects were combined for analyses, as were treatment phases.

An overview of the experimental data was obtained by calculating adjusted averages of all variables (see Tables 8 and 9). The adjusted averages were obtained by replacing missing data for each particular cycle phase with the overall mean for that phase within a given experimental division: baseline, placebo, or treatment.

The variable showing the clearest change from baseline to placebo and treatment is salt intake, which was substantially larger for baseline than for the other two

TABLE 7

Valid Menstrual Cycle Data for Sodium Reduction Subjects

Home Record-keeping Data

Subject Number	Baseline Cycle 1	Baseline Cycle 2	Placebo Cycle 1	Placebo Cycle 2	Treatment Cycle 1	Treatment Cycle 2
1	+				+	+
2	+	+	+	+	+	+
3						+
4				+		
5	+	+		+	+	+
6	+		+	+	+	+
7	+			+		
8			+	+	+	+
9	+	+	+	+		+
10	+	+	+	+	+	+

Office Visit Data (Physiological Measures)

Subject Number	Baseline Cycle 1	Baseline Cycle 2	Placebo Cycle 1	Placebo Cycle 2	Treatment Cycle 1	Treatment Cycle 2
1	+				+	+
2	+	+	+	+	+	+
3	+	+	+		+	+
4				+	+	
5	+	+				+
6	+		+	+		+
7			+	+		
8			+	+		+
9	+	+	+	+		+
10	+	+	+	+	+	+

Plusses indicate cycles with valid data; cycles with invalid data were left blank.

TABLE 8

Adjusted Means for Cycle Phases (N = 10)

	Condition											
	Baseline				Placebo				Treatment			
	1	2	3	4	1	2	3	4	1	2	3	4
MAACL												
Anxiety	2.34	1.50	1.70	1.96	1.97	1.26	2.27	1.60	1.97	1.51	1.39	2.01
Depression	6.57	4.78	5.77	6.28	6.09	4.60	5.85	5.54	5.95	5.35	6.22	6.81
Hostility	6.62	5.72	6.42	6.64	6.41	5.29	6.13	5.86	6.39	5.63	5.69	6.70
Moos												
Water Retention	2.21	1.37	1.39	2.73	2.15	1.28	1.81	2.40	1.90	1.15	1.54	2.44
Anxiety	2.39	2.04	2.16	2.22	2.32	1.92	2.37	2.03	2.17	1.92	1.81	2.01
Depression	2.12	1.58	1.69	1.39	2.08	1.52	2.11	2.02	2.05	1.62	2.05	2.03
Salt Intake	4.78	3.99	4.39	4.62	2.99	2.23	2.32	2.42	2.34	2.37	2.06	2.01
Food Intake	14.89	14.33	14.82	14.98	12.50	13.19	12.88	12.88	10.98	12.59	12.83	12.91
Weight		128.5	128.2	129.1		125.9	126.3	125.7		124.4	126.2	125.2
Blood Pressure												
Systolic		113.0	112.7	113.0		113.8	111.3	108.1		109.8	109.2	108.0
Diastolic		75.0	69.6	70.9		72.9	68.5	68.8		70.8	69.9	66.4

Cycle phases: 1 = Menstrual
2 = Post-menstrual
3 = Luteal
4 = Premenstrual

TABLE 9

Adjusted Means
Baseline, Placebo, Treatment (N = 10)

	Change: Premenstrual minus Post-menstrual			Cycle Average		
	Baseline	Placebo	Treatment	Baseline	Placebo	Treatment
MAACL						
Anxiety	.45	.34	.50	1.85	1.78	1.72
Depression	1.50	.94	1.46	5.85	5.52	6.08
Hostility	.92	.57	1.06	6.35	5.92	6.10
Moos						
Water Retention	1.36	1.12	1.30	1.92	1.91	1.76
Anxiety	.18	.11	.09	2.20	2.16	1.98
Depression	-.19	.50	.41	1.70	1.93	1.94
Salt Intake	.63	.20	-.37	4.44	2.49	2.19
Food Intake	.65	-.31	.37	14.75	12.86	12.33
Weight	.63	-.23	.80	128.6	126.0	125.3
Blood Pressure						
Systolic	.01	-5.72	-1.77	112.9	111.1	109.0
Diastolic	-4.07	-4.11	-4.39	71.8	70.1	69.0

experimental divisions. This finding indicates that according to subjects' self-report food check lists, they did adhere to the modified low-sodium dietary instructions. With the exception of the Moos depression measure, both MAACL and Moos self-report measures show the expected curve for the baseline period, with premenstrual increase in negative symptom levels. Physiological and food measures show the same baseline curve, but with premenstrual increase being very slight. The mood measures and subjective water retention appear to show a similar curve for placebo and treatment cycles as well, with little apparent difference from baseline patterns. The food measures--both salt intake and total food intake--show an overall drop during both placebo and treatment. This pattern indicates that as subjects complied with the dietary reduction of salt, their total food intake decreased slightly. Weight and systolic blood pressure show lower overall cycle levels for treatment and placebo, without premenstrual increases.

Because the amount of missing data precluded more elaborate analyses of treatment effects, a series of paired *t*-tests was performed for all home record-keeping variables, comparing baseline cycle 1 with treatment cycle 2, and placebo cycle 2 with treatment cycle 2. (These cycles of each experimental division were chosen because they had more valid subject data than did the other

cycles of each experimental division.). Table 10 shows results for the premenstrual phase of the selected cycles. While the MAACL hostility scale shows an increase which approaches significance from baseline to placebo, the only significant premenstrual change is a decrease in self-reported salt intake for both placebo and treatment divisions--again, confirming subjects' compliance with the sodium reduction diet. Table 11 shows results of paired *t*-tests comparing within-cycle change scores. No differences among experimental divisions were found. The majority of change scores for all divisions show the premenstrual phase to be higher than post-menstrual for most variables (see also Table 8). Negative *t*-values in column 3 of Table 11 indicate that the change scores during treatment were consistently but not significantly larger than were placebo change scores.

Table 12 shows results of paired *t*-tests when each cycle was averaged over all four phases (see Figures 2-4). Highly significant differences in salt intake confirm the success of the dietary manipulation. A slight decrease in food intake which accompanied the lowered sodium consumption approached significance during the treatment division. A surprising placebo effect is indicated by the significant decrease over baseline in the MAACL hostility scale. The MAACL anxiety scale shows a significant treatment effect; the Moos anxiety scale shows a parallel effect which

FIGURE 2

MAACL Scale Scores Averaged Over Cycles

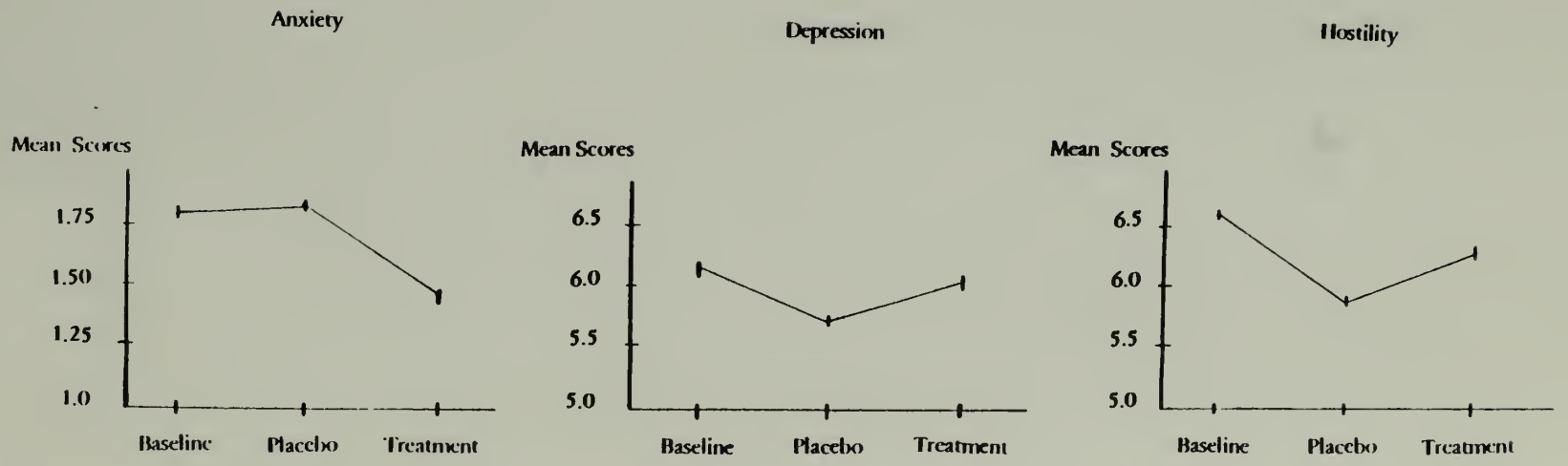

FIGURE 3

Moos MDQ Scale Scores Averaged Over Cycles

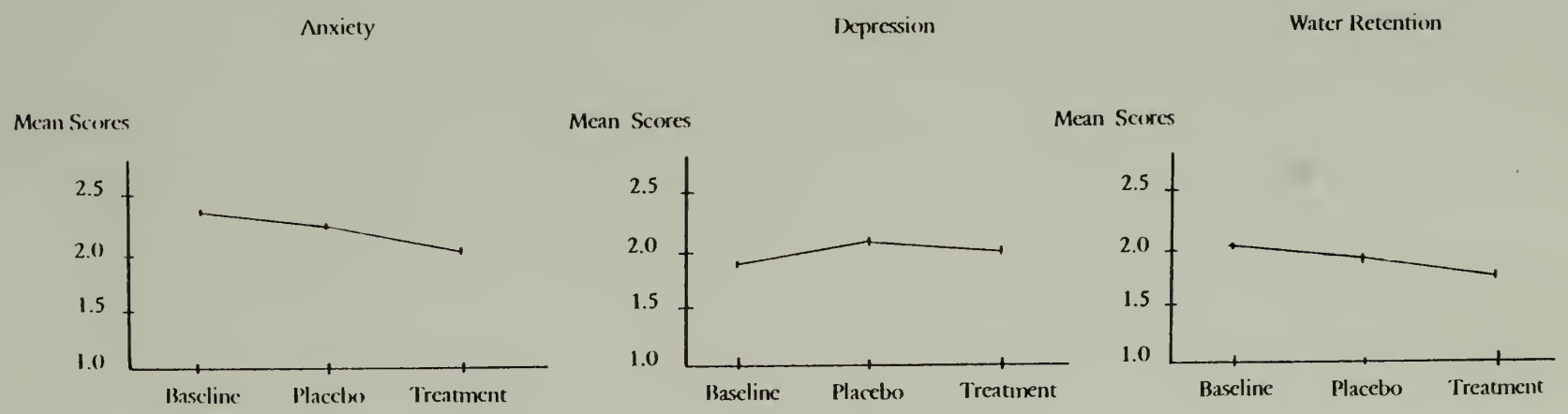

FIGURE 4

Food Scale Scores Averaged Over Cycles

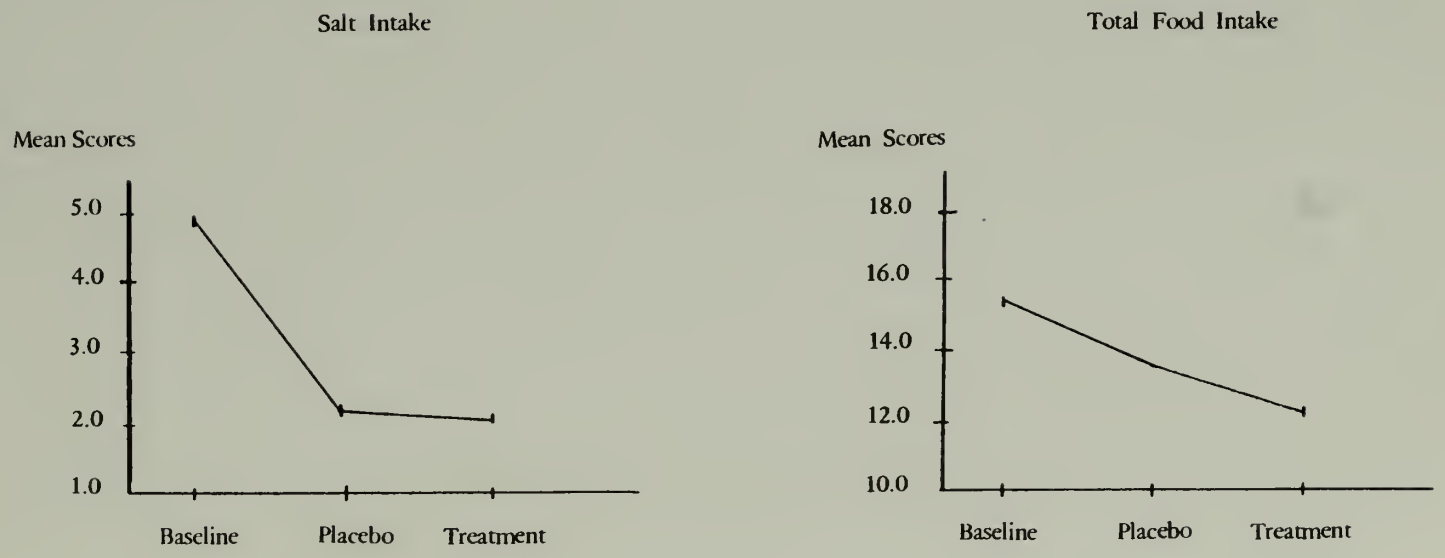

TABLE 10

Paired T-tests, Home Record-keeping Data: Baseline, Placebo, Treatment

	Premenstrual		
	Baseline and Placebo t Value (df = 5)	Baseline and Treatment t Value (df = 5)	Placebo and Treatment t Value (df = 5)
MAACL			
Anxiety	0.370	1.277	-0.025
Depression	1.425	1.382	-0.661
Hostility	2.090*	1.893	-0.983
Moos MDQ			
Water Retention	1.300	0.858	-0.645
Anxiety	0.853	1.477	0.417
Depression	-1.698	-1.089	-0.187
Salt Intake	2.763**	3.426**	-0.676
Food Intake	0.936	1.247	-0.263

*p < .10
**p < .05
***p < .01

TABLE 11

Paired T-tests, Home Record-keeping Data: Baseline, Placebo, Treatment

	Change: Premenstrual minus Post-menstrual		
	Baseline and Placebo t Value (df = 5)	Baseline and Treatment t Value (df = 5)	Placebo and Treatment t Value (df = 5)
MAACL			
Anxiety	0.268	0.180	-0.601
Depression	0.927	0.954	-0.669
Hostility	1.607	0.287	-0.965
Moos MDQ			
Water Retention	0.733	0.000	-0.779
Anxiety	0.250	0.436	-0.165
Depression	-1.234	-1.356	-0.569
Salt Intake	0.721	0.690	-0.544
Food Intake	1.962	0.280	-1.464

*p < .10
**p < .05
***p < .01

TABLE 12

Paired T-tests, Home Record-keeping Data: Baseline, Placebo, Treatment

	Baseline and Placebo t Value (df = 5)	Baseline and Treatment t Value (df = 5)	Placebo and Treatment t Value (df = 5)
MAACL			
Anxiety	-0.290	3.217**	2.347*
Depression	1.311	0.031	-0.486
Hostility	2.835**	0.746	-0.246
Moos MDQ			
Water Retention	0.230	0.952	0.570
Anxiety	1.030	2.067*	2.519*
Depression	-1.159	-0.717	0.100
Salt Intake	6.434***	6.149***	1.286
Food Intake	1.066	2.120*	1.427

*p < .10
**p < .05
***p < .01

approaches significance. There is also a placebo effect on both anxiety scales which approaches significance.

Because cycles with valid office visit (physiological) data were somewhat different than home record-keeping valid cycles (see Table 7), the cycles selected for paired t-tests of physiological measures were different than cycles used in Tables 10-12. Table 13 shows the results of paired t-tests for the physiological variables for all subjects with valid cycle data. The only effect approaching significance was a premenstrual decrease in systolic blood pressure during treatment.

There was one subject who lost over twenty pounds between the beginning and end of the study. Because this extreme weight loss case could obscure more subtle fluctuations or treatment effects on other subjects, the paired t-tests for the physiological data were recalculated without that particular subject (see Figure 5). This subject had valid office visit data for only one treatment cycle in addition to baseline cycle. Therefore the deletion of her physiological data affected only the paired t-tests comparing baseline and treatment (see Table 14). Without the extreme case, a significant treatment effect of weight loss is shown when cycle phases were averaged. A decrease in cycle average systolic blood pressure approached significance.

TABLE 13

Paired T-tests, Physiological Variables: Using All Valid Subject Data
Baseline, Placebo, Treatment

	Baseline and Placebo t Value (df = 3)	Baseline and Treatment t Value (df = 4)	Placebo and Treatment t Value (df = 3)
		Premenstrual	
Weight	1.020	1.750	-1.700
Blood Pressure			
Systolic	1.530	2.410*	-0.290
Diastolic	0.220	0.310	0.770
		Change: Premenstrual minus Post-menstrual	
Weight	0.880	1.300	-1.050
Blood Pressure			
Systolic	1.770	0.850	-0.400
Diastolic	0.310	0.310	0.320
		Cycle Average	
Weight	0.990	1.960	-1.400
Blood Pressure			
Systolic	0.060	2.030	1.080
Diastolic	0.200	0.550	0.350

*p < .10

FIGURE 5

Physiological Scores Averaged Over Cycles

(Excluding extreme case)

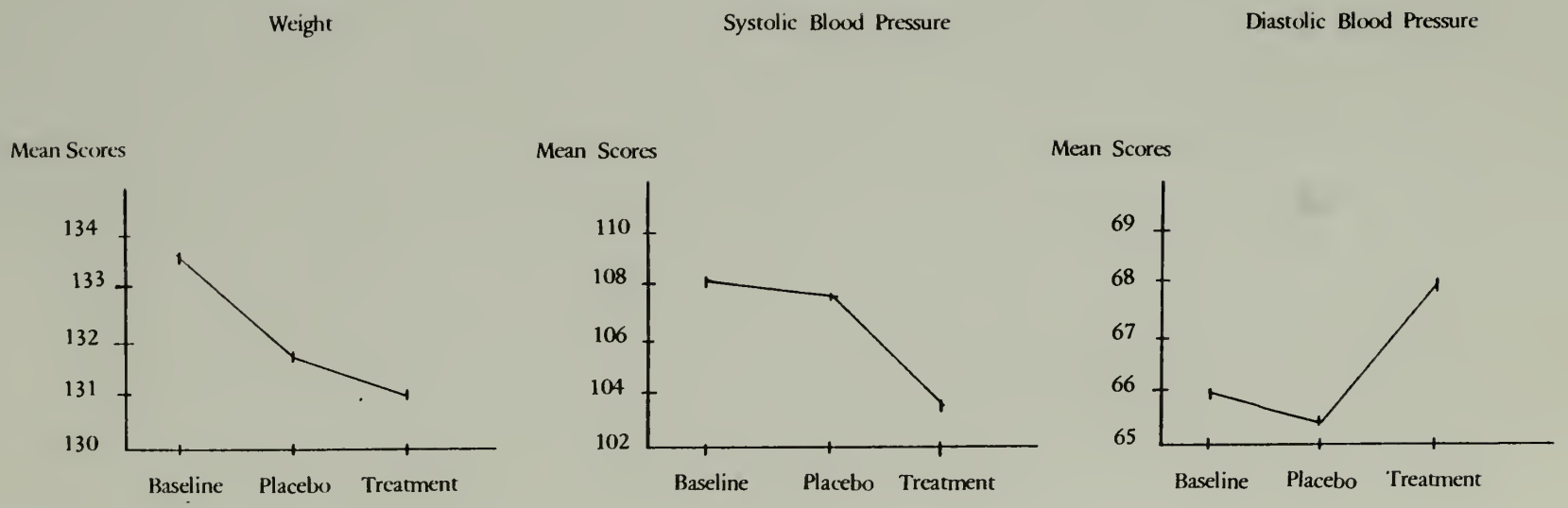

TABLE 14

Paired T-tests, Physiological Variables
(Excluding Extreme Weight Loss Subject)

	Baseline and Treatment t Value (df = 3)
	Premenstrual
Weight	1.910
Blood Pressure	
Systolic	1.950
Diastolic	0.210
	Change: Premenstrual minus Post-menstrual
Weight	0.130
Blood Pressure	
Systolic	0.310
Diastolic	-0.210
	Cycle Average
Weight	3.350**
Blood Pressure	
Systolic	2.780*
Diastolic	-1.620

*p < .10
**p < .05

CHAPTER IV

DISCUSSION

Summary

The purpose of this study was two-fold. First, subjects kept daily home symptom and dietary records for a two-cycle baseline period in order to document patterns of menstrual-cycle symptoms, with a specific focus on the premenstrual syndrome. Second, a reduced level of dietary sodium was instituted so that its effect on the premenstrual syndrome could be tested.

Baseline patterns that emerged from the daily record data corroborated subjects' retrospective reports of some premenstrual symptoms but not others. Subjective experience of water retention was the most consistently reported premenstrual symptom, appearing both in the retrospective measure and in both baseline cycles. Premenstrual mood symptoms--increased anxiety and depression-- were reported retrospectively, but were not confirmed for either baseline cycle. Physiological measures--weight and blood pressure--increased premenstrually in only one of the two baseline cycles, and then, for systolic blood pressure, only marginally.

Conclusions drawn as to the effects of the

experimental manipulation must be considered tentative because of the very small number of subjects with valid menstrual cycle data. None of the hypotheses set forth in this study was confirmed; that is, reducing dietary sodium appeared to have no effect on any premenstrual symptoms, either measured directly or as a change score (premenstrual minus post-menstrual). The sodium reduction treatment did appear to affect levels of some of the symptoms when overall cycle averages were examined. Weight was significantly lower as compared to baseline weight during the treatment cycles but not during placebo cycles. One anxiety measure--the MAACL anxiety scale--was significantly lower than baseline during treatment cycles. The same measure approached significance during placebo cycles while the Moos anxiety scale showed a decrease which approached significance during both placebo and treatment.

Subjects

No differences appeared on initial interview variables as a function of how long subjects actually participated in the study. The issue of the population sample characteristics remains an important one, however, both in terms of practical considerations for conducting future research projects, and because of the question of the genralizability of any conclusions that might be drawn. Although subjects were paid in the current study, the amount of

payment apparently was too low to provide a strong impetus for them to continue through the entire six months. In a study such as this, with very little in the way of external motivations, the self-selected subject sample is likely to be unrepresentative of the general population. In fact, in the present study, an interest in women's issues seemed to be more of a motivating factor for many subjects than extreme premenstrual symptoms. Although most subjects reported regular experiences of premenstrual symptoms (as noted in the responses to the retrospective Moos questionnaire), few women claimed to have severely debilitating symptoms. One exception was a woman who suffered severe premenstrual depression and bloating. She dropped out early in the study when she became discouraged with the long baseline period and with the idea that she might then be given a placebo which wouldn't be likely to help her.

Interviewers noted that most subjects who did not drop out early did have a special interest in the effects of diet and life-style on health. A number of the women were vegetarians or had other special dietary concerns, and several women were interested in exercise as well as in diet. One of those women was eager to continue in the study, but never started menstruating for her second baseline menstrual cycle--in all likelihood because of a significant increase in her daily running distance. Other

kinds of stress--not necessarily with obvious physical manifestations--led to several drop-outs. One woman's father died, another reported an unexpected job change, one marital relationship underwent a crisis.

Not unexpectedly, a large number of subjects dropped out of the study at the end of the second baseline cycle or shortly after the beginning of the experimental phase. A number of these drop-outs simply decided that they didn't want to eliminate salty foods from their diets. Others objected to the capsules, which were, indeed, rather formidable: they were about three-fourths of an inch in length, and subjects had to take eight of them per day. Atlhough subjects had been assured that the capsules did not contain any drugs but rather a "dietary supplement," nevertheless, some subjects felt too uncomfortable about them to be willing to continue the daily swallowing of so many large, mysterious capsules. One subject, a nurse who was extremely interested in participating, finally dropped out after reporting repeated bouts of nausea after taking the capsules. This was the only case where any side effect from the capsules was reported; interestingly, it turned out that this subject had been assigned to the treatment group, so that she was reacting to capsules containing dextrose.

Comparisons of Initial Interview and Baseline Data

Subjects' retrospective reports of their menstrual cycles showed the expected worsening of mood and water retention symptoms premenstrually. Although Moos (1977) has reported that premenstrual syndrome may worsen with age and childbearing, the current study showed no correlation between age or children and reported symptom severity. However, in this study women over thirty were somewhat underrepresented (12 out of 46), as were those with children (eight out of 46), so the effects of these factors could not be adequately tested. The one initial interview variable that did correlate significantly with severity of all three premenstrual symptoms was length of menses. This intriguing finding may simply reflect a tendency for some subjects to emphasize overall severity of menstrual symptoms. However, length of menses did not correlate with menstrual phase (as opposed to premenstrual) symptoms except for water retention. There may, therefore, be some real connection between the premenstrual syndrome and the length of menstrual flow. Further research is needed to shed light on this question.

One important factor which hampered this study was the amount of variability found in length of cycle. Most subjects initially reported that their cycles were quite regular; in fact, subjects who reported irregular cycle

lengths were disqualified from participation in the initial screening. Yet it was not unusual for individual subjects' cycles to vary from their own "norm" by as much as a week, or even more, for at least one or two cycles out of the six cycles followed in this study. The variant cycles were no more likely to be one of the treatment or placebo as opposed to baseline cycles, so it does not appear that the dietary change or capsule supplements had any effect on cycle length. In any case, a considerable amount of information was unusable because of variable cycle length.

The problem of cycle length variablility could be overcome in future research by the use of a more regular method of home record data collection, rather than the four discrete sets of three-day packets based on estimates of cycle length. If subjects were to record their data every other, or even every day, then cycle phases could be determined retrospectively by counting back from the onset of menstruation, and the appropriate data sets could be used. Such a method would have an additional advantage over the current study, whose four data packets served to highlight subjects' consciousness of different cycle phases. If women routinely filled out the data forms every day or every other day, they would be less likely to be self-conscious and therefore biased about which part of their cycle they were experiencing. The primary disadvantage of that method, and the reason it wasn't used in the

current study, is the problem of subjects' willingness to cooperate when asked to fill out so many forms so often. Most subjects, however, in post-study conversations, stated that they wouldn't object to filling out the questionnaires more frequently, since they were not unduly time-consuming.

In addition to cycle length variability, variability of symptom patterns also posed a problem. Considerable between-subject variability had been expected, but the within-subject variability was even greater than expected. Subject inconsistency across the two baseline cycles not only made it difficult to interpret subsequent treatment effects, but also posed a problem in understanding subjects' initial, retrospective reports of symptom patterns. It is possible that in the retrospective symptom reports, subjects were automatically "averaging" their cumulative experience of menstrual cycle symptom patterns. It is also possible that their retrospective reports merely reflected the cultural expectation for premenstrual symptoms. The latter explanation seems unlikely, however, since subjects could just as easily have followed the culturally expected pattern of symptom reporting in their home records, since they were aware of which cycle phase they were going through for each three-day data set. The fact that they did not simply follow an expected norm in their daily records suggests that subjects do in fact experience considerable variation in their cycle patterns

from month to month.

There are a number of factors that may contribute to high within-subject menstrual cycle symptom variability. Environmental stresses, both positive and negative, have an immediate impact on many of the relevant variables--especially mood measures. While it wasn't possible in this study to quantify stressors in terms of their impact, subjects did give brief qualitative reports of perceived stressors as part of their daily records. It was clear that depression and anxiety measures were sensitive to obvious stressors, such as an argument with a spouse or lover, or job-related stress. It is easy to see how daily environmental occurrances could in the short run overshadow the more subtle, though equally real, effects on mood of cyclic hormonal changes. Baseline record-keeping data would have to be collected for many more cycles than two in order for a consistent cyclic pattern to emerge over and above daily fluctuations caused by a variety of life events.

Dietary and physiological data were undoubtedly affected by environmental events as well. Salt and total food intake did not show significant premenstrual increases, expect for a tendency during the second cycle for food consumption to increase premenstrually. In other words, Dalvit's (1981) strong evidence of premenstrual increase in food consumption was only marginally and

inconsistently confirmed. Unfortunately, for many subjects the first baseline cycle and in some cases both baseline cycles coincided with the Thanksgiving-Christmas-New Year holiday season, a time when food consumption for many people is thrown off its usual course. Another possible explanation for the failure to find expected menstrual cycle dietary patterns, as well as for the inconsistent mood patterns, may have involved the fact of the record-keeping itself. A number of subjects in fact commented that they thought their increased awareness of mood and eating patterns resulting from the record-keeping actually did influence their affect and their behavior. Again, more than two baseline cycles may be necessary for behavior changes resulting from self-observation to stablize.

In addition to external factors affecting variability, some within-subject variability may result from varying patterns of monthly hormone fluctuations--variations quite possibly influenced in turn by environmental or seasonal factors. Some of these monthly hormonal pattern differences could result in changing levels or types of menstrual symptoms, or in symptoms occurring at different times. A number of subjects noted that they might experience premenstrual symptoms any time during the two weeks between ovulation and menstruation. In this study earlier luteal phase symptoms were not included in statistical analyses, but it might be important to take the entire

premenstrual time period into account in future research.

Dietary Sodium Treatment Results

The ten subjects who participated in the experimental manipulation for the last four cycles of the study were all interested in diet and health issues as well as in the premenstrual syndrome. It is important to note that their initial dietary patterns were probably not representative of the population at large, either in sodium content or in other respects, although no normative comparison data were available to make such an assessment. An important aspect of the double-blind design was the use of capsules to replace dietary sodium in the placebo phase. Yet for the subject population participating in this study, the daily four grams of salt consumed in capsule form may have replaced more salt in subjects' diets than was actually eliminated through dietary change. On the other hand, the possibility that subjects did not comply with the instructions to take eight capsules per day must also be considered. The effect of subjects taking fewer than the eight capsules per day would differ according to the experimental phase in question. Fewer capsules during the treatment phase would have no effect, since those capsules only contained dextrose. Fewer capsules during the placebo phase, however, would of course mean that subjects were not in fact replacing their dietary sodium, and, depending on

their actual levels of sodium and the number of capsules omitted, they might tend to approximate the treatment phase rather than the placebo phase in dietary salt consumption. Thus, without independent corroboration of actual salt consumption (such as measures of urinary sodium levels), possible placebo effects in this study cannot be distinguished from non-compliance effects in interpreting the lack of differences between treatment and placebo results.

The only clear difference between baseline and treatment phases appeared when overall cycle averages were compared: anxiety, weight, and, more tentatively, systolic blood pressure showed lower levels during treatment than baseline. Part of the reason for this finding, it should be pointed out, is that averaging the four cycle phases eliminates a certain amount of variability--an important factor especially in analyses using so few subjects. Nevertheless these findings have important implications: it may indeed stand to reason that reducing dietary sodium does have an absolute effect on anxiety, weight, and blood pressure irrespective of the menstrual cycle. Although evidence as to the effectiveness of dietary salt reduction as a treatment for hypertension is controversial, Tuthill and Calabrese (1981b) have provided evidence showing that in normotensive populations, systolic blood pressure levels are related to sodium consumption. The evidence from the present study, though inconclusive because of missing data

and small subject sample size, corroborates the findings of Tuthill and Calabrese. The additional evidence in this study that reduced salt intake may be related to lower levels of anxiety also has far-reaching implications for the treatment and/or prevention of hypertension. It has often been postulated that anxiety levels may be an intermediary link in the development and maintenance of hypertension in susceptible individuals. Direct evidence such as the findings in this study can lead to increased understanding of the elements of hypertension--which in turn can further the development of more comprehensive treatment approaches.

Recommendations

Research on the relationship between dietary sodium and the menstrual cycle has widespread implications for many issues in addition to premenstrual syndrome, including hypertension, eating behavior, and the overall health concerns of women. Yet because of the difficulties involved in doing this research, many questions remain to be clarified. Considerable financial and institutional resources are necessary to insure adequate sample sizes and experimental time periods. Length of time is particularly important, as was seen in the present study, because of high within-subject variability. Many months would be required to document baseline patterns that are subject to

the effects of seasonal and environmental factors, as well as endogenous variations. Subjects should be matched for age, children, severity and type of symptom, and even for dietary characteristics. Methods for assuring subject compliance with experimental manipulations must be developed. As the role of dietary sodium in relation to menstrual cycle phenomena is clarified, questions about additional factors, such as other nutritional elements, can also be addressed.

In summary, the surprising discrepancy in the current study between baseline and retrospective menstrual cycle patterns emphasizes the need for undertaking rigorous longitudinal research in order to clarify the elusive nature of the premenstrual syndrome. Furthermore, the overall effect on anxiety of reducing dietary sodium clearly establishes a connection between mood states, dietary factors, and health concerns that demands continued investigation.

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A P P E N D I C E S

APPENDIX A

INSTRUCTIONS FOR A MODERATELY LOW-SODIUM DIET

Most foods already contain varying amounts of salt, so that even if you add no salt to your food and avoid highly salted foods you are getting plenty of sodium.

1. Add no salt to your cooking, or to your food at the table.

2. Avoid the following foods, which are high in salt content:

   Ham
   Corned beef
   Bacon
   Processed meats (sausage, salami, bologna, etc.)
   Pickles
   Relishes
   Catsup
   Mustard
   Soy sauce
   Commercial salad dressings
   Olives
   Sauerkraut
   Canned or dried soups
   Cheese (including cottage cheese)
   Salted snacks (crackers, pretzels, chips, nuts)
   Restaurant food, especially "fast-food" restaurants
   Canned fish
   Pre-prepared processed foods (frozen dinners, pizza, fried chicken, canned pork and beans, etc.)

3. Avoid antacid preparations, such as Alka-Selzer; also, some other common drugs contain sodium. Check with your druggist or physician.

Within a week or two you will find yourself becoming accustomed to the natural tastes of many foods, and salty foods will be distasteful.

There may be occasions when you find it unavoidable to have some of the above listed foods. Don't worry about it, but try to avoid the foods as much as possible.

Let us know about how you are doing, and if there are any questions or problems.

APPENDIX B

INFORMED CONSENT FORM

I understand that in this study I will be asked to keep a regular record of my premenstrual symptoms, moods, dietary intake, and activity level, and that I will come to Tobin Hall three times a month to have my weight, blood pressure, and home record-keeping checked. I understand that after a two month baseline period I may be asked to make some changes in my diet and/or take some daily capsules which may contain either a dietary supplement or a placebo (inert substance), which may or may not affect my premenstrual symptoms. I understand that all of my records and all other experimental data will be kept completely confidential and anonymous.

I understand that the dietary supplement and placebo present no risk to my health. I also understand that if I participate for at least four months I will receive an agreed upon sum of money. I have been informed that I may withdraw my consent and withdraw from the study at any time without penalty. I understand that although during the study I will not be told what the dietary supplement is or whether I will be taking the supplement or the placebo, at the conclusion of the study I will be given all of this information as well as any other information I wish to have about the methods and hypotheses of the study.

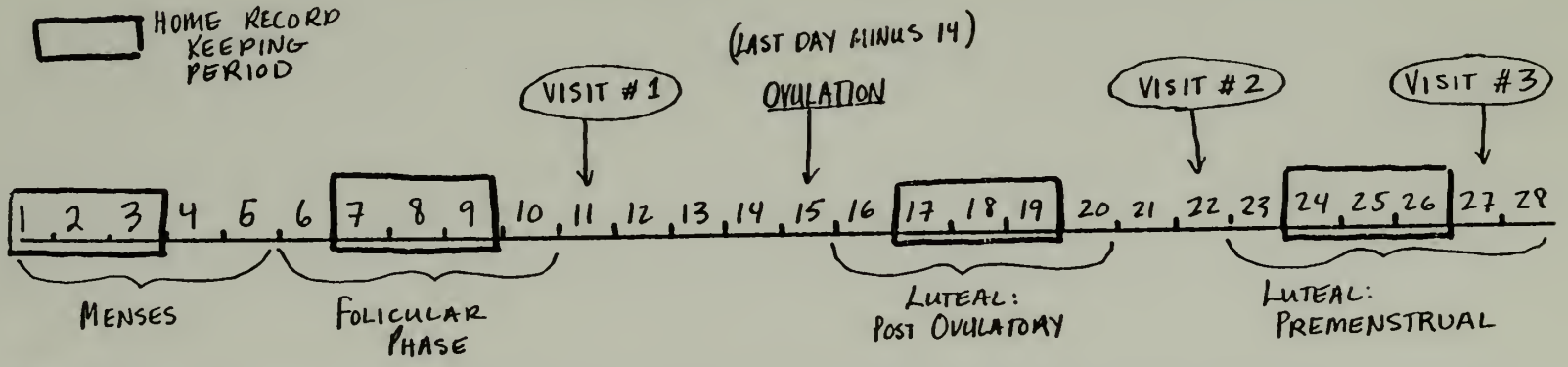
_____ _____

Date Signature

A P P E N D I X C

SAMPLE OF 28-DAY MENSTRUAL CYCLE

SAMPLE OF 28-DAY MENSTRUAL CYCLE
HOME RECORDING and OFFICE VISIT DATES



INTERVIEWER _____

VOLUNTEER'S CYCLE
NUMBER ____

NAME _____
SUBJECT # _____
PHONE # _____

VISITS ?

DATE																									
DAY #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26

VISITS?

DATE																										
DAY #	27	28	29	30	31	32	33	34																		

A P P E N D I X D

INITIAL INTERVIEW QUESTIONNAIRE

Date _____ Name _____

Interviewer _____ Subject # _____

Phone # _____

Today's Blood Pressure _____ Number of Children _____

Occupation _____ Education Level _____

Approximate Income _____ Living Situation _____

Please circle the number which best describes you.

1. What is your appetite usually like?

1	2	3	4
extremely satiated	moderately satiated	slightly satiated	neither hungry nor satiated

5	6	7
slightly hungry	moderately hungry	extremely hungry

2. What is your usual activity level?

1	2	3	4
extremely inactive	moderately inactive	slightly inactive	neither active nor inactive

5	6	7
slightly active	moderately active	extremely active

3. What is your usual caffeine intake per day? Specify cups of coffee, tea, cans of soda, candy bars, etc.

4. List any recent events (within the last month) which might be considered stressful, i.e., marriage, separation, births, deaths, promotion, demotion, increase in income, decrease in income, etc.

5. Please list any medications that you use, including over-the-counter drugs, street drugs, and diet pills.

How often do you use each listed above?

A P P E N D I X E

MULTIPLE AFFECT ADJECTIVE CHECK LIST

Below you will find words which describe different kinds of moods and feelings. For each word, decide whether or not it describes how you feel most of the time. If it does, circle it; if it doesn't, don't mark it at all. Some of the words may sound alike, but we want you to mark all the words that describe your feelings. Work rapidly.

1. active
2. adventurous
3. affectionate
4. afraid
5. agitated
6. agreeable
7. aggressive
8. alive
9. alone
10. amiable
11. amused
12. angry
13. annoyed
14. awful
15. bashful
16. bitter
17. blue
18. bored
19. calm
20. cautious
21. cheerful
22. clean
23. complaining
24. contented
25. contrary
26. cool
27. cooperative
28. critical
29. cross
30. cruel
31. daring
32. desperate
33. destroyed
34. devoted
35. disagreeable
36. discontented
37. discouraged
38. disgusted
39. displeased
40. energetic
41. enraged
42. enthusiastic
43. fearful
44. fine
45. fit
46. forlorn
47. frank
48. free
49. friendly
50. frightened
51. furious
52. gay
53. gentle
54. glad
55. gloomy
56. good
57. good-natured
58. grim
59. happy
60. healthy
61. hopeless
62. hostile
63. impatient
64. incensed
65. indignant
66. inspired
67. interested
68. irritated
69. jealous
70. joyful
71. kindly
72. lonely
73. lost
74. loving
75. low

76. lucky
77. mad
78. mean
79. meek
80. merry
81. mild
82. miserable
83. nervous
84. obliging
85. offended
86. outraged
87. panicky
88. patient
89. peaceful
90. pleased
91. pleasant
92. polite
93. powerful
94. quiet
95. reckless
96. rejected
97. rough
98. sad
99. safe
100. satisfied
101. secure
102. shaky
103. shy
104. soothed
105. steady
106. stubborn
107. stormy
108. strong
109. suffering
110. sullen
111. sunk
112. sympathetic
113. tame
114. tender
115. tense
116. terrible
117. terrified
118. thoughtful
119. timid
120. tormented
121. understanding
122. unhappy
123. unsociable
124. upset
125. vexed
126. warm
127. whole
128. wild
129. willful
130. wilted
131. worrying
132. young

A P P E N D I X F

MENSTRUAL DISTRESS QUESTIONNAIRE

(Form A)

Name _____ Marital Status _____

Age _____ Number of Children _____

Today's Date _____ Occupation _____

Write the approximate dates of your most recent menstrual period (flow) in the space marked "A" below. Then write the dates of the menstrual period which preceded the most recent one in the space marked "D".

from _____ to _____	other times during most recent cycle
D	C
week before most recent flow	most recent flow from _____ to _____
B	A

On the next two pages is a list of symptoms which women sometimes experience. Please describe your experience of each of these symptoms during the three different time periods listed below:

Col. 1 during your <u>most recent</u> menstrual flow (the dates delineated by area A on the diagram above),

Col. 2 during the one week before your <u>most recent</u> flow (area B on the diagram),

Col. 3 during the remainder of your <u>most recent</u> menstrual cycle (area C).

Note: The answers you put in columns 1, 2, and 3 should be accurate for your experience specifically during your most recent menstrual cycle. Please do not simply report your general experience. Also, please report any experience of these symptoms whether or not they seem to you to be related to your menstrual cycle.

For each answer choose the descriptive category listed which best describes your experience of that symptom during that time. Write the number of that description in the space provided. Even if none of the descriptions are exactly correct, choose the one that best describes your experience. Do not leave any blank spaces.

Descriptive Categories

1 - no experience of symptom
2 - barely noticeable
3 - present, mild
4 - present, moderate
5 - present, strong
6 - acute or partially disabling

		1. most recent flow (A)	2. week before (B)	3. remainder of cycle (C)
1.	Weight gain.....	_____	_____	_____
2.	Insomnia.....	_____	_____	_____
3.	Crying.....	_____	_____	_____
4.	Lowered school or work performance.....	_____	_____	_____
5.	Muscle stiffness.....	_____	_____	_____
6.	Forgetfulness.....	_____	_____	_____
7.	Confusion.....	_____	_____	_____
8.	Take naps or stay in bed.....	_____	_____	_____
9.	Headache.....	_____	_____	_____
10.	Skin Disorders.....	_____	_____	_____
11.	Loneliness.....	_____	_____	_____
12.	Feelings of Suffocation.	_____	_____	_____
13.	Affectionate.....	_____	_____	_____
14.	Orderliness.....	_____	_____	_____
15.	Stay home from work or school.....	_____	_____	_____
16.	Cramps (uterine or pelvic).....	_____	_____	_____
17.	Dizziness or faintness..	_____	_____	_____
18.	Excitement.....	_____	_____	_____
19.	Chest pains.....	_____	_____	_____
20.	Avoid social activities.	_____	_____	_____
21.	Anxiety.....	_____	_____	_____
22.	Backache.....	_____	_____	_____
23.	Cold sweats.....	_____	_____	_____

		1. most recent flow (A)	2. week before (B)	3. remainder of cycle (C)
24.	Lowered judgment.....	____	____	____
25.	Fatigue.....	____	____	____
26.	Nausea or vomiting.....	____	____	____
27.	Restlessness.....	____	____	____
28.	Hot flashes.....	____	____	____
29.	Difficulty in concentration.....	____	____	____
30.	Painful or tender breasts.....	____	____	____
31.	Feelings of well-being..	____	____	____
32.	Buzzing or ringing in ears.....	____	____	____
33.	Distractable.....	____	____	____
34.	Swelling (e.g., abdomen, breasts or ankles)....	____	____	____
35.	Accidents (e.g., cut finger, break dish)...	____	____	____
36.	Irritability.....	____	____	____
37.	General aches and pains.	____	____	____
38.	Mood swings.....	____	____	____
39.	Heart pounding.....	____	____	____
40.	Depression (feeling sad or blue).....	____	____	____
41.	Decreased efficiency....	____	____	____
42.	Lowered motor coordination.....	____	____	____
43.	Numbness or tingling in hands or feet.....	____	____	____
44.	Change in eating habits.	____	____	____
45.	Tension.....	____	____	____
46.	Blind spot or fuzzy vision.....	____	____	____
47.	Bursts of energy or activity.....	____	____	____

In what ways, if any, was your most recent menstrual cycle unusual?

APPENDIX G

FOOD FREQUENCY LIST

DATE _____

SUBJECT NUMBER _____
Day of Cycle _____

Count your average serving size as a rating of "1". For each food item listed below, please list the number of times you ate that item today. Specify if vegetables or soups are canned with a check.

MILK
- whole _____
- skim _____
- lowfat _____
- nonfat dry _____
- evaporated _____

CREAM
- half & half _____
- sour _____

PIZZA, with tomato and cheese _____

YOGURT
- plain _____
- vanilla _____
- lemon _____
- fruit types _____

CHEESE
- processed _____
- cheddar _____
- blue cheese _____
- ricotta _____
- roquefort _____
- Swiss _____
- cottage _____

MEAT
- roast beef _____
- steak _____
- corned beef _____
- meatloaf _____
- hamburg _____
- veal _____

MEAT (continued)

- lamb
- tongue _____
- brains _____
- heart _____
- kidneys _____
- liver _____
- pork _____
- goose _____
- venison _____
- _____

CHICKEN

- liver
- heart _____
- kidneys _____
- _____

TURKEY

- liver
- heart _____
- kidneys _____
- _____

PREPARED MEATS

- hot dogs
- bologna _____
- boiled ham _____
- salami _____
- liverwurst _____
- Vienna sausages _____
- deviled ham _____
- sausage _____
- Italian links _____
- kielbasa _____
- bacon _____
- chicken pie _____
- meat pie _____
- turkey pie _____
- chicken salad _____
- ham salad _____
- _____

VEGETABLES — CANNED?

- bean sprouts
- baked beans w/ pork and tomato _____
- chickpeas _____
- lentils _____
- soybeans _____
- tofu _____
- chili _____
- artichokes _____
- asparagus _____
- avacado _____
- bamboo shoots _____

VEGETABLES (continued)

	CANNED?
black beans	
pinto beans	
wax beans	
lima beans	
kidney beans	
beets	
broccoli	
brussel sprouts	
cabbage	
carrots	
carrot juice	
cauliflower	
chives	
celery	
chard	
corn	
eggplant	
miso	
natto	
mustard greens	
kale	
kohlrabs	
leeks	
mushrooms	
onion, dehydrated	
green peas	
baked potatoes	
boiled potatoes	
mashed potatoes	
hashbrowns	
french fries	
potato chips	
scalloped potatoes	
pumpkin	
sauerkraut	
winter squash	
sweet potatoes	
spinach	
tomato puree	
tomato juice	
vegetable juice	
mixed vegetables	
Greek olives	
green olives	
parsnips	
dill pickles	
sweet pickles	
pickle relish	
baker's yeast	
torula	

JUICES

- orange
- grapefruit _____
- apricot _____
- pineapple _____
- prune _____
- V-8 _____
- _____

FISH

- bass
- bluefish _____
- tuna (canned) _____
- carp _____
- clams (canned) _____
- clams _____
- crab _____
- anchovies _____
- eel _____
- haddock _____
- herring _____
- flounder _____
- kelp _____
- fishsticks _____
- lobster (canned) _____
- lobster _____
- scrod _____
- scallops _____
- snapper _____
- swordfish _____
- shrimp (canned) _____
- shrimp _____
- mackerel _____
- oysters (canned) _____
- oysters _____
- perch _____
- pike _____
- pollock _____
- sardines _____

FRUITS

- apricots
  - dried _____
  - water packed _____
  - syrup packed _____

BREADS/CEREALS

- whole wheat _____
- dark rye _____
- hard rolls _____
- soybread _____
- potato bread _____

BREADS/CEREALS (continued)

- waffles
- granola _____
- oat flakes _____
- wheaties _____
- wheat flakes _____
- bulgar _____
- bran _____
- brewer's yeast _____
- wheat germ _____
- buckwheat _____
- breadcrumbs _____
- corn meal _____
- salted crackers _____
- wheat thins _____
- ritz _____
- saltines _____
- pretzels _____
- rice w/ salt _____
_____

NUTS & SEEDS

- almonds
- brazil nuts _____
- salted peanuts _____
- fresh chestnuts _____
- salted mixed nuts _____
- hazel nuts _____
- pecan nuts _____
- sunflower seeds (salted) _____
- English walnuts _____
- peanut butter _____
- popcorn (w/ salt) _____
_____

SOUPS CANNED?

- asparagus
- bean w/ pork _____
- beef broth _____
- celery _____
- chicken _____
- clam chowder _____
- meat and vegetable _____
- minestrone _____
- mushroom _____
- onion _____
- split pea _____
- tomato _____
- veg-veg _____
- other _____

PASTA & CASSEROLES

- macaroni and cheese _____
- spaghetti sauce, tomato, and cheese _____
- ravioli w/ tomato sauce _____
- Lasagna _____
- chop suey _____
- other _____
- _____

DRESSINGS

- butter _____
- Italian dressing _____
- blue cheese dressing _____
- gravy _____
- catsup _____
- _____

SPICES

- salt _____
- soy sauce _____
- worchestershire sauce _____
- _____

COOKIES

- brownies _____
- chocolate chip _____
- oatmeal _____
- peanut butter _____
- sugar _____
- other _____
- _____

CANDY

- chocolate bar w/ almonds _____
- chocolate mint _____
- chocolate other _____
- caramel _____
- fudge w/ nuts _____
- hard candy _____
- jelly beans _____
- M & M's _____
- peanut brittle _____
- other _____
- _____

DESSERTS

- ice cream _____
- ice milk _____
- sherbet _____
- yogurt _____
- popsicle _____
- cones _____
- custard _____
- pudding _____

PIES

- lemon meringue
- pecan _____
- pumpkin _____
- pie crust _____
- gingerbread _____
- chocolate frosting _____
- other _____
_____

FLAVORINGS

- ovaltine
- chocolate syrup _____
- chocolate powder _____
- Quik _____
_____

BEVERAGES

- hot chocolate
- tea _____
- coffee (caffeinated) _____
- cola _____
- sodas, other _____
- alcoholic _____
- beer
- beer (lite) _____
- sherry _____
- liquer _____
- wine _____
- whiskey _____
- other hard liquors _____
- other _____
_____

JAMS & JELLIES

- blackstrap molasses
- brown sugar _____
- sugar _____
- jam/jelly _____
- honey _____
- syrup _____
- other _____
_____

A P P E N D I X H

LIFE HISTORY AND HEALTH QUESTIONNAIRE

1. Age _____ Sex _____ Height _____ Weight _____

   If you feel you are over- or underweight, what would you like to weigh? _____

2. Marital status (circle one): single, engaged, married, separated, divorced, widowed, remarried, living with someone

3. Living situation (circle one): dorm (how many room-mates? _____), apartment (with how many others? ____), house (with how many others? _____)

4. Personal History: Date of Birth _____
   Place of Birth _____

   Siblings: Number of Brothers _____ Ages: _____
   Number of Sisters _____ Ages: _____

   Father: Living? _____ If alive, give father's present age _____
   Deceased? ___ If deceased, give his age at time of death _____
   Cause of death _____
   Occupation _____ Health _____

   Mother: Living? _____ If alive, give mother's present age _____
   Deceased? ___ If deceased, give her age at time of death _____
   Cause of death _____
   Occupation _____ Health _____

Circle any of the following that applied during your childhood/adolescence:

Happy childhood	Family problems
Unhappy childhood	Drug abuse
Emotional/Behavior problems	Medical problems
Legal trouble	Alcohol abuse
School problems	

5. Family Health History (Circle any of the following that apply to you or members of your family, and note who had or has the problem):

Thyroid disease _____
Kidney disease _____
asthma _____
neurological problems _____
infectious diseases _____
diabetes _____
cancer _____
gastrointestinal disease _____
glaucoma _____
epilepsy _____
heart or circulatory problem _____
depression _____
emotional problems _____
addiction _____
obesity _____
allergy _____

6. Personal health

Describe any head injuries or loss of consciousness you have had: _____

Describe any surgery you have had, and when _____
_____

Describe any accidents or injuries you have had, and when _____

Describe any serious illnesses you have had, and when
_____

Describe any other health problems you have had _____
_____

7. For each of the following, check the appropriate column as it applies to you:

	Never	Rarely	Moderately Often	Very Often
Marijuana	_____	_____	_____	_____
Tranquilizers	_____	_____	_____	_____
Sedatives	_____	_____	_____	_____
Aspirin	_____	_____	_____	_____
Cocaine	_____	_____	_____	_____

	Never	Rarely	Moderately Often	Very Often
Painkillers				
Narcotics				
Stimulants				
Hallucinogens (LSD, etc.)				
Stomach pain or discomfort				
Diarrhea				
Constipation				
Allergies				
Nausea				
Vomiting				
Insomnia				
Work too hard				
Loss of control				
Suicidal attempts				
Nervous tics				
Concentration difficulty				
Phobia				
Lazy				
Aggressive behavior				
Crying				
Temper outbursts				
Headaches				
Backache				
Fatigue				
Fitful sleep				
Dizziness				
Palpitations				
Muscle spasms				
Tension				
Sexual disturbances				
Tingling				
Numbness				
Tremors				
Fainting spells				
Hearing things				
Skin problems				
Visual disturbances				
Hearing problems				
Overeating				
Poor appetite				
Eat "junk foods"				

8. Which meals do you have at home regularly (circle)?
   Breakfast lunch dinner

9. If you eat some meals out regularly, which ones?
   Breakfast lunch dinner

10. Which is your heaviest meal of the day?
    Breakfast lunch dinner

11. Do you regularly do without or skip any meal? _____
    If so, which? _____

12. Do you regularly snack between meals or in the evening? _____
    What are your typical snacks? _____

13. List the main foods you dislike and do not eat.
    _____

14. List your favorite foods (foods you would have difficulty giving up). _____
    _____

15. Have you ever been on a diet? _____
    How often? _____ When? _____
    What kind of diet(s)? _____
    For how long? _____

16. How often do you drink alcoholic beverages? (circle)
    Never rarely a few times a week every day
    What kind? Wine beer mixed drinks

17. How much coffee do you drink per day? _____ cups
    What kind? ____ cups brewed regular
    ____ cups brewed decaffeinated
    ____ cups instant regular
    ____ cups instant decaffeinated
    How many soft drinks do you have per day? _____
    What kind? _____

18. Do you eat chocolate regularly? _____
    In what form? _____ How much? _____
    Other candy or sweets? _____

19. Do you eat refined, pre-packaged or highly processed foods regularly? _____ What kinds? _____
    How much? _____

20. Describe any alergies you have to food or other substances _____

21. Do you smoke? ____ What? _____ How much? _____

22. How often do you catch colds or flu? (circle)
More often than 1/month — less than 1/month, but at least 6 or 8/year
Three to 5/year — two or less per year

23. How many hours do you usually sleep? _____
What time do you usually go to sleep? _____
What time do you usually wake up? _____
Do you have trouble going to sleep? _____
Do you wake up in the middle of the night and have trouble falling asleep again? _____
Do you wake up early and have trouble getting back to sleep? _____
Do you usually remember dreaming? _____

24. Activity:
During a typical waking day, how many (estimated hours do you spend:
sitting down? _____ standing up? _____
walking? _____ being active or exercising? _____
If you engage in activity or exercise on weekends or other occasions describe: _____
how often? _____

A P P E N D I X I

RECORD KEEPING QUESTIONNAIRE

Date _____ Name _____

Interviewer _____ Subject # _____

Phone # _____

Please circle the number which best describes you TODAY.

1. What was your appetite like today?

1	2	3	4
extremely satiated	moderately satiated	slightly satiated	neither hungry nor satiated
5	6	7	
slightly hungry	moderately hungry	extremely hungry	

2. What was your activity level?

1	2	3	4
extremely inactive	moderately inactive	slightly inactive	neither active nor inactive
5	6	7	
slightly active	moderately active	extremely active	

3. What is your usual caffeine intake per day? Specify cups of coffee, tea, cans of soda, candy bars, etc.

4. List any recent events within the last week which might be considered stressful, i.e., marriage, separation, births, deaths, promotion, demotion, increase in income, decrease in income, etc.

5. Please list any medications, over-the-counter drugs, street drugs, or diet pills that you have taken today.

How much of each of those listed did you take?

6. Did you crave a certain food today? _____

If yes, what food? _____

What time of day? _____

Did you eat the food? _____

How much did you eat? _____

APPENDIX J

MULTIPLE AFFECT ADJECTIVE CHECK LIST, SHORT FORM

Below you will find words which describe different kinds of moods and feelings. For each word, decide whether or not it describes how you feel today. If it does, circle it; if it doesn't, don't mark it at all. Some of the words may sound alike, but we want you to mark all the words that describe your feelings. Work rapidly.

1. active
2. adventurous
3. afraid
4. agreeable
5. aggressive
6. alive
7. alone
8. amiable
9. amused
10. angry
11. awful
12. bashful
13. blue
14. bored
15. calm
16. cautious
17. cooperative
18. cruel
19. daring
20. devoted
21. disagreeable
22. discouraged
23. displeased
24. fearful
25. fine
26. forlorn
27. frank
28. frightened
29. gay
30. gloomy
31. healthy
32. hopeless
33. impatient
34. kindly
35. lonely
36. lost
37. low
38. mad
39. merry
40. mild
41. miserable
42. nervous
43. panicky
44. polite
45. powerful
46. rejected
47. satisfied
48. shaky
49. stubborn
50. suffering
51. sunk
52. sympathetic
53. tender
54. tense
55. terrible
56. timid
57. tormented
58. understanding
59. unhappy
60. upset
61. warm
62. wilted
63. worrying

APPENDIX K

MENSTRUAL DISTRESS QUESTIONNAIRE

(Form T)

Name _____

Today's Date _____

On the next two pages is a list of symptoms which women sometimes experience. For each symptom choose the descriptive category listed below which best describes your experience of that symptom today. Circle the number of the category which best describes your experience of the symptom today. Even if none of the categories is exactly correct, choose the one that best describes your experience. Please be sure to circle one number for each symptom. Please also remember to put your name and date in the blank spaces at the top of this page.

Descriptive Categories

1 - no experience of symptom
2 - barely noticeable
3 - present, mild
4 - present, moderate
5 - present, strong
6 - acute or partially disabling

1.	Weight gain.....	1	2	3	4	5	6
2.	Insomnia.....	1	2	3	4	5	6
3.	Crying.....	1	2	3	4	5	6
4.	Lowered school or work performance.....	1	2	3	4	5	6
5.	Muscle stiffness.....	1	2	3	4	5	6
6.	Forgetfulness.....	1	2	3	4	5	6
7.	Confusion.....	1	2	3	4	5	6
8.	Take naps or stay in bed.....	1	2	3	4	5	6
9.	Headache.....	1	2	3	4	5	6
10.	Skin Disorders.....	1	2	3	4	5	6
11.	Loneliness.....	1	2	3	4	5	6
12.	Feelings of Suffocation.	1	2	3	4	5	6
13.	Affectionate.....	1	2	3	4	5	6

14.	Orderliness.....	1	2	3	4	5	6
15.	Stay home from work or school.....	1	2	3	4	5	6
16.	Cramps (uterine or pelvic).....	1	2	3	4	5	6
17.	Dizziness or faintness..	1	2	3	4	5	6
18.	Excitement.....	1	2	3	4	5	6
19.	Chest pains.....	1	2	3	4	5	6
20.	Avoid social activities.	1	2	3	4	5	6
21.	Anxiety.....	1	2	3	4	5	6
22.	Backache.....	1	2	3	4	5	6
23.	Cold sweats.....	1	2	3	4	5	6
24.	Lowered judgment.....	1	2	3	4	5	6
25.	Fatigue.....	1	2	3	4	5	6
26.	Nausea or vomiting.....	1	2	3	4	5	6
27.	Restlessness.....	1	2	3	4	5	6
28.	Hot flashes.....	1	2	3	4	5	6
29.	Difficulty in concentration.....	1	2	3	4	5	6
30.	Painful or tender breasts.....	1	2	3	4	5	6
31.	Feelings of well-being..	1	2	3	4	5	6
32.	Buzzing or ringing in ears.....	1	2	3	4	5	6
33.	Distractable.....	1	2	3	4	5	6
34.	Swelling (e.g., abdomen, breasts or ankles)....	1	2	3	4	5	6
35.	Accidents (e.g., cut finger, break dish)...	1	2	3	4	5	6
36.	Irritability.....	1	2	3	4	5	6
37.	General aches and pains.	1	2	3	4	5	6
38.	Mood swings.....	1	2	3	4	5	6
39.	Heart pounding.....	1	2	3	4	5	6
40.	Depression (feeling sad or blue).....	1	2	3	4	5	6
41.	Decreased efficiency....	1	2	3	4	5	6
42.	Lowered motor coordination.....	1	2	3	4	5	6
43.	Numbness or tingling in hands or feet.....	1	2	3	4	5	6
44.	Change in eating habits.	1	2	3	4	5	6
45.	Tension.....	1	2	3	4	5	6
46.	Blind spot or fuzzy vision.....	1	2	3	4	5	6
47.	Bursts of energy or activity.....	1	2	3	4	5	6

APPENDIX L

Subjects Grouped According to Length of Participation
Means and Standard Deviations for Initial Interview Variables*

	Groups			
	Initial Interview Only N = 11	Baseline or Partial Baseline N = 13	Began Treatment N = 8	Completed Study N = 14
Age	26.5 (5.9)	27.7 (3.8)	28.9 (4.9)	28.3 (4.0)
Menstrual Length	5.5 (.82)	5.7 (.95)	4.9 (.84)	5.9 (.67)
Initial Weight	133 (16.9)	137 (17.2)	137 (26.3)	129 (18.3)
Day of Cycle of Initial Interview	18 (6.5)	15 (9.5)	19 (10.6)	17.8 (10.0)
MAACL				
Anxiety	8.0 (2.4)	6.9 (4.4)	6.9 (3.0)	7.1 (2.6)
Depression	14.1 (3.6)	12.7 (6.5)	12.4 (4.5)	12.6 (4.9)
Hostility	7.2 (3.4)	7.6 (4.5)	5.8 (2.1)	7.4 (3.1)
Moos				
Premenstrual water retention	3.2 (.85)	3.3 (1.39)	3.6 (.94)	4.1 (1.33)
Premenstrual anxiety	3.4 (.99)	3.5 (1.09)	3.2 (1.15)	3.8 (1.13)
Premenstrual depression	3.2 (1.07)	2.5 (.95)	3.5 (1.31)	3.6 (1.21)

*The first number in each cell is the mean, followed by the standard deviation in parentheses.

A P P E N D I X M

Pearson Correlation Coefficients
, Moos Menstrual Distress Questionnaire Form A (Retrospective)
and Moos Menstrual Distress Questionnaire Form T (Daily Records)

Water Retention

	Form A			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Form T				
Cycle 1				
Menstrual	$r = .60$ $p < .001$			
Post-menstrual		$r = .30$, $p < .079$		
Premenstrual			$r = .42$, $p < .024$	
Change: Premenstrual minus post-menstrual				$r = .43$, $p < .021$
Cycle 2				
Menstrual	$r = .49$, $p < .027$			
Post-menstrual		$r = -.06$, $p < .406$		
Premenstrual			$r = .65$, $p < .003$	
Change: Premenstrual minus post-menstrual				$r = .28$, $p < .148$

A P P E N D I X N

Pearson Correlation Coefficients
Moos Menstrual Distress Questionnaire Form A (Retrospective)
and Moos Menstrual Distress Questionnaire Form T (Daily Records)

Anxiety

	Form A			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Form T				
Cycle 1				
Menstrual	$r = .49$, $p < .009$			
Post-menstrual		$r = .06$, $p < .385$		
Premenstrual			$r = .39$, $p < .035$	
Change: Premenstrual minus post-menstrual				$r = .36$, $p < .048$
Cycle 2				
Menstrual	$r = -.14$, $p < .300$			
Post-menstrual		$r = -.15$, $p < .286$		
Premenstrual			$r = .11$, $p < .345$	
Change: Premenstrual minus post-menstrual				$r = .30$, $p < .130$

A P P E N D I X O

Pearson Correlation Coefficients
Moos Menstrual Distress Questionnaire Form A (Retrospective)
and Moos Menstrual Distress Questionnaire Form T (Daily Records)

Depression

	Form A			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Form T				
Cycle 1				
Menstrual	$r = .10$, $p < .323$			
Post-menstrual		$r = .13$, $p < .274$		
Premenstrual			$r = .60$, $p < .001$	
Change: Premenstrual minus post-menstrual				$r = .05$, $p < .420$
Cycle 2				
Menstrual	$r = .44$, $p < .045$			
Post-menstrual		$r = -.03$, $p < .457$		
Premenstrual			$r = .23$, $p < .199$	
Change: Premenstrual minus post-menstrual				$r = -.34$, $p < .096$

A P P E N D I X P

Pearson Correlation Coefficients
Moos Menstrual Distress Questionnaire Form T, Cycle 1
and Moos Menstrual Distress Questionnaire Form T, Cycle 2

Water Retention

	Cycle 1			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Cycle 2				
Menstrual	$r = .61$, $p < .024$			
Post-menstrual		$r = .33$, $p < .164$		
Premenstrual			$r = .71$, $p < .008$	
Change: Premenstrual minus post-menstrual				$r = .56$, $p < .037$

A P P E N D I X Q

Pearson Correlation Coefficients
Moos Menstrual Distress Questionnaire Form T, Cycle 1
and Moos Menstrual Distress Questionnaire Form T, Cycle 2

Anxiety

	Cycle 1			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Cycle 2				
Menstrual	$r = .75$, $p < .004$			
Post-menstrual		$r = .18$, $p < .297$		
Premenstrual			$r = .22$, $p < .254$	
Change: Premenstrual minus post-menstrual				$r = -.30$, $p < .186$

A P P E N D I X R

Pearson Correlation Coefficients
Moos Menstrual Distress Questionnaire Form T, Cycle 1
and Moos Menstrual Distress Questionnaire Form T, Cycle 2

Depression

	Cycle 1			
	Menstrual	Post-menstrual	Premenstrual	Change: Premenstrual minus post-menstrual
Cycle 2				
Menstrual	$r = .35$, $p < .148$			
Post-menstrual		$r = .60$, $p < .025$		
Premenstrual			$r = .52$, $p < .051$	
Change: Premenstrual minus post-menstrual				$r = -.04$, $p < .451$