The Use of a Behavioral Checklist to Delimit and Define the Premenstrual Syndrome

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THE USE OF A BEHAVIORAL CHECKLIST TO DELIMIT AND DEFINE
THE PREMENSTRUAL SYNDROME

by
R. Hope Kerr

A Thesis
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Master of Arts
Department of Psychology

Western Michigan University
Kalamazoo, Michigan
April 1988

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For the premenstrual syndrome (PMS), there is no consensus as to specific symptoms comprising the syndrome or their temporal relationship to the menstrual cycle. The purpose of this study was to delimit and define PMS by comparing contemporaneous, behavioral data collected by 3 groups of subjects.

Based on the results of this study, PMS is suspected of being a misnomer for frequently random symptoms which may or may not be menstrually-related. "Syndrome" is misleading since there is no group of symptoms specific to one group of women. "Pre-" and "menstrual" are also misleading because the symptoms do not occur consistently before menses onset and can occur in women who no longer menstruate. The term PMS may have developed out of a sense of convenience for diagnosing and treating, as a single entity, certain behavioral, emotional and physical responses. However, this approach often leads to misdiagnosis and mistreatment of discrete, non-hormonally related responses.
ACKNOWLEDGMENTS

I am indebted to Howard E. Farris, Ph.D., R. Wayne Fuqua, Ph.D., and Jack L. Michael, Ph.D. for their guidance and assistance.

R. Hope Kerr
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The use of a behavioral checklist to delimit and define the premenstrual syndrome

Kerr, R. Hope, M.A.
Western Michigan University, 1988

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TABLE OF CONTENTS

ACKNOWLEDGMENTS ................................................................. ii
LIST OF TABLES ........................................................................ iv
LIST OF FIGURES ....................................................................... v
CHAPTER
   I. INTRODUCTION ..................................................................... 1
   II. REVIEW OF SELECTED LITERATURE ................................. 8
   III. DESIGN AND METHODOLOGY. ......................................... 15
       Subjects ................................................................................ 15
       Materials ............................................................................. 15
       Dependent Variables ........................................................... 17
       Procedure ............................................................................ 17
   IV. RESULTS ........................................................................... 21
   V. DISCUSSION ....................................................................... 46
APPENDICES
   A. Initial Interview Form ....................................................... 55
   B. Informed Consent Form ..................................................... 57
   C. Premenstrual Syndrome Symptom Checklist ..................... 59
   D. Daily Health Status Checklist ........................................... 61
   E. Human Subjects Approval Form ......................................... 63
BIBLIOGRAPHY ......................................................................... 67

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LIST OF TABLES

1. Average Number of Each Symptom Per Group ............ 23
LIST OF FIGURES

1. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #1 of the Symptomatic Group .................................................. 25
2. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #2 of the Symptomatic Group .................................................. 26
3. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #3 of the Symptomatic Group .................................................. 27
4. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #4 of the Symptomatic Group .................................................. 28
5. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #5 of the Asymptomatic Group .................................................. 31
6. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #6 of the Asymptomatic Group .................................................. 32
7. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #7 of the Asymptomatic Group .................................................. 33
8. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #8 of the Asymptomatic Group .................................................. 34
9. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #9 of the Asymptomatic Group .................................................. 35
10. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #10 of the Asymptomatic Group .............................................. 36
11. Frequency and Intensity of Symptoms Across 2 Months for Subject #11 of the Acyclic Group .............................................................. 37

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List of Figures—Continued

12. Frequency and Intensity of Symptoms Across 2 Months for Subject #12 of the Acyclic Group ........................................... 38
13. Frequency and Intensity of Symptoms Across 2 Months for Subject #13 of the Acyclic Group ........................................... 39
14. Frequency and Intensity of Symptoms Across 2 Months for Subject #14 of the Acyclic Group ........................................... 40
15. Frequency and Intensity of Symptoms Across 2 Months for Subject #15 of the Acyclic Group ........................................... 41
16. Frequency and Intensity of Symptoms Across 2 Months for Subject #16 of the Acyclic Group ........................................... 42
17. Frequency and Intensity of Symptoms Across 2 Months for Subject #17 of the Acyclic Group ........................................... 43
18. Average Symptom Scores for All Subjects in the Symptomatic, Asymptomatic, and Acyclic Groups ........................................... 44
CHAPTER I

INTRODUCTION

Premenstrual syndrome (PMS) has been described as a hormonal disorder distinguished by its symptoms and by the time of their occurrence. The symptoms can be mild so that the woman's level of functioning is, if at all, only slightly lowered, or they can be severe enough to render her unable to function at all. A varied cluster of physical and emotional responses have often been labeled PMS when they occur at approximately the same phase of each menstrual cycle (usually during the last 14 days of the menstrual cycle) followed by a symptom-free phase of at least 7 days (Dalton, 1982). PMS has affected millions of women in the world every month. Further research on PMS has become important for the following reasons:

1. Millions of dollars have been lost in productivity per year by the women who become incapacitated (Reid & Yen, 1981).

2. It has perpetuated the myth that women are unstable, out-of-control, and at the mercy of their "raging hormones" (Lamb, 1985).

3. Women have been ineffectively and expensively treated with diuretics, tranquilizers, birth control pills, synthetic hormones, or even hysterectomies (Dalton, 1978).

4. There have been a number of attempts to self-treat with alcohol and/or other drugs as well as several cases of suicidal behavior which have been attributed to PMS (Laursen & Stukane, 1983).
Literature on PMS, regarding the temporal boundaries and the symptomatology has indicated that the syndrome has yet to be clearly defined (Abplanalp, 1983; Clare, 1979; Dalton, 1982; Hackett, Steiner, & Osmun, 1980; Moos, 1968; Halbreich, Endicott, Schacht, & Nee, 1982). Consistently in the articles the temporal boundaries were arbitrary so that the temporal aspect lost its value as a defining feature of PMS. Also, because delimitation of the symptoms has not occurred, PMS has remained a "catch-all" phrase for any behavioral, physical, or emotional responses which happen to occur within that particular time period. Continuing to attribute any and all changes which occur during the premenstrual phase to hormonal fluctuations is likely to affect the likelihood of changing behaviors which are due to external causative factors in certain situations. To further confuse things, the symptoms within this cluster have varied with regard to their definitional clarity. Most of the physical components have been easy to identify because they are observable and measurable. The emotional components, however, have remained poorly defined due to being of a private, idiosyncratic nature (Dalton, 1978).

The existing controlled research in the area of PMS has focused primarily on hormonal or other pharmaceutical treatments of the syndrome. There have been many articles describing PMS, which have reviewed the available literature and discussed which direction future research should take, but all of them have agreed that they were approaching a phenomenon which has yet to be defined adequately.
Only recently have researchers begun to delineate the syndrome (Haskett et al., 1980) and develop evaluation and assessment procedures for women with PMS (Sampson & Prescott, 1981).

Presently, the first step in the screening process to determine whether or not a woman has PMS is the verification of the presence of certain physical and/or emotional symptoms by using questionnaires and/or checklists. The Menstrual Distress Questionnaire (Moos, 1968) has often been given at random phases of the menstrual cycle. When symptoms were reported retrospectively, however, the woman may have recalled and recorded fewer or more symptoms than actually occurred. Also, completing a questionnaire in the absence of the symptoms has been found to affect the validity of the data, especially with less severe symptoms (Halbreich et al., 1982). Of course, there have also been problems with subjective reports of symptoms, but the accuracy is likely to increase if they are recorded the same day. The Menstrual Symptomatology Diary (MSD) is a symptom checklist which has served as a daily data collection sheet so that responses are acknowledged as they occur, rather than in retrospect, and are rated for intensity (Abraham, 1980). The MSD, however, has been presented to the woman simultaneously with instructions for treatment intervention. While this allowed more rapid alleviation of the symptoms, it rendered the data useless as baseline data for research purposes. There have also been semantic problems with the currently available forms. All three of these tools contain, but do not define, items referring to nervous tension, mood swings, irritability, anxiety,
depression, and confusion. Thus, the data used to elucidate the
definition of PMS were based on symptoms which themselves were
vaguely and idiosyncratically defined by each of the subjects. In
other words, in past research, unconscious determinants and processes
have been almost totally relied upon to explain the more "emotional"
conditions. It has been pointed out in the literature that many of
the "emotional" constructs are inferentially far removed from the
actual clinical observations made. If we continue to rely on uncon-
scious criteria for diagnosis, we are, in effect, using untestable
hypotheses. The operationalization of criteria (i.e., specifying
behaviors per unit of time) increases both agreement and utility of
such terms (Maloney & Ward, 1986).

Since the assessment and measurement based on the already exist-
ing data collection devices impacts treatment research, a modified
device was developed as part of this descriptive study in the form of
a Premenstrual Symptoms Checklist. This behavioral checklist was
comprised of more observable and measurable behavioral and physical
symptoms. Its advantage was that it facilitated data collection for
the subjects, thus increasing the likelihood of compliance. Such a
checklist also rendered more useful data since each of the emotional
symptoms was defined in behavioral terms, thus avoiding the sub-
jective, idiosyncratic definitions otherwise applied by each individ-
dual using the checklist. The symptoms were charted on the checklist
daily for 2 complete menstrual cycles prior to the introduction of
intervention techniques. If treatment was initiated prior to comple-
tion of data collection, the data were not used in this study. However, most women had been living with their symptoms for a number of years without treatment, so the delay of treatment during data collection was considered very low risk. Each subject also charted daily basal temperature and weight so that any correlation between cyclic variations in these measurements and changes in symptom dimensions (e.g., frequency, intensity and/or duration) could be observed. The symptoms on the checklist were charted according to the intensity and duration of each when appropriate. In some cases, however, it was impossible to rate them according to either of these dimensions so they were simply charted in terms of increase or decrease from the average level of occurrence (e.g., appetite, activity level, sleep hours). Several other symptoms were charted according to occurrence only (e.g., increased heart rate, respiratory rate, hitting, yelling, and throwing objects). The checklist was administered to three groups of subjects and the data obtained were compared between subjects for variations in frequency, intensity, duration, and any clustering of symptoms. For definitional purposes, the differences in these dimensions of the symptoms were then documented and contrasted between the women who reported having premenstrual symptoms, those reporting no premenstrual symptoms, and a presumably acyclic group (i.e., men).

In summary, this study was concerned with four issues related to PMS. First, the data were collected without confounding treatment variables being implemented during this time period. If treatment of
any of the symptoms was initiated during this period, the data were not included in this study. Second, the development of a contemporaneous behavioral data collection sheet was undertaken in order to eliminate retrospective data-gathering and the idiosyncratic definitions applied to certain emotional concepts. Third, correlation between changes in basal temperature with changes in frequency, intensity, and/or duration of symptoms was analyzed in order to more clearly differentiate symptoms of PMS from already existing symptoms which were simply exacerbated by hormonal changes. Fourth, a comparison was made between subjects in each group and between groups of the variations in the dimensions of symptoms to ascertain whether significant differences existed, which would further contribute to a more clear definition of PMS. The intent was that analysis of these issues would lead to the final goal of this study, which was to identify specific defining characteristics of PMS.

The importance of further delimiting the symptomatology was to facilitate diagnosis by providing data for comparison of intensity and temporal and grouping characteristics between women with symptoms of PMS, women without symptoms of PMS, and presumably acyclic people (i.e. men). Treatment efforts would also have benefited from definition and delimitation of the syndrome since observable and measurable behaviors would be more precisely and effectively treated than private emotions. In the future, as research proliferates in the area of PMS, a behavioral definition of the symptoms will permit assess
ment of changes in the symptoms with treatment intervention and enable comparison of one subject with others (Sampson & Prescott, 1981).
CHAPTER II

REVIEW OF SELECTED LITERATURE

Prior to 1980, much of the literature on PMS discussed the etiology and pharmaceutical treatment of the syndrome. In 1981, a review paper by Gonzalez summarized that the precise physiological mechanisms underlying the syndrome remain unclear, but that the general consensus at that time was that it must be recognized as somatic, not psychological. It was further postulated that psychological factors may intensify the patient's suffering, but did not cause it. Among the most popular etiological factors were inadequate progesterone levels, excessive estrogen levels, vitamin B6 deficiencies, altered glucose metabolism, and an allergy to endogenous hormones. Although results were mixed, progesterone supplementation was the treatment which received the most widespread attention. Unfortunately, progesterone deficiency has not been verified due to the hormone being secreted in spurts. Also, the studies showing very successful results with progesterone have not been replicable. A placebo effect was demonstrated in at least one study. PMS symptoms disappeared during a woman's first month on sugar pills, but gradually returned during a 4 - 5 month long period. Most studies, however, were not continued long enough to allow for abatement of the placebo effect. The author reported that there is an absence of controlled, double-blind studies of natural progesterone's
effectiveness.

Since 1983, literature on the topic of PMS has focused on diagnosing the syndrome and differentiating between the symptoms of PMS and those of other etiologies. One of the major problems with defining PMS has been that it is interrelated with various physical, psychological, and environmental factors to such an extent that it has been virtually impossible to clearly and precisely separate it from these factors. There still has not been a consensus as to the definition of the syndrome, however, Rubinow and Roy-Byrne (1984) have suggested defining it as the "cyclic occurrence of symptoms that are of sufficient severity to interfere with some aspects of life, and which appear with a consistent and predictable relationship to menses" (p. 163). Hormonal changes have exacerbated already-existing physical and psychological symptoms. On the other hand, PMS symptoms have been similar to certain disorders of the endocrine system (i.e. hypothyroidism, benign adrenal tumors and pituitary dysfunction) and psychological disorders (i.e. psychosis, manic-depression, and severe depression). Therefore, in some cases, PMS has continued to be misdiagnosed and as a result, mistreated. While there have been no blood or psychological tests to determine whether symptoms were those of PMS, most of the other disorders mentioned above have been ruled out by such testing.

Considered to be more helpful in making a diagnosis was the temporal relation between the symptoms and the menses. One source identified PMS symptoms as those that occurred between ovulation and
the onset of menstruation and were followed by a symptom-free phase each cycle (Bender & Kelleher, 1986). However, several different temporal patterns have been identified by other observers (Norris, 1983). According to Ronald Norris, an endocrinologist and founder of the first PMS clinic in the United States, (Vinocur, 1983):

some symptoms start three to four days before the period and end with the onset of menses. Some appear for a few days at the time of ovulation and then disappear for a while then start up again and continue until menses. And, some last three to four days into the menses. (p. 35)

There has been little success in delimiting the symptoms of PMS from those of a different source. When a physical, psychological, emotional, cognitive, or behavioral symptom occurred within the last half of the menstrual cycle and abated soon after the menses began, it was added to the list of PMS symptoms. In fact, some descriptions of the syndrome have gone so far as to attribute such symptoms as dry, flaky skin and greasy hair to PMS. To further confuse the issue, the symptoms of PMS have been reported by women who do not menstruate.

Recent literature has acknowledged environmental events having various effects on PMS symptoms. Stress, dietary and exercise factors reportedly have delayed, promoted, or intensified PMS symptoms. Undue stress, nutritional deficiencies and a lack of or overindulgence in exercise have also resulted in many of the same symptoms attributed to PMS. Frequency and intensity of symptoms have also been reported to vary in the same woman from month to month. Some women have reported a pattern across cycles. Therefore, accord-
ing to the most recent literature, identifying and diagnosing PMS primarily by its symptomatology may lead to misdiagnosis and mis-treatment of certain symptoms (Bender & Kelleher, 1986).

In 1984, Rubinow, Roy-Byrne, Hoban, Gold, and Post obtained prospective longitudinal confirmation of menstrually-related mood changes using a visual analogue scale for twice daily self-rating of mood. The advantages offered by such a rating instrument included simplicity for the subjects resulting in increased compliance, ease of graphic presentation, evaluation of severity, measurement of in-creases and decreases in certain symptoms, and the relationship of the symptoms to menses. The data obtained with this instrument were graphed daily for 2 cycles showing the relationship of the symptom occurrence and intensity to the menses, ovulation, and paramenstrual portion of the cycle. This approach would facilitate uniformity among this and future studies of menstrually related syndromes and also would facilitate identifying those women whose symptoms are present throughout the cycle and, therefore, causally unrelated to hormone fluctuations.

In 1984, the article "Premenstrual Syndromes: Overview from a Methodologic Perspective" by Rubinow and Roy-Byrne pointed out that despite 50 years of study, relatively little is known about the relationship between menstruation and disorders of mood which may encompass a wide range of affective, cognitive, behavioral, and somatic symptoms. Since then, as mentioned above, others have attempted to define PMS. These authors reported that the current

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confusion is the inevitable product of serious errors in study design which have resulted in part from the failure of investigators to formulate a set of answerable questions before their studies were initiated.

The necessary questions were relevant to what symptoms were experienced, their intensity, their relationship to menses, and the symptomatic baseline from which the symptoms fluctuated. Even when these questions were asked, there often has been little agreement among investigators as to their answers. In previous studies, there has been tremendous diversity of symptoms and inconsistency in reported frequency. However, the tools used during the past decade have been mostly retrospective in nature and focused primarily on either somatic changes or emotional changes which have not been operationally defined. The question of symptom severity has yet to be addressed. There have been three major problems in this area. First, has been the failure to measure the severity of the symptoms. Second, has been the attribution of clinical importance to statistically significant, but clinically insubstantial, changes in symptoms (from nonexistent to very mild). Third has been the use of scales with insufficient sensitivity to differences in severity and reflecting categories rather than dimensions. Also, the descriptions of the relationship between a symptom's appearance and menstruation have varied greatly and have prompted the creation of numerous terms to denote the timing of relevant symptoms. Finally, only one study differentiated between symptom occurrence and symptom exacerbation.
Rubinow and Roy-Byrne (1984) further emphasized the importance of establishing a more precise criterion for subject inclusion to eliminate the variability from future studies. They also emphasized the need for prospective longitudinal symptom reporting to demonstrate the exact relationship between menstrual cycle change and emotional and behavioral changes. Retrospective ratings have been invalidated by daily concurrent ratings in many cases. Subjective data collection has been the only source of identifying PMS, yet the reliability of this type of data is questionable at best. While the authors acknowledged the bias present in subjects' self-assessment, they also pointed out the absence of more accurate means of objectively rating a syndrome that has most often consisted of subjectively experienced symptoms. At present, daily self-ratings with an ordinal measure of core symptoms may be most effective in identifying women with menstrual phase-related occurrence or exacerbation. They also suggested the potential usefulness of global ratings performed by a significant other in the subject's home environment.

In summary, available literature reflected the difficulties incurred not only in attempting to determine exact etiological factors, but also in concisely defining PMS in terms of both its symptomatology and its temporal characteristics. The scope of the present study did not include the etiology, but was concerned with further defining and delimiting the syndrome by utilizing an improved methodology similar to that suggested by Rubinow and Roy-Byrne (1984).
result of this approach has been recognition of the futility of defining a consistent group of symptoms as those specific to PMS. The variation in symptoms from individual to individual, including their presence even in presumably acyclic people, and from month to month within the same individual, supported this recognition. Studying the temporal aspects of the occurrence of the symptoms, that is, the relationship of their occurrence to the menses has been reported to be more useful. The intention of studying the entire menstrual cycle, including the onset, frequency, intensity, and duration of symptoms, was to enable women and their physicians or clinicians to identify the presence of what is referred to as the premenstrual syndrome and to initiate the most appropriate and effective treatment available.
CHAPTER III

DESIGN & METHODOLOGY

Subjects

The subjects were recruited through the Western Michigan University Health Center, the Center for Women's Studies at Western, Borgess Medical Center, and a local chiropractic office. Posters recruited women between the ages of 30 - 40 who were interested in participating in a study of PMS. The women were assigned to two different groups. The women who reported experiencing any monthly symptoms were assigned to the Symptomatic Group. The women who reported an absence of monthly symptoms were assigned to the Asymptomatic Group. A group of men interested in participating in this study were also recruited. Since men are generally not assumed to have hormonal cycles, this group was entitled the Acyclic Group. Originally there were 8 women assigned to the Symptomatic Group, 8 women assigned to the Asymptomatic Group, and 10 males assigned to the Acyclic Group. Prior to data collection, each of the symptomatic women's typical and recurring monthly symptoms were listed on the information sheet.

Materials

During the first meeting, demographic information was obtained about the respondents. An initial intervi. form was devised for
this purpose (see Appendix A). The criteria for inclusion in this study were that the woman was not using oral contraceptives, had not had a tubal ligation, was not presently pregnant, and was not currently receiving medical treatment for physical or emotional disorders. These criteria were selected because they could mask or exacerbate monthly symptoms. At the end of the initial interview, the subjects were required to sign an Informed Consent form (see Appendix B). They were then presented with the checklists and thermometer.

The Premenstrual Symptom Checklist (for female subjects) and the Daily Health Status Checklist (for male subjects) were of a format that enabled daily charting of the occurrence of 29 symptoms according to intensity, duration, increases, or decreases during the month (see Appendices C and D). It also included daily charting of the basal temperature and weight for the women. Unlike other data collection forms used with women who are being screened for symptoms of PMS, the checklist devised for this study eliminated the use of the emotional constructs of nervous tension, mood swings, irritability, anxiety, depression, and confusion. Instead, the most common behavioral components of these constructs were among the symptoms on the checklist.

Prior to this study, the approval of the Human Subjects Review Committee was obtained (see Appendix E).
Dependent Variables

The responses of interest were the symptoms charted by each subject on the Premenstrual Symptoms/Daily Health Status Checklist. These responses were graphically displayed in terms of frequency and intensity. The graphs facilitated detection of the relationship of the frequency and intensity of the symptoms to the menses and ovulation. The frequency of each of the symptoms was calculated for each subject in all three groups. The average number of each symptom for each group was then displayed graphically.

In order to establish reliability, two spouses agreed to complete checklists based on the responses they observed. Replacing the vague, emotional terms used on other data collection forms with more observable behaviors would facilitate simultaneous, objective data collection.

Procedure

Posters recruiting 30 - 40 year old women with symptoms of Premenstrual Syndrome and asymptomatic women and men interested in participating in this study were placed in several buildings frequented by students on campus, a local hospital, and a doctor's office off campus.

Eight women who reported having symptoms of PMS, but who had never sought treatment for these symptoms, responded to the subject recruitment advertisements. Eight women who reported being symptom-free also answered the advertisement. The Symptomatic and Asympto-
tic Groups were formed, based on subjective reports of symptom occurrence. These women agreed to collect data for 2 consecutive menstrual cycles. Ten males were recruited and agreed to complete the Daily Health Status Checklist for 2 months.

The 2 groups of female subjects were interviewed to ensure that they were not taking oral contraceptives, had not had tubal ligations, and were not pregnant. Meeting these criteria ensured that the symptoms they experienced during their menstrual cycle were neither eliminated nor exacerbated by these extraneous factors. Also, subjects with physical or emotional disorders requiring medical treatment were excluded from the groups.

During the initial interview, demographic information and informed consent were obtained, and the use of the checklist was explained and demonstrated. Practice in charting on the checklist was provided for each subject so that corrective feedback could be given before actual data collection began. Information determining how much each female subject knew about PMS and its treatment was obtained since there was a possibility that level of knowledge would influence reports of symptoms. None of the women were very well-informed about the nature of PMS or its treatment. Only a few of them knew that it was related to hormones. Most of them considered tender breasts, weight fluctuations, and cramps upon starting their menses indicative of PMS. Also, whether the female subjects had at any time undergone treatment for symptoms was ascertained. Respondents who were currently under treatment for their symptoms were not
asked to participate in this study. The women were asked to postpone treating their symptoms until after the checklists were completed. However, 2 of the women were eliminated from the study because they began treatment during data collection. The 10 remaining women were told that they could be referred to either a PMS workshop or a screening clinic if they wished to seek treatment after the study.

For both groups of female subjects, data collection began on the first day of the menstrual cycle and was terminated on the first day of the third cycle so that 2 full cycles' symptoms were charted. The men began data collection on receipt of the checklist and continued for 60 days. All subjects were instructed to chart each symptom as either mild (does not interfere with daily activities), moderate (interferes with some daily activities), or severe (interferes with most or all activities). Duration was to be charted as:

1. A (lasts for less than 1 hour).
2. B (lasts for 1 to 8 hours).
3. C (lasts for more than 8 hours).

Symptoms which could not be rated for either of these dimensions (e.g., increase or decrease in appetite, activity level, and sleep hours) were to be charted as increased or decreased from their average levels to ensure uniformity across subjects. Female subjects were also instructed to take their basal temperature before getting out of bed in the morning and to weigh before ingesting food or liquid. Thermometers and scales were provided when necessary.

During the period of data collection, the subjects were con-
tacted at least biweekly by the researcher in an attempt to maintain daily completion of the checklist. Upon completion and return of each checklist, the subjects were given their choice of two movie passes or a $5 gift certificate to a local department store. Each completed checklist was picked up by the researcher, pertinent feedback was provided, and the gift was presented.
CHAPTER IV

RESULTS

Of the 8 women in the Symptomatic Group, only 4 completed the study. Two of these women were unable to finish because they were required by their physicians to begin medication (Deseryl and birth control pills) during the 2-month period. Because treatment implementation was one of the variables controlled for, their data were not used. Two other women reported that they wished to withdraw from the study due to excessive stress in their lives.

Interestingly, the data from the 8 subjects assigned to the Asymptomatic Group indicated a high frequency of symptoms during the 2-month period. These women had stated prior to the study that they did not experience monthly symptoms. The data of 2 of these women could not be used in this study. One attempted to collect data for 3 consecutive months, but during this time her periods were irregular and longer than 45 days. The other subject collected data for 2 months, but lost the checklists. Seven of the 10 male subjects completed and returned the Daily Health Status Checklists.

As mentioned, the criteria for subject inclusion in both of the female groups were age (30 - 40 years of age), birth control method, pregnancy status, no use of medications, and the absence of major physical or emotional disorders. The criteria were selected on the basis of suggestions in the current literature that symptoms of PMS
reportedly reach their height in frequency and intensity between 30 and 40 years of age, may be exacerbated by oral contraceptives, tubal ligation, and natural termination of pregnancy, and are alleviated altogether during pregnancy (Dalton, 1982; Halbreich et al., 1982). Pharmaceutical agents may have unpredictable effects on one or more PMS symptoms. Other demographic factors that were noted, but not controlled for, are: (a) marital status and (b) frequency of sexual activity.

Previous attempts to define PMS according to its symptomatology have resulted in the inclusion of all physical, behavioral, or emotional changes occurring during the last half of the menstrual cycle as part of the syndrome. The symptoms have ranged from dry skin and greasy hair to child abuse and homicide.

Since there were different numbers of subjects in each group, the averages of the number of symptoms were analyzed. This enabled the comparison of the frequency and intensity of each of the 29 symptoms across all 3 groups (see Table 1).

The Symptomatic Group reported the highest average occurrence of headaches, increased appetite, increased respirations, abdominal bloating, extremity swelling, abdominal cramps, pacing, fidgeting, and startling easily. None of these women reported hitting self/others, throwing/breaking objects, or suicidal verbalizations or gestures. The Asymptomatic Group reported the highest average occurrence of fatigue, food cravings, decreased appetite, increased heart rate, breast tenderness, increased and decreased activity, increased
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<td>Joint Aches</td>
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<tr>
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sleep, trembling/shaking, withdrawal, frowning/crying, and yelling. They also showed the only occurrence of hitting self/others and throwing/breaking objects. The only symptoms not experienced by this group of women were suicidal verbalizations or gestures. The Acyclic Group reported the highest average occurrence of neck/back aches, joint aches, decreased sleep, and negative self-statements. None of the men experienced abdominal bloating, extremity swelling, abdominal cramps, breast tenderness, increased heart rate and respiratory rate, fidgeting, hitting self/others, throwing/breaking objects, or suicidal verbalizations or gestures. This group experienced a total of four severe symptoms.

Each subject's symptoms were graphed individually according to frequency and intensity. These graphs also showed the relationship of the symptoms to the menstrual cycle (see Figures 1–4).

When analyzed, each of the 4 subjects in the Symptomatic Group showed increases and decreases in the frequency and/or intensity of symptoms during the latter half of her cycle. Each cluster of symptoms was followed by only 4 symptom-free days rather than 7 as indicated in one definition (Dalton, 1982). The symptoms reported by Subject #4 were not clearly related to changes in hormonal levels during the menstrual cycle. There were a number of symptoms of varying intensity occurring during the first half of each cycle. The frequency of symptoms did not consistently increase during the cycle, however, the number of more intense symptoms did increase.

Women in the Asymptomatic Group were the subjects who, prior to
Figure 1. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #1 of the Symptomatic Group.
FIGURE 2. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #2 of the Symptomatic Group.
Figure 3. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #3 of the Symptomatic Group.
Figure 4. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #4 of the Symptomatic Group.
the study, reported that they did not experience monthly symptoms (see Figures 5 - 10). Data collection, however, demonstrated the occurrence of symptoms during each cycle of each of these subjects. The data of Subjects #6 and #8 of the Asymptomatic Group clearly showed symptoms present throughout the month with no relationship between frequency and the menstrual cycle. However, again, there did appear to be an increase in intensity over the cycle (see Figures 6 and 8).

While each of the Ayclic subjects experienced a wide variety of the 29 symptoms during 2 months of data collection, it was visually evident that they were, in most cases, evenly distributed across the months in frequency (see Figures 11 - 17). However, the intensity appeared to increase during the last 15 days of the month for most of the subjects as it did for the female subjects.

In order to analyze the difference between the groups in terms of intensity and duration, a symptom score was assigned to each symptom for each subject. The daily average total scores for each group were then graphed (see Figure 18). The symptom scores were assigned as follows:

1. A mildly intense symptom lasting less than 1 hour was scored 1.

2. A mildly intense symptom lasting for 1 to 8 hours was scored 2.

3. A mildly intense symptom lasting for more than 8 hours was scored 3.
4. A moderately intense symptom lasting for less than 1 hour was scored 4.

5. A moderately intense symptom lasting for 1 to 8 hours was scored 5.

6. A moderately intense symptom lasting for more than 8 hours was scored 6.

7. A severely intense symptom lasting for less than 1 hour was scored 7.

8. A severely intense symptom lasting for 1 to 8 hours was scored 8.

9. A severely intense symptom lasting for more than 8 hours was scored 9.

The average symptom scores for all 3 groups were below 45. The Symptomatic Group showed the most scores below 1 and above 10. The Asymptomatic Group showed the most scores between 1 and 5. Finally, the Acyclic Group showed the most scores between 5 and 10. Therefore, the average symptom scores revealed no specific pattern for any of the groups, but were distributed equally among the groups.

Separate analysis of average duration of symptoms for the 3 groups showed that the Symptomatic Group reported a higher average number of symptoms lasting more than 8 hours, and the Asymptomatic Group reported a higher average number of symptoms lasting less than 1 hour and 1 to 8 hours. These data were not considered further for two reasons. First, the specific onset and offset of many of the symptoms were difficult, if not impossible, to determine. Second,
Figure 5. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #5 of the Asymptomatic Group.

Legend.  
M = Menses  
0 = Ovulation
Figure 6. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #6 of the Asymptomatic Group.
Figure 7. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #7 of the Asymptomatic Group.
Figure 8. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #8 of the Asymptomatic Group.
Legend. M = Menses
0 = Ovulation

Figure 9. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #9 of the Asymptomatic Group.
Figure 10. Relationship of Frequency and Intensity of Symptoms to the Menstrual Cycle for Subject #10 of the Asymptomatic Group.
Figure 11. Frequency and Intensity of Symptoms Across 2 Months for Subject #11 of the Acyclic Group.
Figure 12. Frequency and Intensity of Symptoms Across 2 Months for Subject #12 of the Acyclic Group.
Figure 13. Frequency and Intensity of Symptoms Across 2 Months for Subject #13 of the Acyclic Group.
Figure 14. Frequency and Intensity of Symptoms Across 2 Months for Subject #14 of the Acyclic Group.
Figure 15. Frequency and Intensity of Symptoms Across 2 Months for Subject #15 of the Acyclic Group.
Figure 16. Frequency and Intensity of Symptoms Across 2 Months for Subject #16 of the Acyclic Group.
Figure 17. Frequency and Intensity of Symptoms Across 2 Months for Subject #17 of the Acyclic Group.
Figure 18. Average Symptom Scores for All Subjects in the Symptomatic, Asymptomatic, and Acyclic Groups
in general, the subjects were inconsistent in charting the dimension of duration even when it could be determined. These two factors resulted in questionable reliability of these data.
CHAPTER V

DISCUSSION

The purpose of this study was to obtain descriptive data on the premenstrual syndrome (PMS) in order to more precisely determine the symptoms comprising the syndrome and their relationship to the menstrual cycle. This information would greatly facilitate diagnosis of PMS and would also suggest the most appropriate treatment for the individual. The data obtained in this study are considerably more valid and reliable compared to that obtained in some other studies. This is due to the data having been collected by each subject on a daily basis rather than retrospectively. It is also because no treatments were implemented during data collection. Also, charting ambiguous emotional responses was eliminated through the use of behavioral definitions for most of the responses. The data are also likely to be more useful since specific symptoms and their relationship to the menses was clearly demonstrated across 2 complete cycles for a group of women who reported having menstrually related symptoms and a group of women who reported to be free of menstrually related symptoms.

The PMS symptoms and patterns of occurrence have been commonly attributed to hormonal fluctuations rather than environmental factors. Therefore, a third group, consisting of men, was included to determine whether presumably acyclic people experience similar symptoms in
any discernible pattern during the month. Such symptoms in men, of course, would not be attributed to hormonal fluctuations, but are more likely to be attributed to environmental factors.

This study revealed many important points that will be instructive for further research in this area. First, the futility of identifying PMS according to its symptomatology became obvious. The women who reported menstrually related symptoms prior to the study reported a higher average frequency of symptoms for only 9 out of 29 symptoms. The average number of the same symptoms for the women who claimed to be asymptomatic prior to data collection was only slightly lower. The Asymptomatic Group reported a higher average frequency of 14 of 29 symptoms. The men reported a higher average frequency for four of the symptoms and exhibited 19 of the 29 symptoms that have been previously identified as symptoms of PMS. The men did not report several symptoms that have previously been functionally related to hormonal changes, including abdominal bloating, extremity swelling, abdominal cramps, and breast tenderness.

This analysis indicates that women have no clear monopoly on the symptoms identified as PMS. Both genders report many of these symptoms monthly. In the past, defining PMS according to its symptoms has led to the inclusion of all symptoms occurring within the latter half of the cycle. This is problematic because it can result in other disorders being mislabeled as PMS, and, therefore, mistakenly attributed to hormonal changes. This approach is often accompanied by overlooking environmental factors as causal and by implementing
ineffective, expensive, or even potentially harmful treatment. In reality, the causal factors may be transient in nature and the response could be modified with less invasive and more reasonable treatment. In other words, the response could become conditioned, and the woman would learn to view the response as beyond her control. This would then support the "out-of-control" notion commonly reported by women seeking treatment for PMS (Bender & Kelleher, 1986). Alternatively, she could learn to identify the factors that evoke and maintain a specific response. Thus, she could learn effective skills to manage the present and similar, future situations.

Of further importance for research in this area is the graphing of the daily frequency of occurrence of the symptoms and their level of intensity. This provides a means of visualizing unique patterns of occurrence. Visualization of the temporal characteristics and variations in frequency and intensity, enables easier identification of those women who may not have PMS. It became obvious, for example, that Subjects #6 and #8 in the Asymptomatic Group, reported symptoms throughout their menstrual cycle. These symptoms appeared unrelated to the menses or ovulation in terms of their frequency. The symptoms did, however, increase in intensity during the last half of the cycle. This indicates that the etiology of these symptoms was not cyclical, hormonal fluctuations, but that these symptoms were exacerbated by hormonal changes. Subject #4 also reported an unusual variation in symptom frequency and intensity during the preovulation phase of her second cycle (see Figure 2). Such patterns may repre-
sent the presence of symptoms related to environmental variables rather than the fluctuation of hormones. Future research could attempt to determine whether the exacerbation of already existing symptoms is to be considered PMS. Thus, these women may not be appropriate subjects in future PMS research and would require further evaluation to determine the nature of their disorder and the most appropriate and effective treatment.

Several factors might facilitate delimitation of PMS in further research. First, a reliable means of determining the exact day of ovulation would be necessary so that the symptoms can be functionally related to hormonal changes occurring at this time. In this study, women were required to chart their basal temperatures every morning. However, upon analysis, the accuracy of the basal temperatures for most of the subjects was questionable. This was based on the variance in degrees from day to day and the absence of the textbook-typical ovulatory pattern in temperature changes. Upon further investigation, it appears that there is some controversy as to how to determine ovulation by changes in basal temperature. One method reportedly used in "Fertility Awareness" classes is to take the highest basal temperature between days 6 and 10 and to identify ovulation as the first subsequent day on which the basal temperature exceeds that temperature. Another method, according to one author, is to identify ovulation by a drop in the temperature, followed by a rise for a couple of days, followed by another drop. In this sequence, the rise in the basal temperature represents ovulation.
(Dalton, 1978). The subjects' basal temperatures in this study followed neither of these patterns. Therefore, it was impossible to determine exactly when ovulation occurred. It was also difficult to assess whether the proper technique of obtaining the basal temperature was used. Consistency in taking the temperatures prior to rising in the morning, after having been at rest for at least 3 hours, was impossible to control. One study suggested, if all else fails, assume that ovulation occurs during the middle of the cycle (Abraham, 1980). This was the approach resorted to in this study.

Another important aspect of future research would be establishing reliability of the data. Two of the partners of the women in this study agreed to collect data on their spouses for this purpose. However, many of the physical symptoms were neither directly observable nor measurable by the observer. These symptoms would, by nature, depend on subjective reports of the subject. Operationalization of the symptoms would resolve this problem in some cases, but it may not be possible with the pain-related and sensory-related symptoms that are the result of private stimuli and are usually accompanied by few overt behaviors of sufficient magnitude to enable observation and/or measurement. Establishing a unit of measure for as many as possible of the symptoms could also be helpful in identifying the duration of the symptoms. However, this would complicate charting symptoms and, as a result, may meet with a lower rate of compliance by the subjects. Two specific changes in the symptoms on the checklist suggested by this study would be to eliminate the
bipolar symptoms such as increase and decrease in appetite, activity level, and sleep hours. Appetite could be replaced with the number of times eating occurs and a list of foods ingested during the waking hours. This would reflect increases as well as decreases in appetite. Also, it would result in a nutritional survey which can be computer-analyzed to detect and rule out nutritional deficiencies (Abraham, 1980). Increases and decreases in sleep could be replaced with the number of hours slept, which would also reflect increases or decreases as long as a baseline is obtained prior to data collection. However, it would be more difficult to operationalize activity level. Second, a baseline heart rate and respiratory rate could be taken at the beginning of data collection. Rather than charting an increase in either, the subject could count and document the pulse and respiratory rate when subjectively experiencing stress or anxiety.

This study revealed several interesting features of the existing definitions of PMS. The definition provided by the American Journal of Psychiatry eliminated all mild symptoms (Rubinow & Roy-Byrne, 1984). In this study, mild symptoms were defined as those that do not interfere with daily activities. Examination of the individual graphs (see Figures 1 - 17) reveals that this would eliminate 50% of the female subjects (excluding Subjects #6 and #8, who are presumably not suffering from PMS). A second problematic feature of this definition was the use of consistency and predictability in identifying the syndrome. It has been demonstrated repeatedly that the frequency
and severity of premenstrual symptoms have been inconsistent and unpredictable when comparing different women or when comparing more than 1 cycle of the same woman. Another definition of PMS suggested that it is "a group of symptoms that occur between ovulation and the onset of menstruation and which are followed by a symptom-free phase each cycle" (Lauersen & Stukane, 1983, p. 82). By definition, this would eliminate a majority of the female subjects in this study. It has been repeatedly documented that many women do not experience a sudden cessation of symptoms with the onset of the menses. Also, most of them do not consistently experience a totally symptom-free phase during each cycle. This has been further documented by the data reported in this study.

It should be noted that symptom frequency in both the Symptomatic and Asymptomatic Groups is quite skewed. There are 1 or 2 subjects in each group who reported a much greater number of symptoms than the others. These data could be analyzed in table form, demonstrating the mean and median of symptom occurrence for each of the symptoms. However, the numbers were fractional in most cases and the significant differences between the mean and median would have to be statistically established with a greater number of subjects to eliminate arbitrariness which would limit the usefulness of the resulting figures.

The difficulty incurred in previous and present research on PMS may be partially semantic in nature. A syndrome is defined as "a group of symptoms that are together characteristic of a specific
disease" (Random House Dictionary, 1980, p. 1442). Previous studies have repeatedly and unsuccessfully attempted to mold PMS to fit this definition. However, there appears to be no consistent or predictable group of symptoms for each menstrual cycle, nor for each woman. The use of the term "premenstrual syndrome" seems to have evolved out of a sense of convenience for diagnosing and treating, as a single entity, certain hormonally influenced behavioral and emotional responses. As much as the non-recognition of the responses which are undoubtedly related to hormonal changes—showing noticeable variation from woman to woman and from cycle to cycle for the same woman—has led to misdiagnosis and mistreatment, it appears that attempting to label them and treat them as a single entity may lead to the same ends. The daily charting of cyclical symptoms and their frequency, intensity and duration is certainly useful and appropriate for women reporting recurring symptoms of any type. More extensive data collection by many more subjects, should include environmental events that are antecedent and consequent to the responses. This would be helpful in determining the causal factors as external or internal (i.e., physiological). Patterns in responding to various stimuli across the menstrual cycle may become obvious with this type of charting. As to which treatment to implement according to whether the woman is reporting what appears to be PMS, it would take many months of consecutive, reliable charting to determine whether certain symptoms are hormonally related. It seems that the preferred approach would be to begin with the least invasive treatment of each
major symptom and observe its effects on the response for a long
enough period to eliminate placebo effects.

Most of the research on PMS has been done by physicians. This has resulted in a predominance of a medical model approach. According to this model, the underlying physical disorder responsible for symptoms for PMS is, most popularly, progesterone deficiency which occurs between mid-cycle and menses onset. In order to neatly fit this model, then, it must follow that certain symptoms occur together when the progesterone level drops and then disappear when it reaches a certain level again. In the case of all but a few, the symptoms attributed to PMS often occur at other times of the month and can often clearly be related to environmental events. Also, as this study demonstrates, only a few of the symptoms appear to be gender-specific. The men in this study reported regular occurrence of 19 of the symptoms during 2 consecutive months. Attempting to fit all symptoms that occur premenstrually into a syndrome label and to treat them as a whole is analogous to labeling any and all symptoms that occur while we have a cold as part of a "cold virus syndrome." To the detriment of the victim, attributing a variety of temporally related symptoms to a single organic etiological factor, may result in overlooking a process of a different nature that would require a different treatment.
Appendix A

Initial Interview Form
# Initial Interview

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<td>Occupation:</td>
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<td>Parity:</td>
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<td>Sterilization:</td>
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<td>Onset of PMS symptoms:</td>
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<td>Prior knowledge of PMS:</td>
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<tr>
<td>Comments:</td>
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</table>
Appendix B

Informed Consent Form
Informed Consent

Name:

Address:

Phone:

I understand that I will be participating in a study which requires that I record any or all physical and behavioral responses on the checklist provided for a minimal period to two months.

The use of the checklist and all aspects of the study have been explained to me and any questions have been adequately answered. I understand that I may ask questions at anytime throughout the study.

Since there is no treatment being applied in this study, I understand that there is no risk involved in participating. I also understand that treatment of any of the responses on the checklist received during the recording period must be reported to the researcher.

All information will be treated as confidential and names will be coded in order to ensure privacy and all personally identifiable records will be destroyed at the conclusion of the study. Only the researcher and her advisors will have access to the records. The information collected will be used only for professional purposes and any reports of the study in professional meetings or journals will preserve anonymity of the participants.

I can withdraw from participation and request that my record be destroyed at any time during or after the project. I realize that I will receive a stipend or gift only on completion of each checklist.

With full knowledge of the above, I volunteer my participation in this project.

Date:   Signature:

Witness:
Appendix C

Premenstrual Syndrome Symptom Checklist
### PREMENSTRUAL SYNDROME SYMPTOM CHECKLIST

<table>
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<tr>
<th>NAME</th>
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**CHART EACH SYMPTOM WITH 1, 2, 3:**
- 1 = MILD, doesn't interfere with daily activities
- 2 = MODERATE, interferes with some activities
- 3 = SEVERE, interferes with most or all activities

**AND WITH A, B, C:**
- A = Lasts for less than one hour
- B = Lasts for one to eight hours
- C = Lasts for more than eight hours

| DAY OF CYCLE | 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 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 |
|--------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| DATE         |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| MENSES (M)   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| BASAL TEMPERATURE |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| BASAL WEIGHT |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

### Symptoms

- HEADACHE
- DIZZINESS/FAINTNESS
- FATIGUE
- FOOD CRAVINGS
- I OR I APPETITE (indicate which)
- I HEART RATE
- I RESPIRATORY RATE
- ABDOMINAL BLOATING
- SWELLING OF EXTREMITIES
- ABDOMINAL CRAMPS
- BREAST TENDERNESS
- NECKACHE/BACKACHE
- JOINT ACHES/PAINS
- I OR I ACTIVITY LEVEL (indicate which)
- I OR I SLEEP HOURS (indicate which)
- PACING
- FIDGETING
- TREMBLING/SHAKING
- NEGATIVE SELF STATEMENTS
- WITHDRAWAL
- STARTLE EASILY
- FROWNING/CRYING
- YELLING AT OTHERS
- HIT OTHERS/SELF
- THROW/BREAK OBJECTS
- SUICIDAL STATEMENTS TO SELF/Others

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Appendix D

Daily Health Status Check List
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<td><strong>CHART EACH SYMPTOM WITH 1, 2, 3:</strong></td>
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<td>1 = MILD, doesn't interfere with daily activities</td>
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<td>2 = MODERATE, interferes with some activities</td>
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<td>3 = SEVERE, interferes with most or all activities</td>
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<td>A = Lasts for less than one hour</td>
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<td>B = Lasts for one to eight hours</td>
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| **HEADACHE**     |
| **DIZZINESS/FAINTNESS** |
| **FATIGUE**       |
| **FOOD CRAVINGS** |
| 1 OR 1 APPETITE (indicate which) |
| 1 HEART RATE      |
| 1 RESPIRATORY RATE |
| **ABDOMINAL BLOATING** |
| **SWELLING OF EXTREMITIES** |
| **ABDOMINAL CRAMPS** |
| **BREAST TENDERNESS** |
| **NECKACHE/BACKACHE** |
| **JOINT ACHES/PAINS** |
| 1 OR 1 ACTIVITY LEVEL (indicate which) |
| 1 OR 1 SLEEP HOURS (indicate which) |
| **PACING**       |
| **FIDGETING**    |
| **TREMBLING/SHAKING** |
| **NEGATIVE SELF STATEMENTS** |
| **WITHDRAWAL**   |
| **STARE EASILY** |
| **FROWNING/CRYING** |
| **YELLING AT OTHERS** |
| **HIT OTHERS/SELF** |
| **THROW/BREAK OBJECTS** |
| **SUICIDAL STATEMENTS TO SELF/Others** |

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Appendix E

Human Subjects Approval Form
Western Michigan University
Human Subjects Institutional Review Board

DIRECTIONS: Please type or print each response - except signatures. Refer to the Western Michigan University Policy for the Protection of Human Subjects to determine the appropriate level of review.

<table>
<thead>
<tr>
<th>PRINCIPAL INVESTIGATOR</th>
<th>Home Phone</th>
<th>Office Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoje Kerr</td>
<td>386-5274</td>
<td>386-2124</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DEPARTMENT</th>
<th>Home Address</th>
<th>Office Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychology</td>
<td>1801 South Norwegian Ave</td>
<td>1801 South Norwegian Ave</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROJECT TITLE</th>
<th>PROPOSED PROJECT DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master's Thesis: The use of a behavioral checklist to delineate the prematurity syndrome</td>
<td>3-1-85 TO 6-1-85</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SUBMISSION DATE</th>
<th>PROPOSED PROJECT DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-1-85</td>
<td>3-1-85 TO 6-1-85</td>
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</table>

Note: The principal investigator should not initiate the research project until the protocol has been reviewed and approved by the Human Subjects Institutional Review Board.

APPLICATION IS: [ ] New [ ] Renewal [ ] Continuation [ ] Supplement

SOURCE OF FUNDING: [ ] Investigator

Signature of Investigator: [ ]

STUDENT RESEARCH (Fill out if applicable.)

<table>
<thead>
<tr>
<th>Name of Student</th>
<th>Phone</th>
<th>Address</th>
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<tbody>
<tr>
<td>Hoje Kerr</td>
<td>386-5274</td>
<td>1801 South Norwegian Ave</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>The research is:</th>
<th>Undergraduate Level</th>
<th>Graduate Level</th>
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<tbody>
<tr>
<td>Faculty Advisor</td>
<td>Howard Parks</td>
<td>Department</td>
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</tbody>
</table>

Signature of Faculty Advisor: [ ]

<table>
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<tr>
<th>Signature of Investigator</th>
<th>Phone</th>
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<tr>
<td>Hoje Kerr</td>
<td>386-5274</td>
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VULNERABLE SUBJECT INVOLVEMENT (Fill out if applicable.) [ ]

Research involves subjects who are: (check as many as apply)

<table>
<thead>
<tr>
<th>(check)</th>
<th>approximate age</th>
<th>mentally retarded persons</th>
<th>mental health patients</th>
<th>prisoners</th>
<th>pregnant women</th>
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<tbody>
<tr>
<td>1.</td>
<td>children</td>
<td>check if institutionalized</td>
<td>check if institutionalized</td>
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<td>2.</td>
<td>Other subjects whose life circumstances may interfere with their ability to make free choices in consenting to take part in research</td>
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(Describe Please)
LEVEL OF REVIEW: Please indicate here if you think that the research project is exempt from review, subject to expedited review, or subject to full review.

---

Exempt (Forward 1 application to IRB Chair)

Which category of exemption applies? ______

Expedited (Forward 2 applications to IRB Chair)

Subject to full IRB review (Forward 8 applications to IRB Chair)

Comments: Subjects are not high risk, nor are they exposed to a treatment variable.

---

Your application was reviewed and the Human Subject Institutional Review Board (HSIRB) has determined that:

1. The proposed activities, subject to any conditions and/or restrictions indicated in Remarks below, have (a) provided adequate safeguards to protect the rights and welfare of human subjects involved, (b) established appropriate procedures and/or documents to obtain informed consent, and (c) demonstrated that the potential benefits of the research substantially outweigh the risks.

2. The proposed activities, for reasons indicated in Remarks below do not provide adequate protection for the rights and welfare of the human subjects.

At its meeting on 3/13/85, the HSIRB (approved) (provisionally approved... see remarks) this application with regard to the treatment of human subjects. The HSIRB categorized this application as:

1. Involving subjects at no more than minimal risk.

2. Involving subjects at more than minimal risk.

REMARKS:

---

Michael J. Rotella 3/13/85
signature HSIRB Chair date

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Dear Investigator:

Upon review of your proposed research, the Board has the following recommendations:

1. In the Informed Consent form, substitute the word "study" for the words "experimental project" as no manipulation of variables is evident.

2. Include in the Informed Consent form that all personally identifiable records will be destroyed at the conclusion of the study.

3. Remove name from the data sheets; provide only a code for each subject.

If you have any questions regarding the above, please feel free to contact Mike Pritchard at 383-1657. The Board wishes you success with your research.
BIBLIOGRAPHY


