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Symptom Severity, Treatment Acceptability, and Motivational Predictors Related to Patient Improvement for Insomnia

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Symptom Severity, Treatment Acceptability, and Motivational Predictors Related to
Patient Improvement for Insomnia

By

Shelby Afflerbach

A Thesis Submitted in Partial Fulfillment of the

Requirements for the Degree of

Master of Arts

In

Clinical Psychology

Minnesota State University, Mankato

Mankato, Minnesota

May 2014

Symptom Severity, Treatment Acceptability, and Motivational Predictors Related to
Patient Improvement for Insomnia

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Symptom Severity, Treatment Acceptability, and Motivational Predictors Related to
Patient Improvement for Insomnia

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Master of Arts in Clinical Psychology

Minnesota State University, Mankato

Mankato, Minnesota, 2013

Abstract

With the widespread presence of sleep disorders in the United States, especially insomnia, it is pertinent to investigate beliefs that patients have about insomnia, symptom severity, and treatment acceptability in order to assess patients' motivation for behavioral change. Participants in this archival study were thirty-one patients seeking help for sleep-related issues, whom were primarily from a Midwestern metropolitan area. Patients had completed pre-treatment measures that assessed insomnia symptoms, outcomes, treatment acceptability, and willingness to change and one post-treatment measure assessing insomnia outcomes. Because the purpose of the present study was to examine whether these variables predict patient improvement (higher scores on the post-treatment measure), a linear regression was used to analyze the data. Results indicated that pre-treatment insomnia outcomes, symptoms, change, and treatment acceptability did not predict higher scores of patient improvement. Because there has not been a significant amount of research conducted on the topic of predictors of insomnia treatment outcome and the fact that novel outcome measures were used, future research should focus on developing more psychometrically sound outcomes measures.

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Symptom Severity, Treatment Acceptability, and Motivational Predictors Related to
Patient Improvement for Insomnia

In the United States today, sleep disorders and exiguous sleep quality is becoming a national pandemic. According to the Center for Disease Control (CDC), 50 to 70 million Americans suffer from sleep disorders that cause wakefulness, such as insomnia. Sleep disorders like insomnia can create issues with everyday functioning (“Insufficient sleep”, 2014). For insomnia specifically, the National Sleep Foundation reports that almost 50% of the American population experiences insomnia every now and again, while 22% of the population suffers from insomnia almost every day of the week. Within the U.S. population, “females are 1.3 times more likely to report insomnia than males. Also, those over the age of 65 are 1.5 times more likely to complain of insomnia than younger people. Divorced, widowed and separated people report more insomnia” (“Sleep aids”, 2013).

While examining the symptomatic spectrum of insomnia effects, areas of life commonly disrupted by insomnia can range anywhere from difficulty concentrating and trouble with remembering things to more hazardous consequences such as having driving skills affected or struggling to perform occupational duties. Also, those who experience inadequate sleep are more apt to be affected by other abiding syndromes such as “hypertension, diabetes, depression, and obesity, as well as from cancer, increased mortality, and reduced quality of life and productivity” (“Insufficient sleep”, 2014). Not only does insomnia cause problems for each individual suffering from the disorder, but

the United States also suffers from insomnia as a whole, economically speaking. The most recent yearly update on the direct costs of insomnia's effect on the United States' population equaled more than 14 billion dollars. These costs include treatment for insomnia and other healthcare costs, such as doctors' visits and hospital stays. Lastly, besides the direct cost of insomnia symptoms to the U.S. healthcare system, the indirect costs of insomnia reach up to 35 billion dollars annually and the cost of productivity lost to insomnia alone is approximately equal to 18 billion dollars a year (National Sleep Foundation, 2013).

With the widespread presence of sleep disorders in the United States, especially insomnia, it is pertinent to investigate beliefs that patients have about insomnia, symptom severity, and treatment acceptability in order to assess patients' motivation for behavioral change that can lead to overall improvement. Recent empirical literature has examined these very topics. For instance, Montserrat Sánchez-Ortuño and Edinger (2010) conducted a study that investigated the relationships between patients' maladaptive beliefs about insomnia, their presenting symptoms, and treatment progression. This study used a sample of over 250 insomnia patients and had the patients complete the Dysfunctional Beliefs about Sleep questionnaire (DBAS-16). After completing this scale, patients also completed an Insomnia Symptoms Questionnaire (ISQ), the Stanford Sleepiness Scale (SSS), the Beck Depression Inventory (BDI), the State-Trait Anxiety Inventory (STAI), and, lastly, a sleep history questionnaire.

Overall, the results from the DBAS-16 were aggregated into four distinct subgroups, according to the patients' scores on the questionnaire itself. These subgroups

were labeled as the “Worried and Medication-Biased” cluster, the “Low Endorsement” cluster, the “Mild Sleep Worries” cluster, and the “Worried and Symptom-Focused” cluster. Out of these subgroups, Montserrat Sánchez-Ortuño and Edinger (2010) noted that the “Low Endorsement” cluster held beliefs about sleep-related symptoms that would constitute an average individual’s beliefs with relatively low sleeping problems altogether. In general, two of the subgroups showed elevated scores in relation to insomnia symptoms, while the others were more representative of a “normal” sample (Montserrat Sánchez-Ortuño and Edinger, 2010). Subsequent to the completion of all of the questionnaires, the authors of the study conducted a Cognitive-Behavioral Therapy (CBT) program for the participants, with the number of treatment sessions spanning over one to eight weeks in length. All in all, the results of the study demonstrated that because of the differing and negative beliefs about insomnia amongst participants, one standard type of CBT treatment administration does not produce adequate treatment outcomes. These results suggest that CBT programs for insomnia should be specifically tailored to the individual in regards to their beliefs about sleep and their beliefs about treatment methods for overcoming insomnia (Montserrat Sánchez-Ortuño and Edinger, 2010).

Another study conducted by Sidani, Miranda, Epstein, Bootzin, Cousins, and Moritz (2009) examined individuals’ personal beliefs about insomnia. Although similar in nature to the study authored by Montserrat Sánchez-Ortuño and Edinger (2010), this study specifically analyzed the relationship between personal beliefs, treatment acceptability, and preferences for behavioral interventions. Sidani, et al.’s (2009) analysis used data from over 400 individuals with insomnia that participated in one of two clinical

trials that targeted treatment options for insomnia. During these clinical trials, participants were presented with treatment options for insomnia and were asked to rank these treatment options according to the acceptability of such methods and their preferences for the treatment options prescribed to them. The treatment options that participants were given included sleep education and hygiene or a multi-component intervention that included the education component, but also included stimulus control features and sleep restriction therapy to establish a regulated sleep-wake schedule. In addition to preferences and treatment acceptability, demographic, clinical, and personal belief information was recorded for each participant as well. This information was recorded in order to prevent confounding effects for each participant's preferences for insomnia treatment.

Comprehensibly, the results of Sidani, et al.'s (2009) investigation of beliefs about insomnia demonstrated that participants with persistent or chronic insomnia symptoms preferred behavioral interventions for the treatment of insomnia because of its lack of side effects and hope for long-term insomnia maintenance. Although behavioral interventions were preferred by a few patients, they would choose the most convenient method of treatment as the most preferable treatment, regardless of other types of treatment methods available. Also, as the current study plans to expound upon treatment acceptability, Sidani's (2009) findings display a predictive relationship between patients' acceptability and beliefs about treatment and their preferences for treatment in general. Although the patients' acceptability of certain treatment predicted and helped to guide their preferences toward certain treatments, the results of the study indicated that there

was not a relationship between the patients' personal beliefs about insomnia, the condition itself, and their treatment preferences.

When continuing to evaluate the impact that insomnia has on a given population, it is imperative to measure patient preferences and acceptability of insomnia treatment methods in conjunction with their history of insomnia symptoms. As highlighted by Epstein, et al. (2012), specific methods of insomnia treatment, such as Cognitive Behavioral Therapy for Insomnia (CBT-I), have demonstrated to be highly efficacious in modern empirical literature, however, it is important to note how crucial patient motivation and willingness to accept treatment play apart in overall patient improvement. Treatment programs like CBT-I are usually very time-consuming and require patients to put forth a great deal of effort. If patients are not motivated enough and do not “have their hearts” in the treatment being provided, whether or not the method of treatment is “proven” to be effective, then the ultimate outcome for patients could be disappointing, at best (Epstein, 2012).

Another interesting finding to consider from Epstein's (2012) study was the fact that clinicians and patients held significantly different attitudes and views towards the acceptability and preference of certain insomnia treatment. For instance, as mentioned above, many patients, especially in the case of this study with Veterans, participants felt that medications were the most acceptable form of treatment and were the most preferred method for symptom improvement. However, although providers rated medication highly as well, they differed in that they viewed sleep restriction practices and stimulus control therapies as better alternatives for overall insomnia improvement due to their empirical

effectiveness. Veterans tended to shy away from these methods of treatment due to their time-consuming nature and required effort. Both the clinicians and Veterans agreed that medication could create negative long-term effects, such as chemical reliance on the medication. Overall, the study found that most patients found the treatments they preferred the most to be the treatments that deemed as most acceptable.

When patient improvement is assessed in terms of treatment acceptability and willingness to change, some researchers have examined how patients perceived and viewed their own insomnia symptom improvement after a structured six-component CBT treatment program, which was the case in Vincent, Penner, and Lewycky's (2006) groundbreaking study. Other studies have merely focused on the effectiveness of behavioral treatments or the preference levels and motivational factors related to treatment acceptability. However, very few have investigated how patients feel about their improvement, which could provide important information as to how and why patients felt that their symptoms improved throughout their treatment process.

Vincent, Penner, and Lewycky (2006) demonstrated that certain aspects or characteristics of sleep itself are predictors of patients' perceived symptom improvement. The Clinical Global Improvement Scale (CGI) was utilized during the course of this study and researchers allocated patient responses into two different categories of "primary" and "secondary" measures of sleep characteristics. Such primary measures include sleep characteristics of: sleep quality, sleep duration, and sleep efficiency. On the other hand, secondary measures included characteristics like daytime impairment (due to insomnia symptoms) and mood (Vincent, Penner, & Lewycky, 2006). In general, it was

found that daytime impairment predicted better-perceived improvement and mood predicted a dearth of perceived improvement for secondary measures. For primary measures, sleep quality and duration were the strongest predictors of improvement. Due to the significant findings of prediction for the primary measures, understanding patients' treatment acceptability ratings and motivations for treatment may help to better individually tailor a treatment program to best suit patients, rather than using the standard CBT-I protocol for all patients regardless of their clinical presentation.

Purpose of the Current Study

Considering the research that has been conducted in this area of sleep psychology, the purpose of the present study was to determine whether the variables of insomnia symptoms, treatment acceptability, and behavior change factors affect patient improvement. Specifically, it was hypothesized that insomnia patients with more severe symptoms, that had high ratings of treatment acceptability across a wide array of treatments, and were motivated for changing their behavior would show greater improvements in insomnia symptoms at post-treatment. Specifically, improvement would involve endorsing a greater number of nights per week receiving enough quality sleep according to the post-treatment follow-up Insomnia Outcomes Scale used. Also, it was hypothesized that patients who improved over the course of the study would endorse a greater number of days per week that they were happy with how they felt and endorse fewer number of days per week in which they felt tired or fatigued.

Method

Participants

There were 85 participants recruited for the present study at sleep centers in a large metropolitan area in the Midwestern United States. Other demographic information was not collected from participants to protect their privacy and participants were simply assigned random identification number. Participants were recruited during an initial appointment with a sleep psychologist to address ongoing symptoms of potential sleep disorders. Participants then attended a series of appointments with the sleep psychologist as prescribed by their treatment plan. At the conclusion of the study, a total of 31 patients were included in the analysis because the study required a measure of post-treatment symptoms and 54 of the original patients recruited did not complete the post-treatment insomnia symptoms measure.

Measures

Insomnia outcomes scale. Dr. Donald Townsend at Fairview Health Systems in Minnesota developed the Insomnia Outcomes Scale. This scale includes four questions regarding the severity of insomnia symptoms in terms of how many nights per week the patient got enough sleep, how many nights per week the patient slept well, how many days per week the patient felt tired or fatigued, and how many days per week the patient was happy with how he or she felt. All of these items had a Likert-style response scale ranging from “1 or less” to “7” and referred to the nights or days per week that patients experienced symptoms within the past month (see Appendix A). One of the items on the Insomnia Outcomes Scale was recoded due to negative wording (“In the past month, how

many days a week have you felt tired or fatigued?”). Because the Insomnia Outcomes Scale is a newly developed measure of insomnia-related consequences, psychometric properties of the scale have not been tested. The present researcher conducted a preliminary reliability analysis and found the reliability of the questionnaire to be $\alpha = .78$.

Treatment acceptability scale. The Treatment Acceptability Scale was also developed for clinical and research purposes by Dr. Donald Townsend. This measure consists of ten items describing ten different methods of insomnia treatment. These treatment methods include behavior modification treatment methods (relaxation CD, changing my sleep habits, reading a book about sleep, stop using caffeine, alcohol, and tobacco products, and getting out of bed if the patient cannot sleep), medication treatment (prescription medication and over-the-counter medication), and medical expert professional treatment (talking to my primary care physician, talking with a counselor/therapist, and seeing a sleep therapist). Items on the treatment acceptability scale have a Likert-style response scale with responses ranging from “Not effective at all” to “Highly effective” (see Appendix B). A reliability analysis was also conducted for this measure, with $\alpha = .80$.

Change scale. The Change Scale was also developed by sleep psychologist Dr. Donald Townsend for clinical and research purposes. This scale includes eleven items on a 1 to 5 Likert scale with responses ranging from Strongly Agree (1) to Strongly Disagree (5). Items on the scale captured patients’ motivation to change behaviorally in regards to their insomnia symptoms and personal characteristics (see Appendix C for specific scale items). Five of the items on the Change Scale were recoded in order to account for their

negative wording (“My sleep problems are not that important.”, “I’ve given up on trying to improve my sleep problems.”, “It is very difficult for me to make changes in my life.”, “I don’t think there is anything I can do to improve my sleep problems.”, and “Most of what happens to me is bad luck.”). Because the Change Scale is a newly developed measure and has not yet been psychometrically tested, a reliability analysis of the scale was conducted, demonstrating results of $\alpha = .46$.

Procedure

Patients whom presented with or complained of symptoms of insomnia were asked if they would like to participate in the current study at their first appointment with a sleep psychologist. Data collected for the current study was archival data that was originally used to assess the use of an insomnia outcomes scale. In order to participate in the study, patients had to give consent for participation in the study and for treatment by signing a detailed consent form (see Appendix D). Patients also received a recruitment flyer at the time of consent in order to provide an outline of the requirements of the study (see Appendix E). Participants who had consented to participating in the study were subsequently given the Insomnia Outcomes Scale, the Treatment Acceptability Scale, and the Change scale to complete. Responses to each of these questionnaires were recorded and organized into a Microsoft Excel spreadsheet and then were later transferred to the Statistical Package for the Social Sciences (SPSS) for further data analysis. Data that was missing in SPSS was labeled as missing with the response, “999”.

Six months after the initial appointment when the original questionnaires were completed, participants were mailed another copy of the Insomnia Outcomes Scale to

complete as a post-treatment follow-up questionnaire. If patients did not return the follow-up Insomnia Outcomes Scale to the sleep clinic via the postage-paid envelope given to them within a month of receiving the questionnaire, then a second copy of the questionnaire was sent. When patients did respond either of the copies of the follow-up questionnaire that was sent, a last reminder was given to patients of whom patients were contacted via telephone. If a patient responded on the telephone, the follow-up Insomnia Outcomes Measure was administered to the patient during the telephone call, as was stipulated by a standardized procedure of greeting the patients, administering the questionnaire, and finally, concluding the call by welcoming any patient comments about their experiences with treatment for insomnia.

Once data was gathered from the follow-up outcomes measure, it was entered into the SPSS database. However, as mentioned previously, data from 54 of the participants was excluded from data analysis because they did not complete the post-treatment Insomnia Outcomes Scale measure.

Data Analysis

Because the hypothesis of this study proposes that responses on the initial Insomnia Outcomes Scale, Treatment Acceptability Scale, and the Change Scale predict overall patient improvement (as indicated by higher levels of responding on the post-treatment follow-up Insomnia Outcomes Scale), a multiple linear regression analysis approach was used to test the hypothesis. For data analysis purposes, the Treatment Acceptability Scale was divided into three groups based upon the item type, resulting in

three treatment acceptability variables: “Medication Treatment”, “Behavior Modification Treatment”, and “Medical Expert Professional Treatment”.

Results

With the data remaining from the 31 participants who completed the follow-up Insomnia Outcomes Scale, a multiple linear regression was conducted. The initial Insomnia Outcomes Scale, the Treatment Acceptability Scale variables (“Medication Treatment”, “Behavior Modification Treatment”, and “Medical Expert Professional Treatment”), and the Change Scale were used as predictors in the regression model, while the follow-up Insomnia Outcomes Scale was used as the criterion. To conduct the regression analysis, the pre-treatment variables (the four items on the questionnaire, utilizing the recoded item) of the Insomnia Outcomes Scale were combined together to compute a new variable, as were the post-treatment variables (the four items on the questionnaire, utilizing the recoded item) of the follow-up Insomnia Outcomes Scale in order to create a measure of both pre- and post-treatment outcomes. Similarly, the eleven variables, or items, on the Change Scale (utilizing the five recoded items) were combined to create a new variable of the scale’s responses as a whole.

The results of the multiple linear regression analysis demonstrated that the overall model of the study’s hypothesis was non-significant, where $F(5, 26) = 1.27, p > .05$ (see Figure 1 in Appendix F). Because the overall model was non-significant, the individual predictors were non-significant as well (see Table 1 and Table 2 in Appendix F). However, the pre-treatment Insomnia Outcomes Scale was marginally significant at $\beta = .42, p = .06$.

In addition to the multiple linear regression, a one-way repeated measures ANOVA was conducted to assess the differences between the pre-treatment insomnia outcomes measure and the post-treatment insomnia outcomes measure. This analysis was conducted because the results within the regression model for prediction between these two variables were marginally significant. The results of this analysis demonstrated non-significant results, $F(13, 27) = 1.01, p > .05$. This result indicates that there are no significant differences between responding on the pre- and post-treatment insomnia outcomes measures, suggesting that the functioning of patients in regards to their insomnia symptoms did not significantly improve.

Also, it is imperative to note the variance in responding on the various measures used for this study as well. For the pre-treatment insomnia outcomes measure ($M = 9.32, SD = 5.33$), the post-treatment insomnia outcomes measure ($M = 17.35, SD = 6.90$), the medication treatment acceptability subscale ($M = 35.18, SD = 178.88$), the medical expert professional treatment acceptability subscale ($M = 35.18, SD = 178.88$), and the change scale ($M = 33.30, SD = 3.57$), the variance amongst the data of responding was relatively large, as indicated by higher standard deviation scores. This indicates that the data for these measures does not accurately represent the mean. However, the behavior modification treatment acceptability scale ($M = 2.34, SD = 0.79$) had lower variance in responding and includes data that more accurately represents the mean. This result could suggest that behavior modification treatments were perceived as more acceptable to participants of this study, compared to other treatment options.

Discussion

Although previous research in the area of sleep psychology has demonstrated that patient improvement is dependent on an individual's insomnia symptoms, willingness to change, and treatment acceptability, the present study failed to demonstrate similar results. In this case, insomnia outcomes and symptoms, willingness to change, and treatment acceptability did not predict patient improvement.

The non-significant findings of this study can be understood in terms of limitations of the study's design and use of measures with unknown psychometric properties. One of the greatest limitations of this study concerns the small sample size. Original recruitment efforts at the sleep clinic resulted in an initial pool of 86 participants. But, with the low response rate of participants for the post-treatment Insomnia Outcomes Scale at 36%, only 31 participants were included in the study. According to Hager, Wilson, Pollak, and Rooney (2003), the acceptable rate of survey responses for a study varies within different fields of research, ranging anywhere from as low as 50% to as high as 75%. Some researchers even suggest that response rates below than 60% are atrocious (Schutt, 1999). By these standards the response rate for the current study was relatively low, which calls into question whether a representative sample was obtained for this study.

In addition, response bias may pose a limitation in that certain individuals are simply more likely to respond to mailed surveys than others, which also limits the representativeness of the sample. Lastly, although the post-treatment outcomes measure was sent to participants twice and a standardized phone call was used to follow up,

variables such as not having the envelopes addressed using handwritten words, not having a real stamp on the envelope (instead of a pre-paid business reply postage), or not having any monetary incentive for the completion of the questionnaire could have negatively affected the response rate (Hager, et al., 2003).

Besides addressing the importance of the study's sample size in terms of acceptable response rates, it is vital to address the role of sample size and how it relates to the power of this study. With such a low sample size, the power of the current study is only at a 0.71 level (calculated using the statistical software, G*Power). In most cases, a .80 level of statistical power is deemed appropriate for a study (Field, 2013). Because sample size affects the level of power for data analyses (because it is difficult to discover effect sizes within smaller populations), a lower level of power can impact significance levels in deleterious ways, such as failing to detect effects that are present.

Another limitation of the current study includes the significance of the pre-treatment Insomnia Outcomes Scale in the regression analysis. Although the overall model for the regression used in this study was found to be non-significant, the marginally significant result for the pre-treatment Insomnia Outcomes Scale potentially indicates that pre-treatment functioning of patients predicts overall post-treatment improvement. For example, higher ratings on the pre-treatment Insomnia Outcomes Scale would predict lower endorsement ratings on the post-treatment Insomnia Outcomes Scale. However, the results of the one-way ANOVA test in this study demonstrate that there were no significant differences between these two variables. It is possible that the marginally significant results occurred due to chance. With that being said, one factor

that could potentially influence the significance of this outcome is the small sample size in this study. Future studies with larger samples may find significant relationships between pre-treatment and post-treatment insomnia outcomes.

The lack of significant results could also possibly be explained by the psychometric properties of the scales and questionnaires used. For instance, because the three measures used in the study were recently developed, they have yet to be psychometrically tested. As mentioned previously, the reliability of the scales were analyzed, however one measure, the Change Scale, had an unacceptable Cronbach's alpha value of $\alpha = .46$. Because the reliability for this measure was low, there should be caution when using it to evaluate patient improvement for individuals experiencing insomnia. Also, because there is a lack of psychometric data available for these three scales, it is highly recommended that future research assess their validity before using them in primary care settings, given that utilizing these measures in primary care was the original intent in their creation.

In regards to the construction of the measures themselves, it is suggested that the actual construction of individual items be revisited for future use. For example, many items within the instruments are "double-barreled" with more than one query in each item, such as "Stop using caffeine, alcohol, and tobacco products". The problem with "double-barreled" items is the fact that participants may choose their response based on one part of the item, instead of all parts of the item. In this instance, a participant may choose "Strongly agree" if they use caffeine and alcohol, but this neglects to address tobacco products in the item if the participant does not use tobacco. Also, participants

may have difficulty differentiating between scale anchors. For example, in the Treatment Acceptability Scale differences between anchors such as “Slightly Effective”, “Unclear Effectiveness”, and “Moderately Effective” may be difficult for respondents to distinguish. To subjectively quantify the difference between whether a treatment is slightly effective or moderately effective may prove to be an arduous task. Lastly, because participants completed the Treatment Acceptability and Change questionnaires during the same period of time, the response scales may have created incorrect responding because the response scales were opposite of one another. In other words, the Treatment Acceptability measure uses the first anchor as the most negative response (“Not Effective at All”) and the Change Scale uses the first anchor as the most positive response (“Strongly Agree”). From a visual perspective, the left to right placement of anchors being opposite from one questionnaire to the next may have enabled erroneous responding on behalf of participants.

Results of the current study demonstrated that pre-treatment insomnia outcomes, treatment acceptability, and motivation for change did not predict improvement for patients’ insomnia outcomes. These results can be accounted for by numerous limitations such as a low response rate, small sample size, low power, and weak psychometric properties of some measures. Future research should focus on refining test construction of the three measures used as well as working to increase the sample size to provide a more robust test of the study’s hypothesis.

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Appendix A

Insomnia Outcomes Scale

1. In the past month, about how many **nights** a week did you get enough sleep?

1 or less 2 3 4 5 6 7

2. In the past month, about how many **nights** a week did you sleep well?

1 or less 2 3 4 5 6 7

3. In the past month, how many **days a week** did you feel tired or fatigued?

1 or less 2 3 4 5 6 7

4. In the past month, how many **days a week** were you happy with how you felt?

1 or less 2 3 4 5 6 7

Patient signature _____ *Date* _____ *Time* _____

Appendix B

Treatment Acceptability

Please check the box that best describes HOW EFFECTIVE you believe that each of the following treatments would be at improving YOUR OWN sleep problems.

	Not at all effective	Slightly Effective	Unclear Effectiveness	Moderately Effective	Highly Effective
Prescription medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over the counter medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation CD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Changing my sleep habits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Talking to my primary care physician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stop using caffeine, alcohol and tobacco products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Talking with a counselor / therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reading a book about sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting out of bed if I can't sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seeing a sleep expert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix C

Change Scale

Please check the box indicating to what level you either agree or disagree with the following statements.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I will do anything to improve my sleep problems					
My sleep problems are not that important.					
I've been trying to make change to improve my sleep problems.					
I've given up on trying to improve my sleep problems.					
If I put my mind to doing something I can usually be successful.					
It is very difficult for me to make changes in my life.					
I try harder when confronted with a problem.					
I don't think there is anything that I can do to improve my sleep problems.					
My problems are usually because I've made bad decisions.					
Most of what happens to me is bad luck.					
I enjoy a good challenge.					

Appendix D

CONSENT FORM

Using a Computerized Self-Report Questionnaire to

Assess Sleep Disorders Presenting with Insomnia Symptoms

You are invited to join in a research study examining the usefulness of a questionnaire to help diagnosis symptoms of insomnia. You were selected as a possible participant because you described symptoms of insomnia, which include difficulty falling to sleep, frequent nighttime awakenings sometimes with difficulty falling back to sleep, waking too early and inability to return to sleep or feeling as though your sleep is poor quality. We ask that you read this form and ask questions before agreeing to be in the study.

This study is being conducted by: Don Townsend, PhD, Con Iber, MD, Louis Kazaglis, MD, from Fairview Health Systems and Shelby Afflerbach, BA of Minnesota State University, Mankato.

Background Information

The purpose of this study is to determine whether a brief questionnaire that inquires about various symptoms of insomnia can differentiate between different causes of insomnia.

Procedures:

If you agree to be in this study, we would ask that you complete a short, computerized questionnaire in the office today and then again on the internet in about 2 weeks. The questionnaire should take about 10 minutes to complete.

Risks and Benefits of being in the Study

The risks involved in this study are that you may feel uncomfortable answering questions about your problems with insomnia.

There are no direct benefits to you for your participation. Your assistance will help us learn whether this type of questionnaire can help distinguish between different sleep problems that may look like insomnia but that need a different type of treatment.

Compensation: You will not receive any payment for participation in this study.

Confidentiality:

Appendix D (continued)

The questionnaire is completed on the computer and your responses are stored on a secure server. The only link between your name and the questionnaire is a unique ‘study number’ assigned to you during participation. The reason we need your name and email address is to send you an Internet link to complete the questionnaire a second time while you are at home in about two weeks. We need to be able to match the two questionnaires that you have completed. Any report we might publish from this information will not include anything that will make it possible to identify you. Research records will be stored at Fairview Sleep Clinics in a password-protected file and only researchers will have access to the records. Study data will be stored on a secure server according to current University policy for protection of confidentiality.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Fairview Health System or the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions:

The researchers conducting this study are: Don Townsend, PhD, Con Iber, MD, Louis Kazaglis, MD, and Shelby Afflerbach, BA. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact Dr. Townsend at the Fairview Brooklyn Park office at (763) 528-6985, (507) 398-5518 or with email at dtownse4@fairview.org.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researchers, **you are encouraged** to contact the Research Subjects’ Advocate Line, D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455; (612) 625-1650.

You will be given a copy of this form at your request.

Statement of Consent:

I have read the above information. I know that I will not receive payment or compensation for my participation in this study. I have had a chance to ask questions and had my questions answered. I consent to participate in the study.

Participant Signature: _____ Date: _____

Office Staff Signature: _____ Date: _____

Signature of Investigator: _____ Date: _____

Appendix E

**Using a Computerized Self-Report Questionnaire to
Assess Sleep Disorders Presenting with Insomnia Symptoms**

Primary Investigators: Don Townsend, PhD and Con Iber, MD

Do you experience difficulty sleeping?

Do you have difficulty falling or staying asleep?

If the answer is yes to either of these questions, then please help us with a project to learn whether a computer program can help determine the possible underlying cause of your sleep problem. Not everyone with sleep problems can see a sleep specialist for their problem. We want to learn if people complete some questions on a computer whether the computer can then suggest what the problem is and what the treatment options are.

Here is what we are asking you to do:

1. Complete a questionnaire on the computer today. It has 70 questions and takes about 10 -15 minutes.
2. Provide an email address, if you have one, so that we can send you a link to the questionnaire for you to complete a second time in about 2 weeks.

If you are willing to help with this project please let the receptionist or nurse know that now. They will answer any questions that you have. Then we will need you to sign the consent form that says you are willing to participate.

Don Townsend & Conrad Iber

Appendix F

Table 1

Overall Regression Model for Patient Improvement

Model	Sum of Squares	df	Mean Square	F	Sig.
Regression	311.126	5	62.225	1.274	.312 ^b
1 Residual	1025.541	21	48.835		
Total	1336.667	26			

Dependent Variable: PostTreatmentOutcomes

b. Predictors: (Constant), ChangeScaleReCoded, Medical_Expert_Professional_Treatment, Medication_Treatment, PreTreatmentOutcomes, Behavior_Modification_Treatment

Table 2

Coefficients for Patient Improvement

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
	(Constant)	-.695	17.039		
1 PreTreatmentOutcomes	.559	.275	.423	2.028	.055
Medication_Treatment	.003	.007	.076	.389	.701
Behavior_Modification_Treatment	1.159	2.268	.117	.511	.615
Medical_Expert_Professional_Treatment	-.326	2.924	-.026	-.111	.912
ChangeScaleReCoded	.322	.431	.150	.746	.464

Dependent Variable: PostTreatmentOutcomes

Appendix F (continued)

Figure 1. Patient improvement regression model

