Characteristics of Individuals With Insomnia Who Seek Treatment in a Clinical Setting Versus Those Who Volunteer for a Randomized Controlled Trial

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Abstract

The generalizability of outcome data derived from insomnia clinical trials is based largely on the extent to which research volunteers resemble clinical patients. This study compared sociodemographic, sleep, psychological, and medical characteristics of individuals who volunteered for an insomnia treatment study (n= 120) to patients who sought treatment in a clinical setting (n=106). The samples did not differ on most sleep and medical variables, but clinical patients had a higher prevalence of mood disorders, greater anxiety and depression symptoms, and higher perceived insomnia severity. Differences on psychological variables were accentuated by the research selection process. It is suggested to minimize exclusion based on psychological comorbidity in order to enhance ecological validity of randomized controlled trials of insomnia treatments.

Introduction

Clinical trials of insomnia treatments have traditionally used stringent selection criteria, excluding people with concurrent medical or psychiatric conditions and those using medications (Martin & Ancoli-Israel, 2002; Morin, Culbert, & Schwartz, 1994; Nowell et al., 1997). Although such methodological rigor yields more homogeneous samples, thereby reducing confounds in the evaluation of treatment efficacy, it may also limit the generalizability of the findings. In the area of behavioral interventions for insomnia, Martin and Ancoli-Israel observed a large heterogeneity in assessment and diagnosis methods across clinic based and research based studies. In addition, they identified some salient differences between the two settings. For example, patients in clinical studies were more likely to have been referred by a physician (rather than having responded to an advertisement), to be using hypnotic medication, and to have a sleep disorder other than insomnia.

Almost 20 years ago, Stepanski et al. (1989) compared the characteristics of 50 patients with insomnia who were referred to a sleep disorders center to 50 people who were recruited to a research study of hypnotic efficacy. The clinical patients reported more severe insomnia and daytime symptoms, higher levels of emotional symptoms, and were more likely to take hypnotics. Although polysomnographic measures of sleep were generally similar for the two groups, the clinical sample experienced more wakefulness during the night and greater variability on several sleep measures. Such findings make the clinician wonder to what extent the results of clinical trials apply to patients seen in practice and whether these differences between research and clinical samples continue to exist. Recent research on this topic with other conditions (Bipolar I disorder and schizophrenia) has revealed differences in age, gender, and comorbidity rates between people seen in practice and people who enter a research trial (Zarin, Young, & West, 2005).

With an increasing shift from efficacy to effectiveness studies (Clarke, 1995; National Institutes of Health, 2005), more studies are examining the application of insomnia treatments

to broader populations. For example, Espie, Inglis, Tessier, and Harvey (2001) evaluated the effectiveness of insomnia treatment services set in community based medical clinics. In addition, recent clinical trials of behavioral insomnia therapies have broadened their inclusion criteria (Morin et al., 2006). As investigators and clinicians, we need to continue to monitor the resemblance of research participants to clinic patients and the applicability of research findings to real clinical practice. There remains a need for comparison—using the same assessment tools—of research samples with naturally occurring clinical samples.

The overall aim of the present study was to compare the baseline characteristics, measured with the same instruments where possible, of individuals with insomnia who sought treatment at a clinic with those who volunteered for a randomized controlled trial. We hypothesized that there would be differences between the groups because of intrinsic differences between clinical patients and research volunteers, as well as extrinsic differences (those imposed by researchers or clinicians). The specific objectives were (a) to compare the characteristics of consecutive individuals who presented with insomnia to a behavioural sleep medicine practice (thereby undergoing an initial clinical assessment) to the characteristics of consecutive individuals who attended an initial evaluation session for an insomnia research trial. These "evaluated samples" represent people who are arriving for the first time at either a clinic or a research facility, and their comparison allows a degree of contrast between the types of people who seek help from a clinician to those who volunteer for research trials; (b) to compare the subsample of the clinical patients who actually received treatment for insomnia to the subsample of research recruits who were actually selected for the randomized controlled trial of insomnia treatments. These "treated subsamples" represent patients for whom clinicians develop treatment plans and volunteers whose data end up in published clinical trial reports, and their comparison is an approximate measure of the applicability and generalizability of published data to clinical practice.

Method

The design of the study, the evaluated samples, the treated subsamples, and the points of comparison are illustrated in the flow diagram (see Figure 1).

Clinical patients

The evaluated clinical sample was composed of 106 consecutive adult patients who came to a private psychological practice, with a primary complaint of insomnia, between January 1998 and May 2000. During that period, 15 other patients were seen but excluded from this report: 14 adults whose primary complaint was not insomnia (e.g., parasomnias, excessive daytime sleepiness) and one child. All patients were seen by a clinical psychologist (CMM) with expertise in behavioral sleep medicine (Diplomate, American Board of Sleep Medicine) who was located in a group practice with four other psychologists. Patients were self-referred or referred by another health care practitioner. Patients paid directly for the services, and many were subsequently reimbursed by their insurance company.

Sixty-eight of the 106 evaluated patients went on to attend at least one clinical treatment session for their insomnia. The other 38 patients did not receive treatment for insomnia for the following reasons: referral for polysomnography (8 people); referral to another health practitioner (7 people); presence of another condition, such as depression or anxiety requiring treatment first (3 people); sleep was no longer the main problem (2 people); or because patients did not return for treatment for various reasons (18 people).

Research Volunteers

The evaluated research sample was composed of 120 consecutive people, recruited predominantly through newspaper advertisements, who completed an eligibility assessment for a randomized controlled trial of cognitive behavior therapy (CBT) alone versus CBT combined with medication, for the treatment of insomnia, between January 2002 and March 2003. During that period, 651 people had telephoned with inquiries about potential participation in the study. Of these, 478 did not continue past the telephone screen for the following reasons:

used medication (195 people), not interested or available (151 people), other sleep problem (46 people), other medical or psychiatric problems (40 people), too young (23 people), insomnia not severe enough (10 people), or for other reasons (13 people). The remainder (173 people) were accepted for a more detailed evaluation for eligibility. Of those, 53 withdrew before their evaluation, and 120 completed the face-to-face evaluation. This last group formed the evaluated research sample of the present study.

Seventy-two of the initial 120 volunteers went on to receive treatment (i.e., were entered into the study). The other 48 participants did not receive treatment because of the presence of a major psychopathology (13 people); alcohol abuse (3 people); another sleep disorder (6 people); a major medical condition (3 people); medication interfering with treatment (2 people); or because their sleep difficulty did not meet research criteria for insomnia (3 people), they were receiving another treatment (2 people), or because they were no longer interested or available (16 people).

Details of the Randomized Controlled Trial

The potential participants for the randomized controlled trial had been recruited predominantly through newspaper advertisements and stories in local media. The ad specified that participants needed to be 30 years or older and to have had sleep difficulties for at least 6 months. In addition, some potential participants had been referred by local physicians and other health care practitioners or by word of mouth from participants of previous studies. During the telephone screen, potential participants were informed about the study and were asked questions to broadly screen for eligibility (e.g., age, insomnia frequency and duration, medications, major medical and psychiatric disorders). At this first level of screening, 3.5% were excluded because they were too young, 1.5% because they did not meet insomnia criteria, 6.1% because they had another major medical or psychiatric disorders, and 30% were excluded because they used hypnotic medications on a nightly or nearly nightly basis. The telephone screen included a description of the main features of the clinical trial, including randomization to either CBT

alone or to CBT in combination with hypnotic medication, the procedures, and the time requirements.

Interested and eligible volunteers who passed the telephone screen were then mailed questionnaires regarding sleep, health, and mood; and a 3-week supply of sleep diaries. They were asked to complete the questionnaires and to bring them in for the subsequent, more detailed, evaluation. This evaluation included a sleep history interview, psychological interview that included the Structured Clinical Interview for DSM-IV (SCID) (First, Gibbon, Spitzer, & Williams, 1997), medical examination (conducted by a physician and including a physical examination, medical history, and documentation of medications), and an overnight sleep laboratory evaluation. The psychological interview was conducted by a clinical psychology graduate student under the supervision of the last author (CMM).

The clinical trial had been designed to be relatively inclusive so that the sample could include people who had some types of stable medical or psychological conditions, or people who were on stable doses of some medications (e.g., antidepressants). The inclusion criteria were the following: (a) 30 years of age or older; (b) subjective complaint of insomnia, defined as an average sleep onset latency or time awake after sleep onset greater than 30 min per night at least three nights per week for 6 months or longer; and (c) evidence that the sleep difficulty and its sequelae were associated with distress or impairment of daytime functioning.

The exclusion criteria were the following: (a) presence of an active and progressive physical illness (e.g., congestive heart failure, cancer, COPD, acute pain) or neurological degenerative diseases (e.g., dementia, multiple sclerosis) directly related to the onset and course of insomnia; (b) use of medications, other than sleep medication, known to alter sleep (e.g., steroids); (c) nightly use of sleep medication; (d) lifetime diagnosis of any psychotic disorder or bipolar disorder; (e) current suicidal ideation or previous suicide attempt; (f) current diagnosis of major depression, dysthymia, or anxiety disorders, unless in remission; (g) history of three or more major depressive episodes; (h) alcohol or drug abuse within the

past 12 months; (i) evidence of sleep apnea (apnea hypopnea index >15), restless legs, or periodic limb movements during sleep (movement index associated with arousal >15 per hour); and (j) nighttime work (work involving any hours between midnight and 6 a.m.).

Individuals using prescribed or over-the-counter sleep promoting agents could be enrolled in the study after they had withdrawn from these medications. People with stable medical (e.g., hypertension) or psychiatric conditions (e.g., dysthymia, generalized anxiety disorder) could also be enrolled if these conditions were not clinically judged to be the only and primary cause of insomnia. Individuals using psychotropic medications (e.g., anxiolytics, antidepressants), other than those specifically prescribed to promote sleep, were not automatically excluded. For example, although individuals who used benzodiazepines daily were excluded, individuals on a stable dosage of an SSRI medication and who were in remission from their depressive episode or anxiety disorder were accepted.

Measures

The data for the current study were extracted from baseline questionnaires, interviews, or other records that had been completed prior to treatment. The following are the specific data sources. Demographic data (age, gender, marital status, and occupation) for the clinical patients were gathered from notes taken during the initial clinical interview. For the research volunteers, these data were from a self-report questionnaire completed prior to the evaluation. Occupations were subsequently coded using the National Occupational Classification–Statistics (Statistics Canada, 2001). Data on medical disorders, psychological disorders, other sleep disorders, and medications for the clinical patients were based on the initial clinical interview. For the research volunteers, data about medical disorders and medications came from the medical history, data about psychiatric disorders came from the psychological assessment and SCID interview, and data about other sleep disorders came from the medical and sleep laboratory evaluation.

Other insomnia related data were obtained, for both groups, from records of the initial interview using the Insomnia Interview Schedule (Morin, 1993), from self ratings on the Insomnia Severity Index (ISI; Morin, 1993), the Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS; Morin, 1993), and from sleep diaries. The Insomnia Interview Schedule is a semistructured interview designed to assist the clinician in conducting a sleep history, a functional analysis of insomnia, and in identifying potential medical and psychiatric comorbidities. The ISI is a 7-item self-report questionnaire designed to assess the perceived insomnia severity and impact on daytime functioning. It is well validated and can be used as a screening or outcome measure (Bastien, Vallières, & Morin, 2001). The DBAS is a 30- item questionnaire developed to assess sleep and insomnia related beliefs potentially involved in maintaining insomnia. Sleep wake data for both groups were from sleep diaries completed daily by patients and research volunteers in the period immediately prior to the initial interview or evaluation. The diaries, completed each morning upon arising, required the person to estimate the following: bedtime, time to fall asleep, number of awakenings, duration of each awakening, time of last awakening, and rise time. The variables derived from sleep diaries were defined as follows: Sleep onset latency was the time to fall asleep after lights-out time, wake after sleep onset was the total duration of all awakenings between sleep onset and final wake time, and total sleep time was the time spent in bed minus total wake time. Weekly mean values were tabulated for each person, and then means for each evaluated sample and treated subsample were calculated.

For the measures of depressive and anxiety symptoms, scores on the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988), respectively, were used for both groups. These are well-validated measures (21 items each) reflecting on the intensity of depressive and anxiety symptoms, respectively. For the clinical sample, typically these self-report measures had been taken home after the initial session and returned at the next session

(although in some cases the questionnaires were sent and completed before the first interview). For the research group, these questionnaires were completed prior to the initial evaluation.

In the coding of data for the present study, a "medical condition" included any of the following conditions or problems: respiratory, pain, cardiac or circulatory problems, gastrointestinal problems, hypothyroidism, and allergies or other significant conditions. "Psychopathology" included any of the following: major depressive disorder, bipolar disorder, dysthymia, psychosis, substance or alcohol abuse, panic disorder, social phobia, specific phobia, obsessive–compulsive disorder, generalized anxiety disorder, or posttraumatic stress disorder (PTSD). "Mood disorder" included major depressive disorder, bipolar disorder, or dysthymia. "Anxiety disorder" included panic disorder, social phobia, specific phobia, obsessive–compulsive disorder, generalized anxiety disorder, or PTSD. "Sleep disorders other than insomnia" included restless legs syndrome, periodic limb movements, sleep apnea, somnambulism, other parasomnias, nightmares, or gastroesophageal reflux interfering with sleep. "Hypnotic use" included use of benzodiazepines or other benzodiazepine receptor agonists.

Statistical Analyses

All data were inspected to identify missing data, outliers, and data entry errors and to assess normality (Tabachnick & Fidell, 2001). Descriptive and inferential statistics were completed using SAS 8.2 statistical software (SAS Institute, 2001). The number of missing data points was generally small (M D 3.1%; range 0%–22.6%), and only 7 of 64 variables (i.e., ISI, duration of hypnotic use, fatigue and mood ratings, DBAS, BAI, and BDI) had more than 10% missing data, which were more frequent in the clinical sample. Because no data were imputed, analyses were based on available data for each variable. Alpha level was set to 5% (two tailed) for all inferential tests. Variables assessed on a continuous scale were analysed using 2 (clinical vs. research sample) x 2 (treated vs. not treated) factorial analyses of variance (ANOVAs).

Of interest to this study were (a) the comparison of the characteristics of the two evaluated samples—those who presented to a clinic for an initial insomnia evaluation versus those who arrived at a research facility for evaluation of eligibility for a study of insomnia treatment, and (b) the comparison of the characteristics of those evaluated clinical patients who actually received insomnia treatment versus those evaluated research volunteers who were accepted into the study and randomized and received one of the two treatments. Therefore, we focused on the main effect of the evaluated sample (clinical vs. research) and the simple main effects for differences between the two treated subsamples (clinical treated vs. research treated). *A priori* contrasts were used to investigate the latter differences. Categorical variables were analyzed by chi-square tests, first by comparing the evaluated samples (clinical vs. research), and then by comparing the two treated subsamples.

Results

Sociodemographics

Table 1 presents the demographic data. The mean age of the evaluated clinical sample was lower than that of the evaluated research sample, $F(1, 222)$ D 16.21, p < .0001. Because there was an age criterion for the research study (i.e., 30 years or older), we repeated the age comparison using the same criterion for clinical patients. With both samples restricted to individuals age 30 and over, the mean age of clinical patients remained significantly lower (46.7 years) than that of the research volunteers (50.0 years), $F(1, 209)$ D 4.19, p D .04. The comparison of the treated subsamples showed a similar pattern, with the treated clinical subsample being significantly younger than the treated research subsample, $t(138)$ D -2.97, p D .003. Because of this significant age difference, all comparisons were repeated while controlling for age. This was done using analysis of covariance (for continuous variables) or logistic regression (for categorical variables). With the exception of insomnia duration, which shifted from being significant to nonsignificant when controlling for age, the results remained essentially the same. Thus, only results from the ANOVAs or chi-square statistics are presented

below.

There were no significant differences in gender representation between the evaluated samples or between the treated subsamples. With regard to marital status, most individuals in both groups were married or cohabitating. However, the clinical sample had a higher proportion of single people than did the research sample, x^2(1, N D 226) D 9.56, p D .002. This was also true for the treated subsamples, x^2(1, N D 140) D 5.75, p D .02. The research volunteers (sample and subsample) tended to have a higher proportion of separated or divorced individuals than the clinical patients, but these differences did not reach statistical significance. Regarding occupational status, the clinical sample had a higher proportion of people on leave from work due to a disability or other reasons, x^2(1, N D 223) D 17.63, $p < .001$; and a lower proportion of retirees, x^2(1, N D 223) D 7.93, p D .005, compared to the research sample. Similar results were observed for the treated subsamples: on leave, x^2(1, N D 139) D 8.73, p D .003; and retired x^2(1, N D 139) D 5.59, p D .018. Inspection of the distributions of occupation codes revealed no differences between clinical patients and research volunteers. For both evaluated samples, the most frequent occupation categories were "business, finance, and administrative"; "social science, education, government service, and religion"; and "management." In both samples, very few people had occupations involving "processing, manufacturing, and utilities"; and none worked in "primary industry."

Medical Comorbidity

As seen in Table 2, the presence of a comorbid medical condition and the number of prescription medications were not significantly different between the evaluated samples or between the treated subsamples. The most common medical conditions were pain, cardiovascular, gastro-intestinal, hypothyroidism, and seasonal allergies or rhinitis. The rates of suspected or confirmed presence of at least one sleep disorder other than insomnia were not significantly different between the samples or between the subsamples. The most common "other" sleep disorders

were restless legs syndrome and periodic limb movement disorder. Only a few individuals (4 and 5 in the evaluated samples) had sleep apnea.

Psychological Comorbidity

Table 2 also presents psychological data. Although the evaluated samples did not differ significantly with respect to the presence of past or current psychopathology, the treated subsamples did differ on one of these variables. The clinical subsample had a higher rate of current psychopathology than did the research subsample, $x^2(1, N D 140) D 4.83, p D$ .028. With regard to anxiety and depression, specifically, the evaluated clinical sample had a higher rate of current mood disorders, $x^2(1, N D 225) D 5.94, p D$ .015; and higher levels of self-rated anxiety, $F(1, 171) D 18.91, p < .0001$; and depressive symptoms, $F(1, 186) D$ 12.63, $p D$ .0005, compared to the evaluated research sample. These variables were also significantly different, and in the same direction, for the comparison of the treated subsamples: presence of mood disorder, $x^2(1, N D 140) D 12.21, p D .0005$; BAI, $t(121) D$ 5.00, $p < .0001$; and BDI, $t(133) D 6.09, p < .0001$. The average scores on both the depression and anxiety measures were in the non-clinical range for the research volunteers and in the mild to moderate intensity range for the clinical patients. Figures 2a and 2b show the frequency distributions of scores on the BAI and the BDI, respectively, for the evaluated samples. As illustrated, there were more individuals in the research sample with scores lower than 10 (indicating no or few symptoms of anxiety and depression) than in the clinical sample.

Insomnia and Sleep Data

Table 3 presents clinical data on insomnia and use of sleep medication. For these data, all variables that were significantly different for the evaluated samples were also significantly different for, and in the same direction as, the treated subsamples. The mean reported age of onset of insomnia was approximately 33 years for all groups. Insomnia was chronic in all conditions ($M D$ 11–17 years), but the duration was even longer, by about 5 years, in the

research sample than in the clinical sample. These differences, which were significant for both the sample and the treated subsample comparisons, were no longer significant after controlling for age. The perceived insomnia severity ratings (mean ISI scores D 18–20) fell in the moderate to severe range for all groups and, along with insomnia related fatigue, was significantly higher in the clinical patients than in the research volunteers treated subsample results: ISI, t(128) D 2.97, p D .003; and fatigue, t(127) D 2.53, p D .012. Scores on the DBAS were not significantly different between the groups.

Clinical patients were more likely to complain of initial (sleep onset) insomnia, whereas research volunteers were more likely to complain of mixed (sleep onset and maintenance) insomnia. The clinical patients were more likely to be taking a hypnotic medication, with a higher frequency of use, than the research volunteers. This may be no surprise given that a large proportion of those considered for the research trial were excluded during the initial screening because of regular use of hypnotic medication. Nonetheless, the higher prevalence of hypnotic use in the treated clinical patients applied both to the use of benzodiazepines, x^2(1, N D 140) D 6.32, p D .012; and other benzodiazepine receptor agonists, such as zopiclone and zaleplon, x^2(1, N D 140) D 7.08, p D .008. The duration of hypnotic use and the frequency of use of non-prescription medication for sleep were not significantly different between the groups.

For both the clinical and research samples, the most commonly reported types of precipitating factors for the onset of insomnia were mental health, physical health, relationship loss, stress (family, job, and general), and pregnancy or childbirth. Physical health reasons were cited more often, and "no reason" less often, by the clinical sample than by the research sample: physical health, 18.9% versus 9.2%, x^2(1, N D 226) D 4.48, p D .03; and no reasons, 2.8% versus 11.7%, x^2(1, N D 226) D 6.32, p D .01. Physical health reasons were also cited more often by the clinical subsample than by the research subsample (20.6% vs. 8.3%), x^2(1, N D 140) D 4.29, p D .038. No other significant differences in the frequencies of

the main precipitating factors were observed.

Table 4 presents the sleep diary data. The amount of time awake after sleep onset was the only variable to show significant differences between the evaluated samples, $F(1, 197)$ D 17.67, $p <$ .0001; and between the treated subsamples, $t(125)$ D -2.92, p D .004. For both comparisons, research volunteers reported more time awake after sleep onset than did clinical patients. The clinical and research groups reported comparable sleep onset latency, awakenings, and total sleep time, seen both at the level of the evaluated samples and treated subsamples.

Discussion

The main findings of this study were that patients seeking treatment for insomnia in a clinical setting (psychological practice) presented similar baseline characteristics on most reported sleep parameters and medical variables to research volunteers evaluated for a randomized controlled trial of insomnia therapies. The clinical sample presented higher perceived insomnia severity and daytime fatigue, higher levels of psychological distress (anxiety and depressive symptoms), and greater comorbidity (current mood disorders) than did the research sample. These differences were present in the initial evaluated samples, and were accentuated in the treated subsamples.

We observed a naturally occurring clinical sample and a sample from an ongoing randomized clinical trial. Because research studies have more levels of screening than do typical clinical practices, the comparison of the samples was complicated by the research pre-selection process, especially concerning age, duration of insomnia, and frequency of hypnotic use. Therefore, the findings related to these factors need to be interpreted with caution, and the discussion will focus primarily on the variables that were not involved in advertising information or telephone screening.

The observation that psychological comorbidity differences between the samples became more significant in the subsample comparisons suggests that the research evaluation

process accentuated pre-existing differences. The subsample results suggest that clinicians who treat insomnia are seeing patients who are more likely to need help for psychological comorbidity, including anxious and depressive symptoms, than the individuals whose data are reported in current randomized controlled trials of insomnia treatments. Moreover, these findings raise the issue of where to draw the line for exclusion of psychological comorbidity in insomnia clinical trials. The few outcome data available indicate that individuals with anxiety and depressive symptoms may also benefit from insomnia specific psychological interventions (Espie, Inglis, & Harvey, 2001; Morin et al., 1994; Perlis, Sharpe, Smith, Greenblatt, & Giles, 2001; Smith, Huang, & Manber, 2005). Thus, although the degree of selection is likely to vary as a function of the specific research questions, exclusion on the basis of psychological symptoms and psychiatric disorders should be kept to a minimum when a study is primarily concerned with generalizability of outcomes to clinical practice (i.e., effectiveness trials).

The data reported here are based on only one clinical practice and one research study. As such, they provide some indication of possible differences and similarities between real patients seen in similar clinical settings and the participants in insomnia clinical trials. We cannot assume that the results are necessarily representative of all clinical and research samples of individuals with insomnia. For instance, the clinical sample was derived from a psychological practice, and it is plausible that a sample of patients recruited from a medical practice might have yielded higher rates of medical rather than psychiatric comorbidity. Likewise, the research study was quite inclusive in its enrollment of heterogeneous individuals with insomnia, and it is plausible that research studies with more stringent selection criteria would find even greater differences with clinical samples. Comparisons of other clinical and research samples are needed to test whether the current findings are replicable.

A strength of this study was that most instruments were the same for both samples, and the assessment was supervised by the same clinician. This addresses, to some extent, one of the biggest impediments to comparison among studies in this area the heterogeneity

of assessment procedures (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006; Martin & Ancoli-Israel, 2002). Although most of the same instruments were used with the two samples, for a few variables the method of measurement was more thorough and systematic for the research sample. Specifically, the presence of psychopathology was determined with the SCID for the research sample and by a clinical interview for the clinical sample; and the presence of other sleep disorders was determined by interview and polysomnography with research participants, and by clinical interview with most clinical patients. In both cases, this might lead to an underestimation of sleep and psychiatric disorders in the clinical sample. Because the results go in the opposite direction (similar or higher prevalence of psychopathology in the clinical patients), these variations in measurement tools are unlikely to alter our main conclusions.

Advertisements and eligibility screening are typical steps in the recruitment of patients for randomized controlled trials, and these two steps reduced our ability to have a clear look at naïve research volunteers to examine intrinsic person related factors, separately from investigator related selection factors, between research volunteers and clinical patients. Future studies could be designed to prospectively study the differences between clinical and research samples by collecting data from interested research volunteers at the point when they know nothing about the study other than the topic of insomnia treatment. Another potentially relevant variable for future research would be socioeconomic status. Whereas the clinical patients in this study provided payment for the assessment and treatment (sometimes reimbursed by an insurance company), the research subjects received their assessment and treatment free of charge. Although the occupation categories of the two samples appear to be similar, the available data preclude a clear statement as to whether financial resources are similar between the groups.

In conclusion, the two tiered design used in this study examination of the evaluated samples, as well as the treated subsamples allowed us to investigate several issues. First,

although we were unable to observe naïve, unscreened research volunteers, we were able to examine the question of whether insomnia research volunteers are inherently different from clinical patients. Second, we were able to estimate the representativeness of randomized controlled trial participants to patients treated in a psychological clinical practice. By examining these two questions in sequence, we were able to observe the effects of the trial's inclusion and exclusion criteria on the representativeness of the final research participants. The main findings were that research volunteers, from a fairly inclusive clinical trial, resembled clinical patients on several variables, including most sleep diary parameters and on the presence of medical comorbidity. On the other hand, there was more psychological distress and comorbidity in the clinical sample differences that were accentuated by the research evaluation process. Overall, the results suggest that clinicians, more so than researchers, can expect to see patients with higher perceived insomnia severity and more who may need treatment for anxiety and depressive symptoms along with their insomnia. For enhanced ecological validity in intervention research, clinical trial investigators should consider broadening their studies' eligibility requirements.
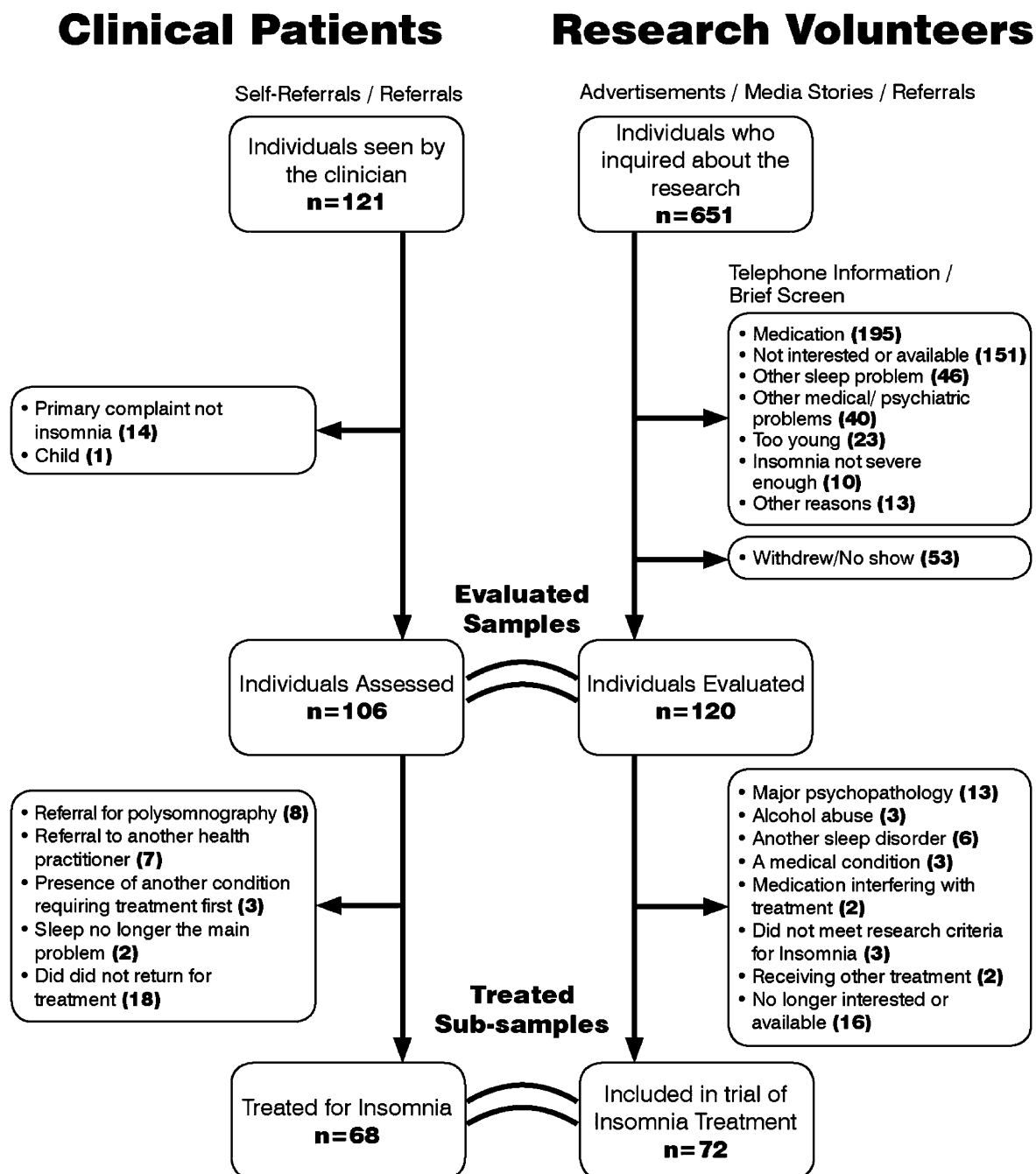
Clinical Patients

Research Volunteers

Self-Referrals / Referrals

Advertisements / Media Stories / Referrals

Individuals seen by
the clinician
n=121

Individuals who
inquired about the
research
n=651

Telephone Information /
Brief Screen

* Medication **(195)**
* Not interested or available **(151)**
* Other sleep problem **(46)**
* Other medical/ psychiatric
  problems **(40)**
* Too young **(23)**
* Insomnia not severe
  enough **(10)**
* Other reasons **(13)**

* Primary complaint not
  insomnia **(14)**
* Child **(1)**

* Withdrew/No show **(53)**

**Evaluated
Samples**

Individuals Assessed
n=106

Individuals Evaluated
n=120

* Referral for polysomnography **(8)**
* Referral to another health
  practitioner **(7)**
* Presence of another condition
  requiring treatment first **(3)**
* Sleep no longer the main
  problem **(2)**
* Did did not return for
  treatment **(18)**

* Major psychopathology **(13)**
* Alcohol abuse **(3)**
* Another sleep disorder **(6)**
* A medical condition **(3)**
* Medication interfering with
  treatment **(2)**
* Did not meet research criteria
  for Insomnia **(3)**
* Receiving other treatment **(2)**
* No longer interested or
  available **(16)**

**Treated
Sub-samples**

Treated for Insomnia
n=68

Included in trial of
Insomnia Treatment
n=72

Figure 1. Flow diagram of the study.

TABLE 1
Comparison of Sociodemographic Data for the Clinical Patients and Research Volunteers

Variable	All Individuals Evaluated			Individuals Who Received Treatment		
	Clinical (n D 106)	Research (n D 120)	pᵃ	Clinical (n D 68)	Research (n D 72)	pᵇ
Age (in years)	44.0 (11.8)	50.0 (10.5)	<.0001	43.9 (9.8)	49.5 (10.5)	.003
Gender (female)	59.4%	53.3%	ns	57.4%	54.2%	ns
Marital status			.011			.021
Married or cohabitating	58.5%	65.8%	ns	67.7%	69.4%	ns
Single	30.2%	13.3%	.002	25.0%	9.7%	.017
Separated or divorced	9.4%	17.5%	.079	7.4%	18.1%	.059
Widowed	1.9%	3.3%	ns	0.0%	2.8%	ns
Work			<.001			.005
Full or part time, studying	72.4%	72.9%	ns	77.6%	77.8%	ns
On leave	16.2%	0.9%	<.001	14.9%	1.4%	.003
Retired	9.5%	23.7%	.005	6.0%	19.4%	.018
Unemployed	1.9%	1.7%	ns	1.5%	1.4%	ns

Note. Age is represented by means (with standard deviations in parentheses). Categorical variables are represented by percentages of the group.
[a]p value based on the analysis of variance main effect of sample (for age variable) or chi-square tests (for categorical   variables). [b]p value based on *a priori* contrasts (continuous variables) or chi-square tests (categorical variables).

TABLE 2
Comparison of Medical and Psychological Comorbidity in the Clinical Patients and Research Volunteers

Variable	All Individuals Evaluated			Individuals Who Received Treatment		
	Clinical (n D 106)	Research (n D 120)	pᵃ	Clinical (n D 68)	Research (n D 72)	pᵇ
Medical comorbidity						
Medical condition present	56.6%	48.3%	ns	57.4%	54.2%	ns
Number of prescription medications (not for sleep)	1.04 (1.23)	1.13 (1.51)	ns	1.10 (1.24)	1.15 (1.51)	ns
Other sleep disorder present	30.2%	28.3%	ns	27.9%	23.6%	ns
Psychological comorbidity						
Past psychopathology	45.7%	51.3%	ns	57.4%	50.0%	ns
Current psychopathology	29.3%	27.7%	ns	30.9%	15.3%	.028
Current anxiety disorder	10.4%	14.3%	ns	13.2%	11.1%	ns
Current mood disorder	20.8%	9.2%	.015	19.1%	1.4%	.001
Beck Anxiety Inventory score	14.35 (9.68)	8.06 (6.56)	<.001	14.06 (10.12)	6.94 (5.44)	<.001
Beck Depression Inventory score	15.21 (9.05)	8.92 (6.55)	.001	15.64 (9.03)	7.70 (5.60)	<.001

Note. Continuous variables are represented by means (with standard deviations in parentheses). Categorical variables are represented by percentages of the group.

[a]p value based on the analysis of variance main effect of sample (continuous variables) or chi-square tests (categorical variables). [b]p value based on *a priori* contrasts (continuous variables) or chi-square tests (categorical variables).
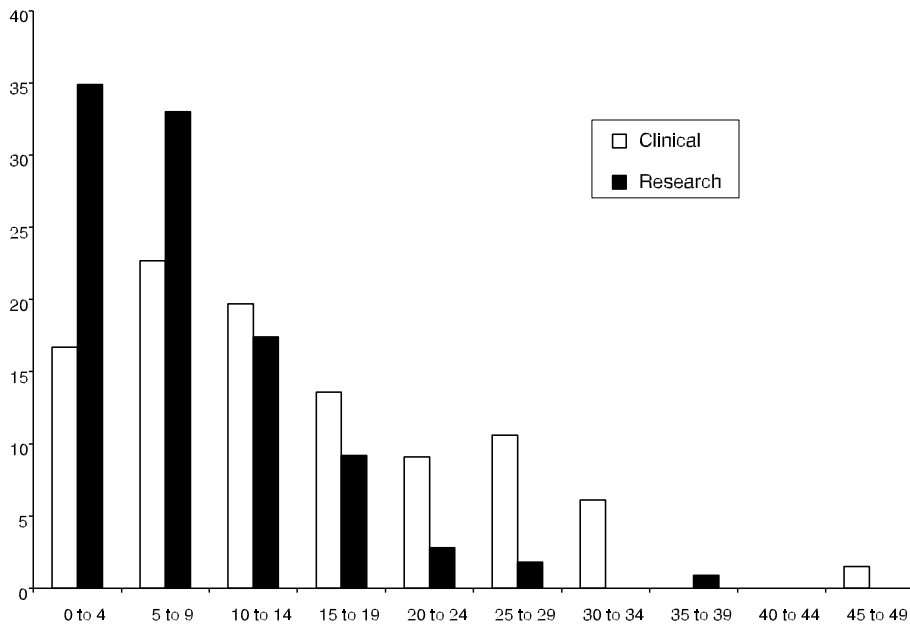
FIGURE 2. Frequency distributions of the Beck Anxiety Inventory and Beck Depression Inventory scores for the clinical and research evaluated samples.
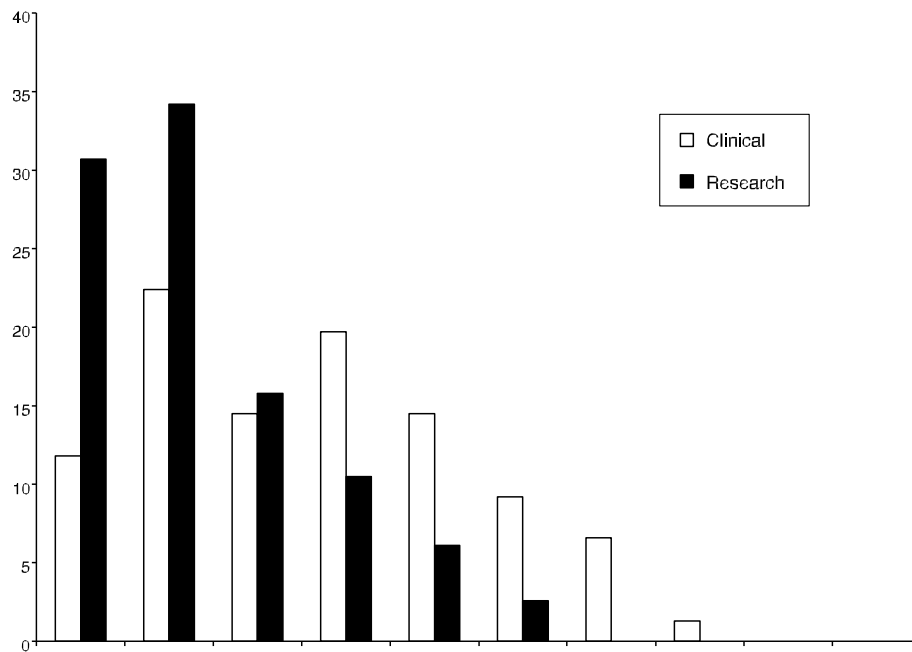

FIGURE 2. (*Continued*).

TABLE 3
Comparison of Insomnia-Related Variables for the Clinical Patients and Research Volunteers

| Variable | All Individuals Evaluated | | | Individuals Who Received Treatment | | |
	Clinical (n D 106)	Research (n D 120)	p[a]	Clinical (n D 68)	Research (n D 72)	p[b]
Age at onset of insomnia (in years)	32.66 (13.31)	33.65 (14.65)	ns	32.98 (12.21)	32.51 (13.68)	ns
Duration of insomnia (in years)	11.27 (10.81)	16.29 (14.05)	.008[c]	10.84 (8.74)	16.99 (14.62)	.005
ISI score	20.02 (4.28)	18.21 (3.90)	.031	20.04 (4.36)	17.91 (3.92)	.003
Rating of consequences of insomnia						
Fatigue (0–4)	2.90 (0.64)	2.56 (0.90)	.022	2.88 (0.61)	2.52 (0.85)	.012
Mood (0–4)	2.42 (0.85)	2.20 (1.06)	ns	2.43 (0.83)	2.18 (1.01)	ns
DBAS score	47.4 (9.7)	46.5 (9.6)	ns	47.8 (9.8)	45.4 (10.2)	ns
Type of insomnia complaint						
Initial	17.8%	3.3%	.001	15.4%	1.4%	.003
Middle	17.8%	16.7%	ns	18.5%	15.3%	ns
Early morning awakening[d]	4.0%	0.8%		1.5%	1.4%	
Mixed	60.4%	79.2%	.002	64.6%	81.9%	.021
Hypnotic use[e]	64.2%	44.2%	.003	63.2%	38.9%	.004
Use of prescription medication for sleep (nights per week)	3.33 (3.14)	1.08 (1.72)	<.0001	3.51 (3.18)	1.11 (1.72)	<.0001
Use of non-prescription medications for sleep (nights per week)	0.78 (2.06)	0.46 (1.58)	ns	0.65 (1.84)	0.39 (1.43)	ns
Duration of hypnotic use (months)	52.71 (75.13)	66.46 (104.56)	ns	51.99 (80.79)	84.45 (121.58)	ns

Note. Continuous variables are represented by means (with standard deviations in parentheses). Categorical variables are represented by percentages of the group. ISI D Insomnia Severity Index; DBAS D Dysfunctional Beliefs and Attitudes about Sleep scale.

[a]p value based on the analysis of variance main effect of sample (continuous variables) or chi-square tests (categorical variables). [b]p value based on *a priori* contrasts (continuous variables) or chi-square tests (categorical variables). [c]Not significant after controlling for age. [d]No statistics were performed for early morning awakenings because of low counts. [e]Benzodiazepines or other benzodiazepine receptor agonists.

TABLE 4
Comparison of Sleep Diary Variables for the Clinical Patients and Research Volunteers

| Variable | All Individuals Evaluated | | | Individuals Who Received Treatment | | |
	Clinical (n D 106)	Research (n D 120)	p[a]	Clinical (n D 68)	Research (n D 72)	p[b]
Sleep-onset latency (in minutes)	46.22 (37.00)	38.56 (36.02)	ns	44.42 (36.11)	35.87 (30.54)	ns
Wake after sleep onset (in minutes)	44.22 (36.73)	66.91 (39.32)	<.0001	47.73 (38.29)	67.78 (37.35)	.004
Number of awakenings	1.95 (1.31)	2.11 (1.09)	ns	2.01 (1.34)	2.14 (1.15)	ns
Sleep efficiency (%)	67.50 (15.48)	66.58 (14.23)	ns	68.31 (14.08)	65.87 (14.51)	ns
Total sleep time (in minutes)	341.53 (98.80)	332.29 (82.74)	ns	341.56 (88.89)	325.74 (85.70)	ns

Note. Sleep diary data are represented by means (with standard deviations in parentheses).

[a]p value based on the analysis of variance main effect of sample. [b]p value based on *a priori* contrasts.

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