Long-term outcome after discontinuation of benzodiazepines for insomnia: a survival analysis of relapse

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Abstract

Discontinuation of benzodiazepine (BZD) treatment for insomnia can be a difficult task. Cognitive-behavior therapy (CBT) for insomnia, combined with a supervised medication taper, can facilitate withdrawal but there is limited evidence on long-term outcome after discontinuation. The objective of this study was to examine medication-free survival time and predictors of relapse (i.e., resumed BZD hypnotics) over a 2-year period in 47 older adults (mean age 62.1 years) with persistent insomnia and prolonged BZD use (average duration of 18.9 years), who had successfully discontinued BZD following CBT for insomnia, a supervised medication taper program, or a combined approach. The Kaplan–Meier product-limit method was used to estimate survival time, defined as time between end-of-treatment and relapse or end of follow-up. By the end of the 24-month follow-up, 42.6\% of the samples had resumed BZD use. Participants in the Combined (33.3\%) and Taper (30.8\%) groups relapsed significantly less than their counterparts from the CBT group (69.2\%). Survival rates at 3 months were 61.5\% (CBT), 100\% (Taper), and 80.9\% (Combined). At 12 months, they were 38.5\%, 83.3\%, and 70.8\%, respectively; and, at 24 months, they were 28.9\%, 64.8\% and 64.9\%, respectively. Mean survival time was significantly longer for both the Taper (18.6 months, SE = 2.1) and Combined groups (12.6 months, SE = 1.4), relative to the CBT group (8.5 months, SE = 1.8). Significant predictors of relapse included treatment condition, end of treatment insomnia severity, and psychological distress. In conclusion, there is a substantial relapse rate following BZD discontinuation among prolonged users. CBT booster sessions might enhance compliance with CBT and prove useful in preventing relapse.

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1. Introduction

Insomnia is a widespread and burdensome health complaint which increases with aging. Chronic insomnia has been associated with functional impairments, reduced quality of life, higher risk for depression, and increased utilization of health-care services (Ohayon & Caulet, 1996; Simon & Von Korff, 1997; Weissman, Greenwald, Nino-Murcia, & Dement, 1997). The higher incidence of insomnia with aging is paralleled by an increased use of hypnotic drugs among older adults. Compared to prevalence rates in middle aged individuals with insomnia complaints, hypnotic use in older adults is more than twice as high (14%). These rates are even higher in elderly patients attending medical practices, with 26% of women and 6% of men using sleep medications (Hohagen et al., 1994; Ohayon & Caulet, 1996).

Benzodiazepines (BZD) are efficacious in relieving insomnia and, as hypnotics, may be indicated in the treatment of acute sleep difficulties. However, this drug class is associated with potential adverse effects (e.g., memory impairments), with altered sleep structure (e.g., reduces stages 3 and 4) and with increased risks of physical and psychological dependence. Because elimination of BZD metabolites slows down with aging, long-term use exposes elderly users to an exacerbation of these risks (Tamblyn et al., 1994). BZD-related health hazards, specific to the aging population, have also been identified. They include increased risk of falls and hip fractures (Leipzig, Cumming, & Tinetti, 1999; Ray, Griffin, Schaffner, Baugh, & Melton, 1987; Ray, Thapa, & Gideon, 2000) and road accidents by elderly drivers (Hemmelgarn, Sussi, Huang, Boivin, & Pinard, 1997; Ray, Fought, & Decker, 1992). According to standard prescription guidelines, hypnotic use should be restricted to a maximum of four weeks (National Institute of Health (NIH), 1984, 1991). Despite this, a significant proportion of the population use BZDs for sleep on a chronic basis. Among these users, older adults are overly represented (Egan, Morides, Wolfson, & Monette, 2000; Morgan, Dallosso, Ebrahim et al., 1988; Tamblyn et al., 1994).

Discontinuation of BZD hypnotics can be a difficult task. Relapse rates often exceeding 50% after discontinuation have been reported at follow-ups (Kirmil-Gray, Eagleston, Thorensen, & Zarcone, 1985; Rickels, Case, Schweizer, Garcia-Espana, & Fridman, 1991; Rickels, Schweizer, Case, & Greenblatt, 1990). Cognitive-behavior therapy (CBT) has been shown helpful in aiding patients suffering from anxiety (Otto et al., 1993; Sanchez-Craig, Cappell, Busto, & Kay, 1987; Spiegel, Bruce, Gregg, & Nuzzarello, 1994) and insomnia (Baillargeon, Demers, & Ladouceur, 1998; Lichstein et al., 1999; Morgan, Thompson, Dixon, Tomeny, & Mathers, 2003; Morin, Colecchi, Ling, & Sood, 1995) discontinue BZD medications. In two recent studies reporting on the use of CBT to facilitate BZD withdrawal, significantly more participants who had received CBT during taper were drug-free by the end of the treatment period compared to those who had not received it (Baillargeon et al., 2003; Morin et al., 2004). CBT has also been shown to decrease relapse rates (return to medication use) and to facilitate long-term abstinence in patients using BZD for anxiety problems (Bruce, Spiegel, & Hegel, 1999). Few studies though have systematically investigated long-term outcome (beyond 12 months) after successful withdrawal and, to our knowledge, none has documented relapse-free survival time (time without medication use) in patients suffering from chronic insomnia.

This study aimed at examining long-term outcome (24 months), in terms of medication-free survival time among individuals with chronic insomnia who had previously discontinued BZD usage. A secondary goal was to examine predictors of relapse.
2. Method

The present report is based on follow-up data from a randomized comparative clinical trial which evaluated the effectiveness of three treatment conditions in helping patients withdraw from BZD hypnotic medication (Morin et al., 2004). In the present study, survival time between end-of-treatment and relapse or end of follow-up was examined in 47 patients who had completely discontinued BZD use in the former study. Information regarding this principal study, essential to the presentation and comprehension of this report’s data, will be presented briefly. The treatment study included 76 older adults (50% women) with chronic insomnia and chronic use of BZDs for sleep. Participants were randomized into three different treatment conditions, each of 10 weeks duration: a medically supervised taper of BZD medications (Taper, \( n = 25 \)), a medically supervised taper plus CBT for insomnia (Combined, \( n = 27 \)); and a CBT for insomnia condition in which patients did not receive the supervised taper program (CBT, \( n = 24 \)). Participants of the latter group were instructed to consult their family physician if they wished to stop medication intake during the course of the treatment. Groups did not differ on any baseline characteristics, insomnia severity and duration or BZD usage (quantity, frequency, duration), number of physical illnesses, or medications used. At the end of the treatment period, 63% of the sample (48/76) was drug-free, 85% (23/27) in the combined group, 48% (12/24) in the Taper group and 54% (13/23) in the CBT only group. A significant between-group difference was observed with regard to discontinuation rate, with more drug-free patients in the combined than either the Taper or the CBT only groups. No significant withdrawal symptom or rebound insomnia was reported (based on self-report and physician evaluation).

2.1. Participants

Forty-seven participants, [47% women, average age: 62.1 years (SD = 6.5; range 55–82)] who successfully discontinued BZD use after participating in the above-mentioned clinical trial were included in this study. All were Caucasian community-dwelling residents, predominantly married (78.7%), and retired (63.8%). The majority of patients (64%) reported mixed sleep onset and maintenance insomnia. The average insomnia duration was 23.3 years (SD = 9.6). Patients had used benzodiazepines for sleep on a regular basis (mean of 6.8 nights per week) for an average duration of 20.7 years (range 2.5–35 years). The average nightly use was 9.52 mg (diazepam equivalent). Patients had made an average of 6.0 attempts (SD = 7.5) to discontinue medications in the past. Most patients (73%) used an intermediate-acting BZD (lorazepam, temazepam, bromazepam, oxazepam and alprazolam); 25.7% used a long-acting agent (flurazepam, clonazepam), and only one used a short-acting BZD (triazolam). Nine patients used two BZDs, three patients used three, and one used four BZDs (Table 1).

2.2. Treatment conditions

A more in-depth description of the treatment procedures summarized below can be found in the original report. All therapy sessions were audiotaped and reviewed regularly with the principal investigator in order to optimize physician and therapists’ adherence to treatment protocol.
2.2.1. Cognitive-behavior therapy

Patients in the CBT group attended 10 weekly 90-min. therapy sessions conducted in small groups of four to six individuals and led by a licensed clinical psychologist. Treatment consisted of a structured, multifaceted, intervention involving behavioral, cognitive, and educational components that targeted different facets of insomnia (Morin, 1993). The behavioral component incorporated sleep restriction therapy (Spielman, Saskin, & Thorpy, 1987) and stimulus control procedures (Bootzin, Epstein & Wood, 1991). The cognitive therapy component was designed to alter faulty beliefs and attitudes that often serve to exacerbate insomnia. A detailed manual outlining each session was utilized (Morin, 1993).

2.2.2. Taper

Subjects enrolled in the medication taper condition, either alone or in combination with CBT, met weekly with a physician for 10 brief consultation sessions (15–20 min). A detailed manual was also used for the tapering sessions. The content of those sessions focused on (a) reviewing the written taper schedule, (b) documenting changes in insomnia symptoms, and (c) monitoring withdrawal effects and any other adverse events. Patients were provided with a step-by-step withdrawal plan, with the goal of eliminating BZD use by the 8th week of treatment.
drawal schedules were individualized according to BZD type (short- vs. long acting), dosage, and frequency of use. The following principles were used in designing those schedules: setting goals, stabilization on a single BZD for patients using more than one BZD, reduction of about 25% of the initial dosage every two weeks until the lowest available dosage of the BZD was reached, introduction of an increasing number of drug-free nights, and scheduled hypnotic use rather than usage on a as needed basis. The specific dose reductions varied as a function of patients’ readiness to discontinue medication and the presence or absence of withdrawal symptoms. However, the time-limited nature of this program was emphasized by setting anchor points. For example, the initial plan was to decrease medication by 25% at week 2, by 50% at mid-treatment, and by 100% at week 8 (Morin, Baillargeon, & Bastien, 2000). Support and encouragement to follow the written withdrawal schedule were provided, but no specific behavioral recommendations for improving sleep were given during those sessions.

2.2.3. Combined CBT and Taper (combined condition)

Patients in the combined CBT + Taper condition received both the tapering program and CBT. Discussion of behavioral sleep management strategies was restricted to CBT sessions to minimize overlap across conditions.

2.3. Measures

2.3.1. Sleep diaries

Participants kept daily sleep diaries for at least two weeks prior to treatment, during the 10-week treatment period, and for two weeks at each of the follow-ups. Several sleep-related parameters were monitored on the diaries (e.g., bedtime, rising time, sleep-onset latency, number and duration of wakening as well as BZD medication intake). Although sleep diary data do not reflect absolute values obtained from EEG, they provide a reliable index of insomnia (Coates et al., 1982) and represent standard outcome assessment in insomnia research (Sateia, Doghramji, Hauri, & Morin, 2000). In addition to allowing for prospective monitoring of sleep in the patient’s home environment, sleep diary data reflect on an important dimension of insomnia, i.e., the subjective perception of sleep.

The Insomnia Severity Index (ISI) is a 7-item scale that yields a quantitative index of insomnia severity (Morin, 1993). Ratings on a 5-point scale (0–4) are obtained on the perceived severity of sleep onset, sleep maintenance, and early morning awakening problems; interference with daytime functioning; noticeability of impairment caused by the sleep problem; concern over the sleep problem; and satisfaction with current sleep pattern. A composite score is obtained by summing up the seven ratings. Higher scores indicate more severe insomnia (total scores range from 0 to 28). The ISI has adequate psychometric properties and has been shown sensitive to changes in clinical trials of insomnia (Bastien, Vallières, & Morin, 2001; Morin, Colecchi, Stone, Sood, & Brink, 1999; Smith & Trinder, 2001).

2.3.2. Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS: Morin, 1993)

This instrument is a 30-item scale tapping various beliefs, attitudes, expectations, and attributions about sleep and insomnia. Respondents rated their level of agreement/disagreement on a 100-mm visual analogue scale anchored by the statements strongly disagree and strongly agree. Except for item number 23, for which the score is reversed, a higher score indicates a more
dysfunctional belief. Adequate psychometric properties are reported with both good and poor sleepers (Morin et al., 1993).

2.3.3. Psychological distress

The Brief Symptom Inventory (BSI, Derogatis & Melisaratos, 1983) measures the presence of a variety of psychological symptoms rated on a 0–4 scale. The 53 items are grouped under 10 dimensions (e.g., anxiety, depression). Three global indexes are also available: (a) number of reported symptoms, (b) distress associated with the reported symptoms and (c) a general severity index which combines number of symptoms and intensity of distress. This instrument presents very good psychometric properties and good convergent validity (Derogatis & Melisaratos, 1983). The Beck Depression Inventory (BDI: Beck, Steer, & Garbin, 1988) and Beck Anxiety Inventory (Beck, Epstein, Brown, & Steer., 1988) were also administered in order to assess symptoms of anxiety and depression (see Table 1).

2.3.4. Coping with Health, Injuries and Problems (CHIP; Endler, Parker, & Summerfelt, 1993)

An adapted version of this instrument was used in order to assess coping strategies with insomnia. This instrument is a 32-item self-report measure tapping four basic coping dimensions (8 items per scale): distraction, palliative, instrumental and negative emotions. Respondents indicate on 5-point Likert-type scales how much they engage in a specific activity when encountering their particular health problem (i.e., insomnia). This measure was developed primarily for assessing coping reactions in individuals encountering a variety of health problems. The four factor structure has been replicated across several clinical populations and alpha coefficients range from 0.78 (men) to 0.84 (women).

2.4. Follow-ups

Participants were followed for a period of 24 months post-withdrawal. All patients were contacted by mail 3, 12, and 24 months after completing treatment. At each follow-up, they were asked to complete the same questionnaires and sleep diaries (for two weeks) as administered at baseline and post-treatment. Data regarding medication use during follow-up period, date of relapse and reasons for resuming hypnotic intake were recorded at each assessment.

2.5. Statistical analyses

Statistical analyses are based on 47 of the 48 subjects who were medication-free at the end of the initial 10-week intervention. One patient had no follow-up data and could not be included in the analyses. One-way analyses of variance were used for comparisons of continuous variables and Chi-square or Fisher’s exact tests (when appropriate) were used for comparisons of categorical variables. The probability of relapse in resuming hypnotic use (after the end of the treatment period) was estimated by the Kaplan–Meier product-limit method (Kaplan & Meier, 1958), and Log-rank tests with post-hoc comparisons were performed to assess between-group differences (differences between survival curves of each group). Variables potentially associated with relapse were investigated using univariate proportional hazard regression (Cox, 1972). Since several variables were significantly associated with relapse time, multivariate Cox stepwise regressions were performed in order to identify independent predictors of survival time and esti-
mate the relative risk of relapse after adjusting for these predictors. Event to predict was relapse, defined as resumption of regular use of any sleep aid medication. Statistical analyses were performed using SAS release 6.12.

3. Results

3.1. Survival time

Of the total sample, 42.6% relapsed, 69.2% in the CBT, 30.8% in the Taper and 33.3% in the Combined group. A total of six patients were censored before the end of the 24-month follow-up period. Mean survival time was 8.5 months (SE = 1.8) for the CBT group, 18.6 months (SE = 2.1) for the Taper group and 12.6 months (SE = 1.4) for the Combined group. Survival at 3 months was of 61.5% in the CBT group, 100% in the Taper group, and 80.9% in the Combined group. At 12 months, survival was of 38.5%, 83.3%, and 70.8%, respectively. At the end of the 24-month follow-up, survival was of 28.9%, 64.8% and 64.9%, respectively (see Fig. 1).

The overall Log-rank test was significant ($p = 0.0385$). Post-hoc Log-rank tests revealed a significant difference between survival times of the CBT versus the Combined groups ($p = 0.0488$) and between the CBT versus the Taper groups ($p = 0.0255$). No significant difference was observed between the Taper and the Combined groups ($p = 0.7488$). Participants in the Taper and in the Combined groups had longer medication-free survival time than their counterparts from the CBT group.

![Fig. 1. Survival distribution according to treatment group.](image)
3.2. Predictors of survival time

Given the exploratory nature of this part of the study, several variables were tested for relationship with medication-free survival time (Cox univariate regressions). They included pretreatment variables such as age, gender, age of insomnia onset, length of insomnia, length of BZD use, type of BZD used (short, medium, or long acting), and number of BZDs used before withdrawal and post-treatment variables such as self-efficacy in not using BZDs, sleep efficiency, BSI subscales scores, BAI, BDI, DBAS, ISI and CHIP subscales scores. Treatment conditions and number of weeks required to discontinue BZD use were also assessed. As shown in Table 2, the following variables were significantly related with survival time: treatment conditions, number of medications used for insomnia before withdrawal, number of weeks required to discontinue BZD use, insomnia severity (ISI scores), BSI distress and somatization subscales and anxiety level (BAI scores).

All variables significantly related with medication-free survival time were entered in a multiple regression model using a stepwise procedure based on the significance of each predictor. The criterion for entry into the model was a significance level of 0.15 (which is standard in exploratory studies). Insomnia severity was entered first \( (p = 0.002) \), followed by BSI Distress subscale \( (p = 0.0617) \) and by number of weeks required to discontinue BZD use \( (p = 0.1054) \). No other variable was further selected from the model. In order to examine if differences in survival time

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number of events</th>
<th>Hazard ratio</th>
<th>95% Confidence Interval of HR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment condition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBT</td>
<td>9 (69.2)</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taper</td>
<td>4 (30.8)</td>
<td>0.292</td>
<td>[0.09; 0.96]</td>
<td>0.0423</td>
</tr>
<tr>
<td>Combined</td>
<td>7 (33.3)</td>
<td>0.361</td>
<td>[0.13; 0.98]</td>
<td>0.0450</td>
</tr>
<tr>
<td><strong>Insomnia medications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One</td>
<td>9 (29)</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than one</td>
<td>11 (68.8)</td>
<td>3.056</td>
<td>[1.26; 7.43]</td>
<td>0.0137</td>
</tr>
<tr>
<td><strong>Age at which insomnia started</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>20 (42.6)</td>
<td>0.969</td>
<td>[0.94; 1]</td>
<td>0.0821</td>
</tr>
<tr>
<td><strong>Weeks required discontinue BZD use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>20 (42.6)</td>
<td>1.528</td>
<td>[1.1; 2.12]</td>
<td>0.0110</td>
</tr>
<tr>
<td><strong>BSI distress</strong></td>
<td>20 (42.6)</td>
<td>57(^{E21})</td>
<td>[94(^{E5}); 4(^{E38})]</td>
<td>0.0047</td>
</tr>
<tr>
<td><strong>BSI somatization</strong></td>
<td>20 (42.6)</td>
<td>2.416</td>
<td>[1.05; 5.58]</td>
<td>0.0386</td>
</tr>
<tr>
<td><strong>BAI</strong></td>
<td>20 (42.6)</td>
<td>1.066</td>
<td>[1; 1.13]</td>
<td>0.0374</td>
</tr>
<tr>
<td><strong>Insomnia severity</strong></td>
<td>20 (42.6)</td>
<td>1.52</td>
<td>[1.05; 1.26]</td>
<td>0.0027</td>
</tr>
</tbody>
</table>

*Note:* BAI, Beck Anxiety Inventory; BSI, Brief Symptom Inventory; Insomnia severity is measured by ISI total score.
between treatment groups were still significant after the other variables were entered, the treatment condition variable (although significant) was not entered in the equation until the end of the testing. Another equation was thus computed which included the three variables selected in the first equation and the treatment condition variable. Differences between treatment conditions remained significant despite the presence of the three other predictors in the model. A significant difference was observed between the Combined and CBT groups [HR = 0.267 (CI = 0.087; 0.824), \( p = 0.0216 \)] and between the Taper and CBT groups [HR = 0.155 (CI = 0.044; 0.548), \( p = 0.0038 \)]. Patients from the CBT group were almost seven times (HR = 6.67) more at risk than patients from the Taper group and almost four times (HR = 3.75) more at risk than the Combined group to relapse following treatment. No significant difference was observed between the Taper and the Combined groups in overall risk of relapse, even when insomnia severity, psychological distress or number of weeks required to discontinue BZD use were considered.

3.3. Descriptive analysis

3.3.1. Lapses

Lapses, defined as a punctual use of any sleep medication, including over-the-counter medications, were recorded. However, these were not submitted to statistical analysis because of small sample size and insufficient number of observations per cell. Time frame used to define lapses was that use had to be circumscribed in time (less than three nights per week and less than 1 month duration) and followed by a medication-free state of at least 3 months. Table 3 presents descriptive data on number of participants who reported lapses in each category (relapse/non relapse). Among participants who relapsed, eight participants reported having had lapses (between 1 and 3) while 12 did not report any. Among those who did not relapse, 11 participants reported having had lapses (between 1 and 4 lapses) while 16 did not report any. The majority of participants had lapses of less than one week duration. Two participants had lapses of three weeks and one month duration, respectively, which were associated with a major life event. These lapses were followed by abstinence the rest of the follow-up period. For patients who reported lapses, most reported 1 or 2 lapses during the follow-up period.

3.3.2. Reasons for relapse

Reasons associated with relapse (i.e., having resumed medication intake on a regular basis) were various and included having chronic pain (\( n = 2 \)); being hospitalized or after surgery

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**Table 3**

Number of patients who reported lapses according to outcome status (relapse versus no relapse)

<table>
<thead>
<tr>
<th>Lapses</th>
<th>Relapse ((N = 20))</th>
<th>No relapse ((N = 27))</th>
</tr>
</thead>
<tbody>
<tr>
<td>No lapse</td>
<td>( n = 12 )</td>
<td>( n = 16 )</td>
</tr>
<tr>
<td>Lapses</td>
<td>( n = 8 )</td>
<td>( n = 11 )</td>
</tr>
<tr>
<td>1 lapse: ( n = 5 )</td>
<td></td>
<td>1 lapse: ( n = 6 )</td>
</tr>
<tr>
<td>2 lapses: ( n = 2 )</td>
<td></td>
<td>2 lapses: ( n = 4 )</td>
</tr>
<tr>
<td>3 lapses: ( n = 1 )</td>
<td></td>
<td>4 lapses: ( n = 1 )</td>
</tr>
</tbody>
</table>
following a major stressful life event such as death of a spouse, divorce or imminent retirement \((n = 4)\); or reporting unspecified anxiety or tension \((n = 8)\); environmental conditions such as noise, a snoring bed partner \((n = 2)\); or being unable to fall asleep (no reasons specified) \((n = 4)\).

4. Discussion

Results of this study showed a substantial relapse rate after BZD discontinuation. Indeed, 20 patients out of 47 (43\%) relapsed during the two-year follow up. This rate is consistent with prior reports on long-term outcome after BZD withdrawal among patients suffering from anxiety disorders (Bruce et al., 1999; Rickels et al., 1990, 1991). No information regarding long-term outcome after participation in a structured BZD discontinuation program was available until now for patients suffering from insomnia.

Significantly more patients who received CBT for insomnia, without a supervised medication withdrawal program, resumed medications compared to the two other groups. A possible explanation for this group effect may be that patients in this group did not receive formal guidance or instructions to discontinue hypnotic use. The results observed in the main parent study (Morin et al., 2004) suggested that the supervised medication tapering was a necessary component to successfully discontinue BZD medications. Results of the present study indicate that this component may also be an essential ingredient in helping patients stay hypnotic-free after discontinuation.

Although there were no significant differences in overall survival time between the Taper and the Combined groups, visual examination of their respective curves (see Fig. 1) suggests that relapse did not follow the same patterns. Although most participants of the Combined group achieved a medication-free status by the end of treatment (23/25; see Morin et al., 2004), more patients relapsed early-on, i.e., within 3 months. On the other hand, while there were significantly fewer medication-free patients in the Taper group (12/24) at the end of treatment, they seemed to show a better survival time at 3 and 12 months compared to patients in the Combined (and CBT) group. For example, none of the patients in the Taper group had relapsed at 3 months. This observation suggests that CBT added to the structured taper program may be more effective than either of its single components to help patients discontinue BZD hypnotics, but may not fully maintain its superiority after the intervention. Although a longer intervention (e.g., 12–15 sessions) might be necessary for some individuals, a more cost-effective method to prevent relapse might involve booster sessions to foster continued compliance with CBT and coping skills developed during treatment. According to the present results, such CBT booster sessions would have to be implemented within the first 3 months after treatment in order to maximize relapse prevention. This time frame is consistent with the literature on addictive behaviors which suggests that a critical time point for relapse to occur would be within 3 months post-intervention (Marlatt & Gordon, 1985). Although the survival curve observed for the Combined group tends to follow this observation that of the Taper group does not. A possible explanation for this may be that patients who succeeded in discontinuing their medication without formal psychological interventions may fare better in terms of abstinence from hypnotic use because they developed or relied on their own self-management skills rather than on pro-
essional guidance. Another explanation may be that these patients were truly ready to discontinue hypnotic use. Prochaska and DiClemente (1986) and Prochaska, DiClemente, and Norcross (1992) stress that change is not necessarily a linear process and that individuals may go through the same phases several times before actually modifying a behavior and reaching the maintenance phase of change (“readiness of change” concept). The authors explain behavior modification in a five-stage spiral model of how people change their behaviors which may be useful in further understanding hypnotic discontinuation (Prochaska et al., 1992). Visual examination of the survival curve shows that more patients of the Taper group relapsed after 18 months, compared to patients of the Combined group. This may indicate a return of the insomnia problem or that the alternative strategies they were using to cope with their sleep problems were no longer efficient.

Several predictors of relapse were identified, but only level of psychological distress, insomnia severity and number of weeks required to discontinue BZD use remained significant predictors in a multivariate model of relapse. Further, the treatment condition variable remained significant despite the presence of these three predictors in the model. Not undergoing the structured medication taper was associated with higher risks of relapse when compared with the two other groups. However, patients who were in the Taper only condition presented a greater protective factor (HR = 0.155) than those who received the Combined intervention (HR = 0.267). This observation again speaks for the need to incorporate CBT booster sessions.

Perceived insomnia severity remained among the predictors of relapse, indicating that patients continue to report sleep difficulties. It is difficult to ascertain which patients should and should not discontinue medication use or who will most benefit from CBT techniques. Some patients still met diagnostic criteria for insomnia at baseline despite hypnotic use, indicating that medications did not completely eliminate their sleep problem. However, it is unclear if their difficulties were exacerbated in discontinuing their hypnotic. Psychological distress also remained a significant predictor; but how distress and insomnia were related to one another was not assessed. Do patients experience psychological distress because of sleep difficulties or are sleep difficulties caused by a stressful event?

One of the most frequently evoked reasons for resuming sleep medications was related to having a medical condition or undergoing surgery. Although such explanations may be justified for older adults, this issue needs further investigation in order to better understand triggers of relapse and to design effective relapse prevention for this population. The findings related to lapses suggest that having such circumscribed episodes of hypnotic use do not necessarily lead to full relapse. Although this observation is tentative, it deserves further attention as it may suggest that patients may use hypnotics in specific and time-limited situations (e.g., jet lag, surgery, bereavement) without necessarily relapsing.

Results of this study must be interpreted with caution. First, patients who were randomized to the CBT only condition were instructed to consult their physician or pharmacist if they desired to withdraw from their medication. Information regarding how withdrawal was conducted, or even if patients did get medical supervision, was not available. Why they did poorly, in terms of greater relapse rate at follow-ups, compared to the other two groups, is difficult to interpret in light of this methodological limitation. Second, conclusions regarding the predictors of relapse, identified through the regression analyses model performed in this study, are tentative. The results should be replicated with an independent and parallel dataset since our sample
size was small. Finally, the generalizability of these findings may be limited by the fact that the sample was composed of healthy individuals who wished to discontinue use and generally did not exceed the recommended therapeutic dosage. Generalization to older patients with chronic medical or mental health problems, or those who are chronic users and do not wish to discontinue use, is not possible at this time.

Further research is needed to identify possible personal characteristics associated with relapse in order to better understand why some patients discontinue BZD use and refrain from medication use without formal psychological help. Apart from psychological distress, this study did not identify other personal or psychological characteristics associated with relapse. Variables such as “readiness to change” and personality characteristics may represent other leads of investigation for future research.

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References


