Tapering off long-term benzodiazepine use with or without group cognitive–behavioural therapy: three-condition, randomised controlled trial


Background Benzodiazepine withdrawal programmes have never been experimentally compared with a non-intervention control condition.

Aims To evaluate the efficacy and feasibility of tapering off long-term benzodiazepine use in general practice, and to evaluate the value of additional group cognitive–behavioural therapy (CBT).

Method A 3-month randomised, controlled trial was conducted in which 180 people attempting to discontinue long-term benzodiazepine use were assigned to tapering off plus group CBT, tapering off alone or usual care.

Results Tapering off led to a significantly higher proportion of successful discontinuations than usual care (62% vs. 21%). Adding group CBT did not increase the success rate (58% vs. 62%). Neither successful discontinuation nor intervention type affected psychological functioning. Both tapering strategies showed good feasibility in general practice.

Conclusions Tapering off is a feasible and effective way of discontinuing long-term benzodiazepine use in general practice. The addition of group CBT is of limited value.

Declaraton of interest None. The study was funded by the Dutch Health Care Insurance Council.

METHOD
Design The study was a randomised, controlled trial comparing tapering off long-term benzodiazepine use alone with tapering off combined with group CBT and with a control group receiving usual care. In order to include only those who were unable to quit of their own accord, all patients who were long-term users were sent a letter by the participating general practitioner in which they were advised to discontinue their benzodiazepine use. The study received ethical approval from the University Medical Centre, Nijmegen, and took place from 1998 to 2001.

Sample size and randomisation The aim was to increase the success rate after the pre-selection procedure (i.e. the letter from the general practitioner) from an expected 55% through tapering off alone, to 80% by combining tapering off with group CBT (Otto et al., 1993). Based on a chi-squared test, this effect size required a sample size (two-sided α=0.05, β=0.20) of 52 participants in each experimental group, or 62 participants based on a corrected chi-squared or Fisher's exact test (Dupont & Plummer, 1990). Participants were randomised in a ratio of 2:2:1 to achieve maximum discriminative power between the two experimental groups. Computerised randomisation took place after at least ten participants within a geographic cluster had given informed consent, in order to form CBT groups with a minimum of four participants at a location near to the participants’ homes.
**Intervention**

**Tapering off**

Participants who were not using diazepam were transferred to an equivalent dose of diazepam for 2 weeks by their own doctor, using the conversion table of Zitman & Couvée (2001). For participants taking more than one benzodiazepine, the dosages were added together. The daily dose of diazepam was reduced by 25% a week during four weekly visits. In accordance with Schweizer et al. (1990) participants had the opportunity to divide the last step into two steps of 12.5% for 4 days. The last visit took place 2 weeks after the last reduction step. The general practitioner filled in a case record form to monitor progress and any adverse events during the intervention period. Two months later, we evaluated participant and doctor satisfaction and the feasibility of the withdrawal programme by means of a postal questionnaire.

**Group cognitive–behavioural therapy**

The participants who were randomised to tapering off combined with group CBT attended five weekly 2-h sessions of group CBT in addition to the dose reduction visits to their general practitioner. The sessions started halfway through the tapering-off period and finished 2 weeks after the conclusion of the withdrawal programme. The aim of the group therapy was to support the participants during the tapering-off process and to prevent relapse thereafter. The therapy programme included:

(a) psychoeducation concerning the advantages and disadvantages of long-term benzodiazepine use;

(b) teaching and practising relaxation exercises by means of progressive relaxation;

(c) cognitive restructuring of the interpretation of withdrawal symptoms.

The sessions were led by registered psychologists, experienced in CBT, who received training and a detailed manual of the therapy. The therapists documented participation and reasons for non-participation at each session. Tape-recordings of a random sample of sessions 3 and 5 were judged by an independent assessor using previously defined criteria, and did not show any protocol violations. Two months later, we evaluated patient satisfaction with the group therapy by means of a postal questionnaire.

**Usual care**

Participants in the usual care control group were informed about the randomisation by letter. They did not receive any help with benzodiazepine reduction.

**Measurements**

Participants received a baseline assessment after giving informed consent, and they received an outcome assessment 3 months after the start of the intervention. Structured interview assessments were carried out at the participants’ homes by a trained research assistant, who explored the self-reported use of benzodiazepines, administered the 15-words test, and assessed the circumstances of filling in the self-report questionnaires.

**Primary outcome measure**

The primary outcome measure was the proportion of participants who successfully discontinued long-term benzodiazepine use, defined as no benzodiazepine use at the outcome self-report assessment. We checked self-reported discontinuation of benzodiazepine use in the general practitioners’ prescription databases, which showed that less than 5% of the participants who reported successful discontinuation had received a benzodiazepine prescription in the month before the outcome assessment.

**Secondary outcome measures**

Secondary outcome measures were the reduction in daily benzodiazepine dosage by participants who did not successfully discontinue drug use; the use of alcohol (including the number of problem drinkers, based on the 18-item list of Cornel et al., 1994); psychological well-being assessed by the General Health Questionnaire 12-item version (GHQ–12; Goldberg & Blackwell, 1970); memory (delayed recall of the 15-words test; Saan & Deelman, 1986); mood (the scales of depression, anger, fatigue, vigour and tension of the 32-item Shortened Profile of Mood States; Wald & Mellenbergh, 1990); and the number and severity of benzodiazepine withdrawal symptoms (Benzodiazepine Withdrawal Symptom Questionnaire; Tyrer et al., 1990).

**RESULTS**

**Study profile**

Of the 2964 persons identified as long-term users of benzodiazepines, 2004 were advised to stop their benzodiazepine use; 1036 were eligible for the trial (Fig. 1). The participation rate was low: 180 out of 1036 (17.4%). Participants (n=180) and non-participants (n=876) did not differ with respect to age, gender or benzodiazepine dosage used. Of the 146 participants assigned to one of the withdrawal programmes, 23 discontinued their benzodiazepine use while waiting for the intervention to begin. In order to...
LONG-TERM BENZODIAZEPINE USERS: 2964
Based on prescription databases, 58 doctors in 30 general practices had an average of 51 patients using benzodiazepines for over 3 months
Patients excluded: 960
- Current psychiatric treatment: 281
- Current treatment for drug or alcohol dependence: 82
- Medical history of psychosis: 80
- Epilepsy: 59
- Insufficient mastery of the Dutch language: 59
- Terminal illness: 26
- Excluded at instigation of the GP: 379

PATIENTS ELIGIBLE FOR PRE-SELECTION: 2004
All 2004 patients received the letter containing advice to stop benzodiazepine use and were invited to visit the GP 3 months thereafter by a second letter
- Did not consult GP: 683
- Stopped use of their own accord: 283

PATIENTS ELIGIBLE FOR TRIAL: 1036
- Refused to participate: 942
- Withdrew consent: 14

RANDOMISED: 180

TAPERING OFF ONLY: 73
- Did not start taper protocol: 22
- Discontinued of their own accord: 16
- Refused to discontinue: 6
- Discontinued BZD use according to CRF: 46 (63%)

USUAL CARE: 34
- Left trial: 13
- Dissatisfied with treatment: 1
- Somatic or psychological problems: 2
- Not motivated for other reasons: 5
- Lost to follow-up: 5
- Discontinued BZD use: 37 (62%)

OUTCOME ASSESSMENT: 57
- Left trial: 16
- Dissatisfied with treatment: 1
- Somatic or psychological problems: 3
- Not motivated for other reasons: 5
- Lost to follow-up: 3
- Discontinued BZD use: 37 (58%)

Fig. 1 CONSORT diagram. BZD, benzodiazepine; CRF, case record form; GP, general practitioner.

Characteristics of the study participants
Comparisons of the three groups did not reveal any significant differences in baseline characteristics (Table 1). In addition, no significant difference in baseline characteristics was observed between those leaving and those completing the study. In the sample as a whole, the decile scores on the 15-words test did not differ from the norm. Sub-analyses revealed that participants who were using 10 mg diazepam equivalents or more per day (n=35) had significantly worse scores than the participants who were using less than 10 mg per day (t=2.25, d.f.=178, P=0.03) and the norm population (t=5.93, d.f.=34, P<0.001).

Benzodiazepine usage
The proportions of participants who successfully discontinued benzodiazepine use differed significantly between the three groups in the intent-to-treat analysis (Table 2). Subsequent pairwise comparisons revealed that the two experimental groups did not differ significantly from each other in the intent-to-treat analysis (whole sample P=0.51, completers sample P=0.68). However, the two experimental groups were significantly more successful than the control group: tapering off alone (whole sample P<0.001; completers sample P=0.001) and tapering off combined with group CBT (whole sample P=0.002; completers sample P=0.002). Corroborating these findings, the per protocol analysis did not show any significant difference between the two experimental conditions (P=0.53). Logistic regression analysis yielded benzodiazepine dosage as the only independent predictor of successful discontinuation (OR=4.5, 95% CI 2.0–10.2). Patients who used 10 mg diazepam equivalents or more had a significantly lower chance of successful discontinuation than patients using less than 10 mg (35% vs. 64%, P=0.009).

Among those failing to quit, dose reduction differed significantly across the three groups (whole sample F₂,102=3.33, P=0.04; completers sample F₂,58=3.98, P=0.02). Tukey HSD post hoc tests showed a significant difference in dosage reduction between tapering off combined with group CBT and usual care (whole sample P=0.03; completers sample P=0.02).

Secondary outcome measures
We used repeated-measure ANOVAs across the three groups to evaluate the effects of the severity of withdrawal symptoms, psychological distress, mood, memory and problem alcohol use. There was a significant time effect only for the delayed recall of the 15-words test, which indicated an improvement. However, no significant interaction effect emerged for any of the secondary outcome measures, thus these measures were fairly comparable in the three groups (Table 3). Moreover,
1. Based on the sum score of the list of Cornel practitioner an average of 5.6 times

drawal programme visited their general

Participants (of the tapering-off strategy

discontinued benzodiazepine use with those

combined with group CBT, and there was no
difference between the participants who
successfully discontinued benzodiazepine
use and those who did not. A total of 43
out of the 58 participating doctors actually
supervised the patients during the tapering-
off process; 42 of them returned the postal
evaluation questionnaire. Analysis of these
questionnaires showed that 37 doctors
(88%) had found the protocol feasible at
their own practice, 35 (83%) would encour-
ge other general practitioners to taper off
long-term benzodiazepine use with the aid of
the withdrawal protocol, and 22 (52%) had
already started using this protocol for

patients not included in the trial. No major
adverse event during the reduction period
(such as epileptic seizure or psychotic
episode) was reported in the case record
forms.

A total of 91 (88%) of the 103 partici-
ants who entered the withdrawal
programme returned the postal evaluation
questionnaire. The results showed that
78 (86%) of those who responded were
satisfied with the ‘treatment’ received;
66 (73%) would be willing to follow the
same treatment again if necessary. With
respect to their supervision, 65 (76%) preferred treatment by their own general
practitioner, 6 (7%) preferred referral
to a specialised treatment setting, 12

Doctor and patient views of the tapering-off strategy

Participants (n = 103) who entered the with-
drawal programme visited their general
practitioner an average of 5.6 times
(s.d. = 1.4, range 1–9). The average number
of visits did not differ between the
participants assigned to tapering off alone
and those assigned to tapering off com-
bined with group CBT, and there was no
difference between the participants who
successfully discontinued benzodiazepine
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<table>
<thead>
<tr>
<th>Table 1</th>
<th>Characteristics of the study participants (n = 180) at baseline assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background characteristics</td>
<td>(n = 73)</td>
</tr>
<tr>
<td>Age (years): mean (s.d.)</td>
<td>61.8 (12.5)</td>
</tr>
<tr>
<td>Gender (female): n (%)</td>
<td>53 (73)</td>
</tr>
<tr>
<td>Marital status: n (%)</td>
<td></td>
</tr>
<tr>
<td>No relationship</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Married</td>
<td>50 (69)</td>
</tr>
<tr>
<td>Divorced</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Widowed</td>
<td>17 (23)</td>
</tr>
<tr>
<td>Living alone: n (%)</td>
<td>21 (29)</td>
</tr>
<tr>
<td>Highest level of education: n (%)</td>
<td></td>
</tr>
<tr>
<td>Primary education</td>
<td>27 (37)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>42 (58)</td>
</tr>
<tr>
<td>University</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Benzodiazepine use</td>
<td></td>
</tr>
<tr>
<td>Dosage (mg diazepam eq.): mean (s.d.)</td>
<td>6.1 (9.8)</td>
</tr>
<tr>
<td>Patients using ≥ 10 mg diazepam eq.: n (%)</td>
<td>12 (16)</td>
</tr>
<tr>
<td>Duration of use (months): mean (s.d.)</td>
<td>160 (116)</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
</tr>
<tr>
<td>GHQ-12 score: mean (s.d.)</td>
<td>2.4 (3.2)</td>
</tr>
<tr>
<td>Profile of Mood States score: mean (s.d.)</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>12.8 (5.8)</td>
</tr>
<tr>
<td>Anger</td>
<td>11.1 (5.1)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12.4 (6.3)</td>
</tr>
<tr>
<td>Vigour</td>
<td>15.0 (4.3)</td>
</tr>
<tr>
<td>Tension</td>
<td>12.0 (5.4)</td>
</tr>
<tr>
<td>Delayed recall (15-words test): mean (s.d.)</td>
<td>6.7 (3.0)</td>
</tr>
<tr>
<td>BWSQ score: mean (s.d.)</td>
<td>7.0 (7.0)</td>
</tr>
<tr>
<td>Patients using alcohol</td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>42 (58)</td>
</tr>
<tr>
<td>Units of alcohol/week: mean (s.d.)</td>
<td>9.2 (8.3)</td>
</tr>
<tr>
<td>Problem drinkers: n (%)</td>
<td>5 (12)</td>
</tr>
</tbody>
</table>

BWSQ, Benzodiazepine Withdrawal Symptom Questionnaire; CBT, cognitive–behavioural therapy; GHQ-12, General Health Questionnaire, 12-item version.

1. Based on the sum score of the list of Cornel et al (1994). Percentages are of those using alcohol in their group.

Comparing participants who successfully discontinued benzodiazepine use with those
who failed to do so did not result in significant time × outcome interaction effects for
any of the secondary outcome measures. Neither the prevalence of alcohol use, nor
the amount consumed by alcohol users, changed.

Doctor and patient views of the tapering-off strategy

Participants (n = 103) who entered the with-
drawal programme visited their general
practitioner an average of 5.6 times
(s.d. = 1.4, range 1–9). The average number
of visits did not differ between the
GHQ^12 score: mean (s.d.)

<table>
<thead>
<tr>
<th></th>
<th>Tapering off only</th>
<th>Tapering off with CBT</th>
<th>Usual care</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole sample (n=180)</td>
<td>1.8 (2.5)</td>
<td>2.4 (3.0)</td>
<td>1.8 (3.0)</td>
<td>0.83</td>
</tr>
<tr>
<td>Completers sample (n=141)</td>
<td>2.4 (3.0)</td>
<td>3.0 (3.0)</td>
<td>2.4 (3.0)</td>
<td>0.86</td>
</tr>
<tr>
<td>Per protocol sample</td>
<td>1.8 (3.0)</td>
<td>2.0 (3.0)</td>
<td>1.8 (3.0)</td>
<td>0.86</td>
</tr>
</tbody>
</table>

1. Based on the sum score of the list of Cornel.

5.02

Table 2  Benzodiazepine use at 3 months' follow-up

<table>
<thead>
<tr>
<th></th>
<th>Tapering off only</th>
<th>Tapering off with CBT</th>
<th>Usual care</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Successful discontinuation: n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>_intent-to-treat sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole sample (n=180)</td>
<td>37 (51)</td>
<td>33 (45)</td>
<td>5 (15)</td>
<td>0.002</td>
</tr>
<tr>
<td>Completers sample (n=141)</td>
<td>37 (62)</td>
<td>33 (58)</td>
<td>5 (21)</td>
<td>0.002</td>
</tr>
<tr>
<td>Per protocol sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completers sample (n=78)</td>
<td>27 (57)</td>
<td>20 (65)</td>
<td>--</td>
<td>0.53</td>
</tr>
</tbody>
</table>

Failure to discontinue: median % dose reduction

<table>
<thead>
<tr>
<th></th>
<th>Tapering off only</th>
<th>Tapering off with CBT</th>
<th>Usual care</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>_intent-to-treat sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole sample (n=105)</td>
<td>23</td>
<td>37</td>
<td>--</td>
<td>0.04</td>
</tr>
<tr>
<td>Completers sample (n=66)</td>
<td>35</td>
<td>53</td>
<td>--</td>
<td>0.02</td>
</tr>
<tr>
<td>Per protocol sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completers sample (n=31)</td>
<td>40</td>
<td>72</td>
<td>--</td>
<td>0.02</td>
</tr>
</tbody>
</table>

CBT, cognitive–behavioural therapy

1. With last observation carried forward.

Table 3  Secondary outcome measures at 3 months' follow-up in the intent-to-treat sample (last observation carried forward, n=180)

<table>
<thead>
<tr>
<th></th>
<th>Tapering off only</th>
<th>Tapering off with CBT</th>
<th>Usual care</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHQ–12 score: mean (s.d.)</td>
<td>1.8 (2.5)</td>
<td>2.4 (3.0)</td>
<td>1.8 (3.0)</td>
<td>0.83</td>
</tr>
<tr>
<td>Profile of Mood States score: mean (s.d.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>12.6 (5.2)</td>
<td>13.8 (6.9)</td>
<td>13.0 (7.5)</td>
<td>0.86</td>
</tr>
<tr>
<td>Anger</td>
<td>11.5 (5.5)</td>
<td>12.0 (6.2)</td>
<td>10.7 (5.1)</td>
<td>0.22</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12.7 (6.4)</td>
<td>12.7 (5.9)</td>
<td>11.7 (7.0)</td>
<td>0.68</td>
</tr>
<tr>
<td>Vigour</td>
<td>14.9 (4.9)</td>
<td>15.0 (4.7)</td>
<td>15.3 (5.9)</td>
<td>0.39</td>
</tr>
<tr>
<td>Tension</td>
<td>11.4 (4.9)</td>
<td>12.6 (5.8)</td>
<td>11.1 (5.6)</td>
<td>0.46</td>
</tr>
<tr>
<td>Delayed recall (15-words test): mean (s.d.)</td>
<td>7.2 (2.9)</td>
<td>8.1 (3.4)</td>
<td>7.6 (2.5)</td>
<td>0.83</td>
</tr>
<tr>
<td>BWSQ score: mean (s.d.)</td>
<td>6.2 (6.8)</td>
<td>6.8 (7.5)</td>
<td>5.8 (7.3)</td>
<td>0.57</td>
</tr>
<tr>
<td>Patients using alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>42 (58)</td>
<td>40 (55)</td>
<td>18 (53)</td>
<td>0.81</td>
</tr>
<tr>
<td>Units of alcohol/week: mean (s.d.)</td>
<td>10.0 (11.0)</td>
<td>8.3 (6.4)</td>
<td>7.3 (6.4)</td>
<td>0.63</td>
</tr>
<tr>
<td>Problem drinkers: n (%)</td>
<td>5 (12)</td>
<td>10 (14)</td>
<td>5 (15)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

BWSQ, Benzodiazepine Withdrawal Symptom Questionnaire; CBT, cognitive–behavioural therapy; GHQ–12, General Health Questionnaire, 12-item version.

1. Based on the sum score of the list of Cornel et al (1994).

(14%) preferred no support with tapering off and 3 (%) had no preference.

Attrition rates and participants’ views on group CBT

Seven (10%) of the 73 participants assigned to CBT discontinued their benzodiazepine use before the start of the intervention. In order to prevent relapse, we invited these participants to the therapy sessions; however, only two actually participated. Of the participants who began the tapering-off process combined with group CBT, only 34 (65%) attended three or more sessions (Fig. 1). The discontinuation success rates did not differ significantly between the patients who were compliant with CBT and those who were not: 20/31 (65%) vs. 6/15 (40%), P=0.12. The postal evaluation questionnaire was returned by 30 (88%) of the 34 compliant participants: 14 (47%) of them would have preferred more sessions; 28 (93%) were satisfied with the group therapy in general. The degree of satisfaction with group CBT was not related to taper success.

**DISCUSSION**

Tapering off was an effective strategy for the discontinuation of long-term benzodiazepine use, even after pre-selection with a letter containing advice to stop, achieving its highest success rates in patients using less than 10 mg diazepam equivalents. Adding group CBT did not increase the proportion of those who successfully discontinued. Although the study was marginally lacking power for some analyses, this is irrelevant since the success rate for patients receiving group CBT was numerically lower than that for the group assigned to tapering off alone. Of those who failed to discontinue benzodiazepine use, those assigned to additional group CBT reduced their dosage significantly more than the participants in the control group. Both withdrawal programmes proved to be feasible in general practice. After the intervention, we did not find any significant differences between the three groups in
the presence and severity of withdrawal symptoms, symptoms reflecting psychological distress, and mood disturbances. Neither the prevalence of problem drinking or alcohol use, nor the amount of alcohol consumed, was influenced by the intervention type or tapering off, which indicates that none of our participants replaced benzodiazepine use with alcohol.

Efficacy of tapering off
This was the first study to show the efficacy of tapering off long-term benzodiazepine use by including a 'usual care' control condition. Although we pre-selected patients by sending a letter advising them to stop their use, our success rates were comparable with those of other benzodiazepine withdrawal studies (Schweizer et al., 1990; Zitman & Couvée, 2001). In the control group, 21% of the participants stopped their benzodiazepine use spontaneously. In addition, 23 (16%) of the 146 participants assigned to the experimental groups discontinued benzodiazepine use without any professional help while waiting for the interventions to start. At first we considered this to be a methodological (but inevitable) problem of our study, because it took some time to fill the therapy groups. However, it appeared to be a cost-effective strategy in view of the 60% success rate among those still using benzodiazepines, as was shown by the per protocol analysis. The proportions of participants who stopped spontaneously were much higher than the estimated 6%. Several explanations can be put forward. First, actually taking part in a discontinuation trial could provide an extra incentive to discontinue benzodiazepine use independently, even if a previous attempt was not successful. Second, owing to the selection process, the proportion of participants in discontinuation trials who are able to stop their use without any professional help might be higher than in long-term users in general.

Generalisability
A participation rate of 17.4% presumes significant selection processes. Although patients gave a variety of reasons for non-participation, dependence on benzodiazepines might have played an important part. Kan et al. (1997) found that 40% of all those prescribed benzodiazepines in general practice were dependent on benzodiazepines according to DSM-III-R criteria (American Psychiatric Association, 1987), and Linden et al. (1998) found that two-thirds of those who were long-term benzodiazepine users rejected a drug 'holiday'. Reluctance to enter group therapy as well as reluctance to hold interview sessions at home might have also contributed to the small number of participants. In clinical practice a higher recruitment rate might be achieved if the patients are not asked to participate in a randomised trial. As participants were representative with respect to not only age and gender, but also to the (only) independent predictor of success, benzodiazepine dosage, it is unlikely that we excluded treatment-resistant patients. As we identified all patients who were long-term users before we recruited participants, it is not possible to compare our attrition rate with that of other studies that recruited referred participants from specialised settings or by advertisement.

Efficacy of group CBT
In our study, adjunctive group CBT focused on the management of withdrawal symptoms did not have any additional value. Previous studies evaluating simultaneous psychological treatment to improve these success rates have considerable methodological problems. Two studies did not compare the efficacy of additional CBT vs. tapering off alone (Sanchez-Craig et al., 1987; Elsesser et al., 1996); the other studies did not use a controlled design (Cormack & Sinnott, 1983; Schmauss et al., 1987; Crouch et al., 1988; Joughin et al., 1991), did not randomise participants over the conditions (Higgitt et al., 1987) or studied a sample of fewer than 10 participants (Tyree et al., 1985; Nathan et al., 1986). The two studies without these methodological problems were restricted to participants who met the criteria for panic disorder; here the addition of CBT to tapering off significantly increased the proportion who successfully discontinued benzodiazepine use (Otto et al., 1993; Spiegel et al., 1994). These results are difficult to generalise, as the prevalence of panic disorder among those who are long-term benzodiazepine users has been estimated to be at most 27% (Rickels et al., 1986). Our success rate for CBT might have been increased by a priori selection on psychiatric morbidity and by introducing disorder-specific elements. A disadvantage of this strategy is that the programme cannot then be used easily in general practice.

Adherence to group CBT
Adherence to group therapy was poor, which may reflect an overall resistance to group therapy among people who are long-term benzodiazepine users. This is in line with findings in other studies (Cormack & Sinnott, 1983; Nathan et al., 1986) and with our interpretation of the personal reasons why patients refused to attend group therapy sessions. Moreover, individual CBT sessions to restructure dysfunctional cognition might be more successful. However, the poor adherence cannot explain the lack of success, as the success rate of patients who were compliant with CBT (n=34) was 65%. Although subanalyses lack statistical power, it is unlikely this would be superior to the 57% success rate of tapering off alone.

Feasibility in general practice
Tapering off was tolerated well in general practice: the general practitioners did not report any major adverse event during or after the tapering-off process. The good compliance and high level of satisfaction with the programme among both doctors and participants further strengthen the feasibility of tapering off as a strategy to discontinue long-term benzodiazepine use in general practice.
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Correspondence: R. C. Oude Voshaar, University Medical Centre St Radboud, Department of Psychiatry (hp 333), PO Box 9101, 6500 HB Nijmegen, The Netherlands. Tel: 24 3613489; fax: 24 3540561; e-mail: r.oudevoshaar@psy.umcn.nl

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CLINICAL IMPLICATIONS

This study is the first to evaluate additional psychotherapy in a randomised, controlled fashion.

Gradual tapering-off is an effective way of discontinuing benzodiazepine use.

Additional psychotherapy does not seem to increase the success rate of the gradual tapering-off approach.

LIMITATIONS

Only one in six patients in this study were willing to take part in a withdrawal programme.

Treatment adherence in psychotherapy was limited.

Patients received no diagnostic psychiatric screening, which made sub-analyses in specific diagnostic groups impossible.


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