

RANDOMISED CONTROLLED TRIAL OF TWO BRIEF INTERVENTIONS AGAINST LONG-TERM BENZODIAZEPINE USE: OUTCOME OF INTERVENTION

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Previous studies have reported that a letter from the patient's General Practitioner (GP) and a short GP consultation led to reduced intake among long-term benzodiazepine (BZD) users, with no evidence of a deterioration in general or mental health. We aimed to replicate these earlier findings in a single, prospective RCT and compare the effectiveness of the two brief interventions. 273 long-term BZD users (≥ 6 mos) identified from repeat prescription computer records of 7 general practices were randomised to: (i) usual GP care + assessment only; (ii) the offer of a short consultation with the patient's GP (or practice nurse/practice pharmacist); (iii) a letter signed by the GP advising gradual reduction in BZD intake. The typical patient entering the study was an elderly woman taking BZDs primarily for sleeping problems. Results showed significantly larger reductions in BZD consumption in the letter (24% overall) and consultation (22%) groups than the control group (16%) but no significant difference between the two interventions. There was no evidence that brief interventions increased psychological distress or had an adverse effect on general health. We conclude that, among long-term BZD users considered by GPs to be suitable to receive advice encouraging them to cut down BZD intake, brief intervention, either in the form of the offer of a short consultation or a letter from the patient's GP, is effective in leading to reduced BZD intake without adverse consequences.

Keywords: Benzodiazepines; Long-term BZD use; General practice; Brief interventions; Outcome of intervention

INTRODUCTION

Despite an overall fall in benzodiazepine (BZD) prescribing in the UK over the last 20 years, a substantial number of long-term users still receive regular prescriptions, especially of hypnotics (Chaplin, 1988; Petursson, 1993; Taylor *et al.*, 1998; Wilcock *et al.*, 1999). In addition to dependence, dangers associated with long-term BZD use among elderly patients include increased falls and fractures, poor memory and acute confusional states (Prescott, 1983; Golombok *et al.*, 1988; Baldessarini, 1990; Bixler *et al.*, 1991).

Two previous studies reported that GP-based brief interventions were effective in encouraging long-term users to reduce BZD consumption. Among 219 long-term

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users in south-west England, Cormack and colleagues (1994) found that both a GP letter to patients and a letter followed by information sheets significantly reduced BZD intake compared to a control group. Bashir *et al.* (1994) in London assessed the effects of a short GP consultation plus self-help booklet compared to routine care. In this study, 18% of 50 patients in the consultation group reduced their BZD medication over the following 6 months compared with 5% in the control group, a difference that was statistically significant. This finding was obtained in a population with high rates of past depression, anxiety and attempted suicide. The consultation did not lead to any observable psychological harm or distress, nor increases in GP consultation rates, suggesting that asking patients to reduce BZDs with brief intervention of this kind is a safe procedure.

The current study was carried out between April 1997 and March 1999, and was designed with the following aims: (i) to attempt to replicate the earlier findings in a single RCT and determine whether brief interventions were effective in a socio-economically deprived geographical area (Newcastle and North Tyneside); (ii) to compare directly the effectiveness of the letter and consultation interventions; (iii) to identify patient characteristics associated with successful response to each intervention and non-response to either; and (iv) to compare the cost-effectiveness of the two brief interventions. The present article addresses the first two aims. Future papers will consider predictors of response to interventions and their comparative cost-effectiveness.

Hypotheses were that (1) both a GP letter (Hypothesis 1a) and a consultation (Hypothesis 1b) would lead to a greater reduction in BZD intake at follow-up than usual care; and (2) a consultation would lead to a greater reduction in BZD intake at follow-up than a letter. Hypothesis 2 was based on the assumption that personal contact with the GP would have a more powerful effect in encouraging reduced BZD intake than a relatively impersonal letter.

METHODS

Power Analysis

Based on the previous study (Cormack *et al.*, 1994), in relation of Hypothesis 1a we assumed a critical effect size for the superiority of the letter intervention over controls of 0.2 (Kraemer and Thiemann, 1987). Since no previous study has compared the two brief interventions under examination here, we assumed the same critical effect size of 0.2 for the superiority of the consultation intervention over the letter in Hypothesis 2. For 80% power and $\alpha = 0.05$ (2-tailed), this resulted in target sample size of approximately 100 subjects per group. Assuming a critical effect size of 0.4 for the superiority of the consultation over the control condition (Hypothesis 1b) results in a power of approximately 99% to detect this effect for the same sample size and a power of 80% to detect a superiority of the consultation over the letter (Hypothesis 2).

Recruitment of General Practices

A one-third sample of the 77 general practices in Newcastle and North Tyneside was selected at random and a letter sent to all GPs in the sampled practices inviting them to participate in the study. Seven practices agreed to take part, four in Newcastle and three in North Tyneside.

Patient Recruitment

Between August and October 1997, the researcher (AB) liaised with Practice Managers to retrieve lists of long-term BZD users from computerised repeat prescription records. The names of 1297 patients thus generated were circulated among the relevant GPs who were requested to remove any patients meeting exclusion criteria (see below). The 591 patients considered eligible were contacted by letter inviting them to participate and return an assessment questionnaire plus a signed consent form included with the letter. If no reply was received within six weeks, patients were contacted by telephone whenever possible. A total of 299 patients consented to take part, 102 refused and 190 did not respond. The trial profile is shown in Fig. 1. Ethical approval for the study was obtained from Newcastle and North Tyneside Health Authority/University of Newcastle upon Tyne/Northumbria University Joint Ethics Committee.

Inclusion and Exclusion Criteria

Long-term BZD users were defined in our study as patients of any age or gender who had taken BZDs continuously for at least six months (i.e., had received at least one prescription for BZDs every two months during the previous six). GPs were asked to exclude patients if they met the following criteria: currently experiencing an acute serious illness; currently receiving specialist psychiatric treatment or with a history of psychosis; currently dependent on alcohol or illicit drugs; taking BZDs for a medical condition such as epilepsy; unable to attend the surgery because of physical infirmity; unable to complete questionnaires for any reason. GPs were also permitted to exclude patients if they felt that requesting a reduction in BZD intake might be harmful for any reason. A total of 706 patients (54%) were excluded by GPs. Among patients not removed by GPs and who agreed to participate, a further 15 were judged by the researcher to be ineligible because they met exclusion criteria or did not wish to attend the follow-up interview.

Allocation to Study Groups

Patients returning an assessment questionnaire and consent form ($n=284$) were allocated randomly to one of three groups:

Consultation Group In this group, 98 patients were sent a letter inviting them to see their GP for a medication review. Before the trial began, the researcher met participating GPs to give guidance on how the consultation should be carried out. Consultations were scheduled to last for 12 min. Written guidelines were produced consisting of information for patients about BZDs, reasons why it might be beneficial to reduce medication and a timetable that could be used to plan withdrawal (see Appendix 1). These guidelines were attached to patients' notes so that the GP could refer to them during the consultation. GPs were allowed discretion as to how the consultation was conducted. Copies of a self-help booklet, entitled *Helping you Cope: A Guide to Starting and Stopping Tranquillisers and Sleeping Tablets*, were supplied by The Mental Health Foundation and given to patients during the consultation, along with a leaflet about sleeping problems. In one practice, the consultation was carried out by the Practice Pharmacist (27 patients) and in another by a Practice Nurse (3 patients).

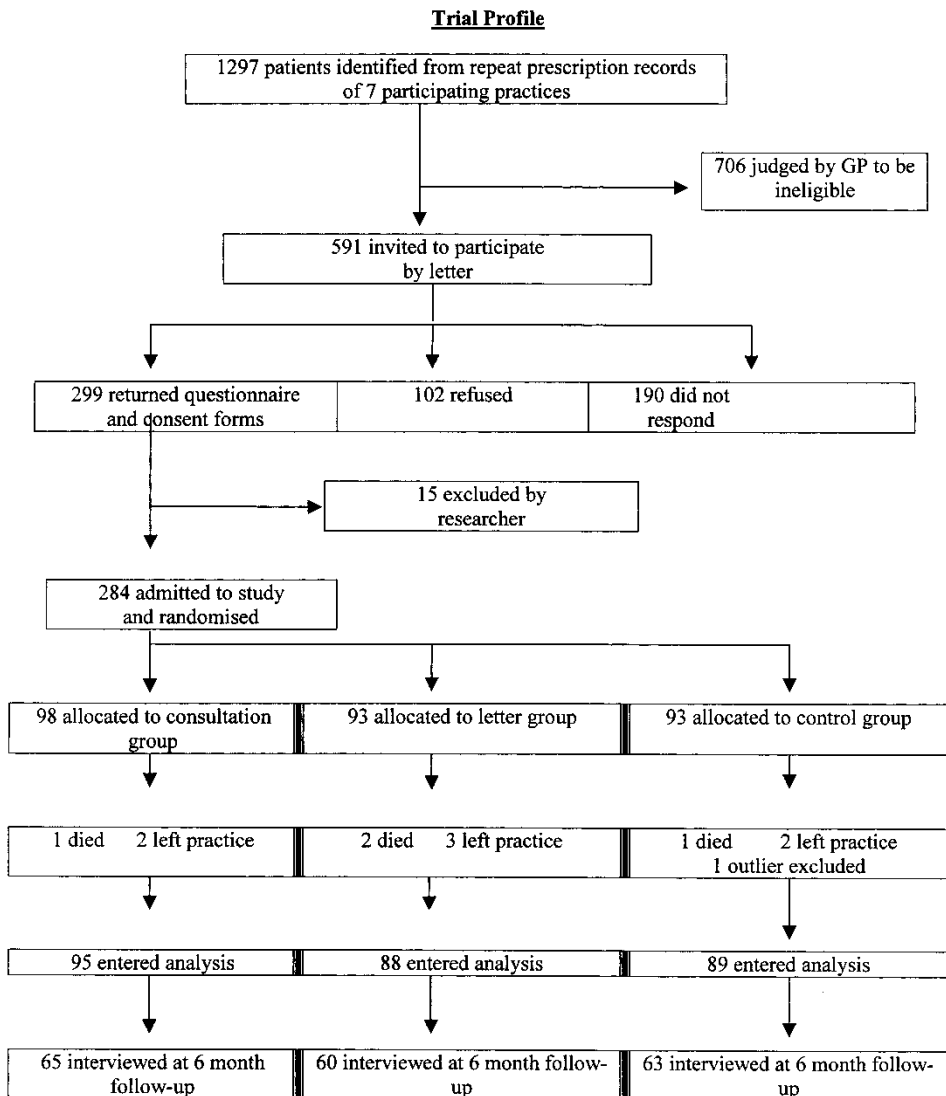


FIGURE 1 Trial profile.

Letter Group In this group, 93 patients were sent an amended version of the letter used in the study by Cormack and colleagues (see Appendix 2). The letter was produced by the research team on practice-headed paper and signed by the patient's usual GP. Patients in the Letter group were not sent the self-help booklet or leaflet.

Control group The 93 patients in this group received usual care but no intervention.

Follow-up Interviews

Six months after entry to the trial, patients were invited by letter to take part in follow-up interview either in the GP surgery or the patient's home. During the interview, patients

filled in the same questionnaire as had been used at the initial assessment and were also asked other questions regarding reactions to intervention, use of coping methods, general satisfaction with life, etc. (not reported here). The research interviewer was initially unaware of the patient's group allocation but at the end of the interview asked patients for their reactions to the intervention they had received, if any.

If the patient failed to respond to the invitation to attend an interview, a questionnaire was sent by post with a return envelope. At this stage, 11 patients were withdrawn from the analysis because they had died during the follow-up interval or had left the practice and information on the main outcome measure (see below) was therefore unavailable. This left 273 patients (95 in the consultation group, 88 in the letter group and 90 in the control group) for analysis (see Fig. 1).

At follow-up, 188 patients (69%) of the original group remained in the study and either attended the surgery, were interviewed at home or filled in a postal questionnaire. No significant differences were detected between data from interviews and postal questionnaires and these data were merged before analysis. Differences in follow-up rates between the three study groups (Consultation Group = 68.4%; Letter Group = 68.2%; Control Group = 70.0%) were not significant ($\chi^2 = 0.29$; $p = 0.87$).

Measures

The main outcome measure was change in BZD intake between the six-month periods before and after the intervention. This was taken from practice prescription records and was available for all 273 patients entering the analysis. BZD intake for each patient was converted to a standard measure of 10 mg diazepam equivalents (Ashton, 1994). A subsidiary outcome measure was whether or not the patient was a "true reducer", defined as having reduced BZD intake by a quarter or more, including those who had stopped intake completely.

At assessment, measures taken included: (a) socio-demographic characteristics; (b) medication history, including currently prescribed BZDs, duration of time on BZDs, who prescribed them, reasons for prescription, previous attempts to cut down and other medication being prescribed; (c) General Health Questionnaire (GHQ-28; Goldberg, 1972); and (d) SF-36 (Stewart *et al.*, 1988). Apart from socio-demographics and medication history etc., the follow-up questionnaire included all measures given at assessment.

Analysis

The distribution of BZD intake over six months was markedly positively skewed and bimodal. Several transformations were tried but all failed to render the distribution approximately normal. For this reason, non-parametric methods were used for assessing the effects of brief intervention on the main outcome variable. Prior to outcome analysis, data from one control group patient were deleted because of an extreme score for 6 month BZD intake at initial assessment (= 1568 10 mg diazepam equivalents, more than twice the next highest score) (Tabachnick and Fidell, 1996, p. 69). Three patients' questionnaire responses indicated that their duration of BZD use pre-dated the first marketing of BZDs in the UK in 1957 and the maximum value of this variable was set at 40 years. These patients' data were retained in the analysis.

Statistical significance for hypothesised differences in BZD intake between groups was set at a p -value of 0.05. For differences between groups on subsidiary outcome variables and for other differences between groups at follow-up that were not directly involved in the main hypotheses, statistical significance was set at $p < 0.01$ to minimise Type 1 errors from multiple comparisons. For comparisons between patients included and excluded from the study, among study groups on baseline measures and between patients followed up and those not followed up, p -value was set at 0.05.

RESULTS

Characteristics of Participating and Non-participating General Practices

One participating practice had 8 GP partners, two had 6, three had 4 and one practice was single-handed. At the outset of the study in 1997, five practices had fund-holding status. The percentage of patients living in electoral wards with any level of deprivation (Jarman, 1983) ranged from 4.2 to 83.7%, with a practice mean of 35.5%. One participating practice had 48.7% of patients from wards with high deprivation.

The 7 participating practices were compared with the remaining 70 practices in the Newcastle and North Tyneside Health Authority in terms of number of hypnotic and anxiolytic prescriptions per 1000 Patient Prescribing Units for the 3 months to December 1997. There was no significant difference between groups and mean levels of prescribing were very similar. There was also no significant difference for number of GP partners. The participating practices included a higher proportion with fund-holding status at the time of the study than the non-participating practices (71.4% vs. 40.0%) but the difference was not significant (Fishers Exact Test, $p = 0.13$). Lastly, there was no significant differences between participating and non-participating practices for percentages of patients living in areas of high deprivation or of any level of deprivation.

Comparison of Eligible and Ineligible Patients

A higher proportion of females (48%) was selected for study than males (40%) ($\chi^2 = 7.85$; $p = 0.005$) and those selected had a higher mean age (69.1 years) than those excluded (62.8 years) ($U = 171, 114$; $p < 0.001$). Significantly fewer patients being prescribed anxiolytics were selected (46%) compared to those prescribed hypnotics (55%) and both anxiolytics and hypnotics (58%) ($\chi^2 = 7.54$; $p = 0.023$).

Comparison Among Eligible Patients of those Included in the Final Sample and the Remainder

There were no significant differences in gender, age or type of BZD prescribed between patients included in the final sample for analysis ($n = 273$) and those who were invited to take part but refused, did not respond, were judged by the researcher to be ineligible or had died or moved away during the follow-up interval ($n = 318$; see Fig. 1).

Comparison of Patients Followed up with those Lost to Follow-up

Among patients in the final sample, there was one significant difference on baseline measures between those who completed a follow-up questionnaire ($n = 188$) and those who did not ($n = 85$). Relatively more retired patients were contacted for follow-up while the non-follow-up group contained relatively more patients who were in employment or were “economically inactive” (i.e., off sick or housewives) ($\chi^2 = 7.86$; $p = 0.019$).

Characteristics of Final Sample at Assessment

Seventy seven per cent (210) of the final sample were female. Mean age was 69.16 years ($sd = 11.52$, range = 40–96), with 66% being 65 or over. Nearly half (48%) were married and 34% were widowed. Forty per cent were living alone. The majority (70%) were retired, with only 11% economically active (3% in full-time employment and 8% in part-time employment). The remaining 19% were classified as either “unemployed” (4%), “housewives” (9%) or “off sick” (7%). Four-fifths of the sample (79.5%) had not continued education after school-leaving age and only 9% reported having a degree or equivalent professional qualification. The majority (89%) were classed in socio-economic category *E* (entirely dependent on the state). To take account of potential differences among retired patients, socio-economic status was re-classified to include retired patients’ previous employment ($A = 0.4\%$; $B = 3\%$; $C1 = 31\%$; $C2 = 16\%$; $D = 37\%$; $E = 12\%$).

The majority of patients (70%) were prescribed a BZD hypnotic, 27% an anxiolytic and the remaining 3% both a hypnotic and anxiolytic. Seventy nine per cent reported that their BZD medication was for night use only. Over half (55%) were prescribed temazepam, 22% diazepam and 14% nitrazepam. Mean number of years patients reported they had been prescribed their current BZDs was 14.08 years ($sd = 9.94$, median = 13 years, range = 1–40). The majority (88%) reported that either their usual GP (55%) or another GP (33%) prescribed their current BZD medication, while 11% were prescribed BZDs by a hospital doctor. Ninety two per cent of the sample were being prescribed other medications: central nervous system drugs (97%), most often analgesics; cardiovascular drugs (96%); and gastro-intestinal drugs (36%). Mean number of other medications was 3.25 (range = 1–11).

There were no significant differences between study groups on demographic characteristics, baseline BZD consumption levels and all but one variable measured by the assessment questionnaire. The only significant difference was for the total GHQ score, with the control group having the lowest and the letter group the highest score ($\chi^2 = 6.53$; $p = 0.04$).

Changes in BZD Intake

Comparing aggregate BZD intake taken from practice records in the six months post-intervention with the six months pre-intervention, there was an overall reduction of 21% (22% in the consultation group, 24% in the letter group and 16% in the control group).

Means, medians and standard deviations of BZD intake over the two six-month periods are shown in Table I. A Kruskal–Wallis One-Way ANOVA on BZD change scores showed a significant difference between the three groups ($\chi^2 = 7.20$; $p = 0.027$).

TABLE I Means and medians (*sd*, range) of BZD intake (in 10 mg diazepam equivalents) by study group in the six months prior to and post-intervention

Study Group	Assessment				Follow-up			
	Mean	Median	<i>s.d.</i>	Range	Mean	Median	<i>s.d.</i>	Range
Letter (<i>n</i> = 88)	161.22	159.50	102.26	12–548	123.17	102.50	98.96	0–540
Consultation (<i>n</i> = 95)	155.63	117.00	111.93	6–600	121.01	94.50	88.50	0–450
Intervention groups combined (<i>n</i> = 183)	158.31	134.40	107.13	6–600	122.04	97.50	93.42	0–540
Control (<i>n</i> = 89)	150.05	126.00	118.97	12–675	126.76	93.75	111.31	0–630
Total (<i>n</i> = 272)	155.61	133.70	110.99	6–675	123.59	94.13	99.45	0–634

There was a significant difference between the two intervention groups combined and the control group ($U = 6595$; $p = 0.009$). There were also significant differences between the consultation and control groups (Hypothesis 1a: $U = 3513$; $p = 0.042$) and between the letter and control groups (Hypothesis 1b: $U = 3082$; $p = 0.012$). There was no significant difference in BZD change scores between the letter and consultation groups (Hypothesis 2: $U = 3922$; $p = 0.47$). The analysis was repeated with sex of patient as an additional independent variable. There was no significant effect of sex or interaction between sex and study group membership (details available on request).

Over a third of patients (34%; 93) achieved a “true reduction” (i.e., a reduction of 25% or more) in BZD intake, including those who stopped completely. Proportions of patients showing a true reduction in each group were: consultation = 37%; letter = 41%; control = 24%. Significantly more patients in the letter group than the control group ($\chi^2 = 5.27$; $p = 0.011$) reduced or stopped but the difference in this respect between the consultation and control groups was not significant ($\chi^2 = 3.16$; $p = 0.076$). According to self-reports at follow-up interview, 25 patients had completely withdrawn from BZDs and, of these, 14 had received no more prescriptions for BZDs after the intervention date according to medical records. There were no significant differences between study groups in numbers of patients who reported stopping BZD intake (consultation = 10; letter = 9; control = 6) ($\chi^2 = 0.92$, $p = 0.37$).

Changes in Mental Health Status

In the overall follow-up sample, there was no significant change in GHQ-total score between follow-up and initial assessment (Wilcoxon Matched-Pairs Signed Rank Test; $z = -1.59$; $p = 0.11$) and no significant differences on this variable between the three study groups (Kruskal–Wallis One-way ANOVA, $\chi^2 = 1.37$; $p = 0.50$). Mean score on the GHQ-A (somatic symptoms) was significantly higher at follow-up than assessment ($z = -3.19$; $p = 0.0014$) but there were no significant differences between groups on changes in GHQ-A or any other GHQ sub-scale. The correlation between changes in BZD intake and changes in GHQ-B (anxiety and insomnia) just failed to reach significance ($\rho = 0.199$; $p = 0.011$).

Changes in General Health Status

In the overall follow-up sample, the following SF-36 sub-scores were significantly higher (i.e., indicating an improved state of health) at follow-up: ‘Physical’

(Wilcoxon: $z = -4.56$; $p < 0.0001$); 'Pain' ($z = -3.04$; $p = 0.0024$); and 'General health' ($z = -2.66$; $p = 0.0078$). There were no significant differences between study groups in changes on any of the nine SF-36 sub-scores. However, there was a significant difference in changes on SF-36 sub-score 'Mental' between patients who had undergone a true reduction and those who had not ($\chi^2 = 7.02$; $p = 0.008$), with "true reducers" showing a mean increase of 5.36 compared to a decrease of 2.19 for other patients.

DISCUSSION

The findings of this study apply to the population of long-term BZD users who would be identified by their GPs as suitable to receive a brief intervention aimed at encouraging a reduction in BZD intake. They do not apply to long-term BZD users in general since the sample upon which the findings were based cannot be considered to be representative of all long-term BZD users receiving repeat prescriptions from GPs. It was established here that patients selected for study were older, more likely to be women and less likely to be taking anxiolytic BZDs than those not selected. Thus the typical patient in the sample entering the study was an elderly female who took BZDs primarily for sleeping problems. GPs also excluded any patient they considered might be harmed by a request to cut down BZD consumption. It is possible that those removed from the study included a substantial proportion of patients with psychiatric morbidity taking anxiolytic medication who would be less likely to respond to brief interventions of the kind under investigation. It should nevertheless be noted that none of the ways in which the patients selected for study differed from those excluded (i.e., age, gender and type of BZD) was predictive of outcome in the final sample.

Comparisons between characteristics of the 7 practices that participated in the study and the remaining 70 practices in the Newcastle and North Tyneside Health Authority revealed no significant differences for number of GP partners, fund-holding status at the time of the study, overall extent of BZD prescribing and levels of deprivation shown by patients' areas of residence.

The only significant difference between the 188 (69%) patients successfully followed up and interviewed and the 85 patients lost to follow-up was that the follow-up sample contained relatively more retired patients, while the lost group contained relatively more patients who were in employment or "economically inactive". This difference could have been due to the greater ease with which retired patients could be contacted and persuaded to complete the follow-up interview. However, this bias applied only to variables measured at interview. A strength of this study is that the main outcome variable (change in BZD consumption) was available from practice records for all patients in the final sample.

Compared to the two previous studies of GP-based brief intervention, the present sample of long-term BZD users ($n = 273$) was larger than that of Cormack *et al.* (1994) ($n = 209$) and Bashir *et al.* (1994) ($n = 109$). In all three studies, mean age was over 60 and the majority of patients were female. The number of patients being prescribed hypnotics in our study (70%) is comparable to that in the Bashir *et al.* study (67%) and higher than that in the Cormack *et al.* study (57%). The mean number of years patients had been maintained on BZDs is comparable, although our study included a greater range of years that patients reported being prescribed BZDs (1–40 years). Despite the possible tendency for patients with psychiatric morbidity

to have been excluded, 45% of our sample were classified as showing significant psychological problems by the GHQ, with over a quarter of these defined as “severe cases”. As measured by the SF-36, general health status, and physical health in particular, was poor. The present data suggest that long-term BZD users are highly morbid population in terms of physical health, since 92% of the sample were prescribed, on average, three other types of medication, most commonly for pain relief, heart problems and gastro-intestinal problems. Follow-up interviews revealed that half the patients interviewed complained of suffering from debilitating problems – most commonly, arthritis and angina. These findings concur with those of an earlier study (Ashton and Golding, 1989) where there were significant correlations between BZD use and malaise and ill health. These authors noted that long-term use of BZDs does not seem to control or prevent the development of morbidity and may actually aggravate symptoms.

Comparing study groups at assessment, the only significant difference was for GHQ Total score, with the control group showing a lower score than the two intervention groups. Given the large number of comparisons made, this difference may have been due to chance. There were no significant differences on the main outcome variable and the study groups may therefore be regarded as equivalent for purposes of statistical analysis. With regard to variables measured at follow-up interview, follow-up rates were not significantly different between study groups.

The first hypothesis of the study was confirmed. Both the letter intervention and the short consultation led to greater reduction in BZD intake than the control condition. Thus it may be concluded that the findings of both Cormack *et al.* (1994) and Bashir *et al.* (1994) have been replicated in a different geographical area of the United Kingdom showing a high level of socio-economic deprivation.

The second hypothesis, that the consultation would lead to a better outcome than the letter, was not confirmed. Overall reduction in BZD consumption, mean reduction and proportions of patients achieving a true reduction were larger in the letter group, though not significantly so. Thus, the study provides no grounds for concluding that a more personal type of intervention from the GP results in greater reduction of intake among long-term BZD users in general than a letter signed by the GP advising patients to reduce and offering guidance on how to do so. The finding may seem surprising but there are several relevant factors. First, although every effort was made to ensure that GPs carried out the consultation according to guidelines, patient interviews suggested that not all patients allocated to the consultation group in fact received a consultation. Several reported that, after examining their medical notes, the GP made the decision not to go ahead with the consultation. Secondly, because patients were invited to attend the surgery, this did not ensure that they arrived for the consultation. (Unfortunately, we have no accurate information on which patients attended the consultation; GPs were asked to complete a form after each consultation but in many cases this was not done.) In other words, the consultation involved an active step on the patient's part (i.e., attending the surgery) which was not required by the letter, while the letter guaranteed that nearly all patients offered the intervention received it.

It is of interest that there was a significant reduction in BZD intake in all three groups, including the control group. This may have occurred because the assessment questionnaire sent to all patients eligible for the study also acted like an intervention, prompting patients to think about their BZD use because of specific questions about BZDs. The letter or consultation may then have acted as “secondary” interventions

for patients assigned to these groups, resulting in a significantly greater effect on BZD use than the control condition. We considered using a “pure” control group that received no assessment or other contact with the researchers but decided that this would have prevented the acquisition of valuable information from the baseline questionnaire and follow-up interview.

In the sample as a whole, there was no significant increase in the GHQ Total score from before intervention to follow-up and no differences between the study groups in this respect. There was, however, a statistically significant difference between true BZD reducers and the remainder of the sample on the SF-36 sub-scale measuring mental health; reducers showed an improvement in mental health and the remainder did not. While this latter finding suggests wider benefits from a reduction in BZD use, a cautious conclusion is that our data provide no evidence for deterioration in mental health among patients receiving a brief intervention aimed at encouraging them to reduce BZD intake. Thus we have confirmed Bashir *et al.*'s (1994) finding that brief intervention aimed at reducing BZD intake does not result in increased psychological distress.

In the sample as a whole, there was a significant increase in “somatic symptoms” as measured by the GHQ. The reason for this is unclear but, since there were no differences on this measure between study groups, it cannot be related to the effects of brief intervention. With this exception, there was no evidence from our study of a deterioration in general health among patients. There were, in fact, overall improvements in some aspects of health, as demonstrated by increases in SF-36 sub-scores ‘physical’, ‘pain’ and ‘general health’. There were no differences between study groups in changes on SF-36 sub-scores.

Given the demonstration that two types of brief intervention are effective in leading to a reduction in BZD consumption among long-term users without adverse consequences, the relative cost-effectiveness of the two interventions is an issue clearly of some importance when considering applications in practice. A further paper will report an economic evaluation of the changes in BZD intake reported here. Another important issue is whether it is possible to identify characteristics of patients who are likely to benefit more from brief interventions than others, or might-benefit differentially from either type of intervention. Another forthcoming paper will describe an analysis of predictors of change among these recipients of BZD brief interventions.

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APPENDIX 1

Guidelines provided to GPs in the Consultation Group

The consultation should ideally consist of **five** stages:

- 1. Explanation of what benzodiazepines are**
- 2. Explanation of the risks of long-term benzodiazepine use**
- 3. Reassurance about reducing or stopping benzodiazepine medication**
- 4. Advise reduction and suggest how to go about reducing with a view to eventually stopping**
- 5. Hand out self-help leaflets and suggest they follow the advice in the leaflets**

1. Explanation of what benzodiazepines are

- Drugs that end in ‘azepam’ eg ‘temazepam’, ‘diazepam’.
- All from the same group of drugs called benzodiazepines.
- Defined as ‘**sedatives**’ or ‘**mild tranquilisers**’ – normally used to help with sleep problems or some anxiety problems.

2. Explanation of the risks of using benzodiazepines over a long period of time

The main risks of long-term use with this type of drug/medication are:

- **Side effects** (can include **dizziness**, **loss of balance**, **lack of co-ordination**, **poor**

memory and concentration, muscle pains, change of personality and emotional deadness).

- **Chemical dependence** where the body ends up relying on the drug/medication to function normally.
 - **Tolerance** where the body gets so used to the drug medication it needs more and more to keep going.
 - **Withdrawal symptoms** where the person can become physically or nervously ill when deprived of the drug/medication in usual amounts.
 - If people remain on these drugs/medication for a long term they can experience **depression, chronic vague ill health and greater risks of accidents.**
 - **In more elderly people they can experience confusion that can be mistaken for senility and loss of balance, so even a small reduction of dosage can be beneficial.**
- 2. Reassurance about reducing or stopping benzodiazepine medication**
- Most people feel better for reducing or stopping their benzodiazepines.
 - If patient is severely dependent on their benzodiazepines, it is still possible to come off them and recover completely from the symptoms caused by withdrawal.
 - Not all people become dependent or experience withdrawal symptoms.
 - This is a **voluntary reduction** – their medication/tablets are not being taken from them – all to be carried out in the patient’s time and pace.
- 4. Advise reduction and suggest how to go about reducing with a view to eventually stopping**
- The key is to go about it **very slowly.**
 - For most patients it is helpful to follow a timetable of reduction (see overleaf for examples) which involves cutting tablets down into halves. It would be helpful if the GP was able to draw up a timetable of withdrawal for each individual patient.
 - The reduction in dose should take place every two to four weeks.
 - If patient can’t get past say week 5, a reduction can be just as beneficial.
- NB Blank sheets are available to enable the GP to draw up an individual timetable of reduction for patients**
- 5. Hand out self-help leaflets and suggests they follow the advice in the leaflets**
- The booklet repeats some of the advice that the GP will have given the patient about withdrawing from benzodiazepines and is to be handed out at the end of the consultation.
 - There is an inserted leaflet for patients about managing sleep problems to give them some practical advice about alternative means of coping with sleeplessness. This should be of use even for patients who are not on benzodiazepines for sleep problems.

APPENDIX 2

Letter sent to patients allocated to Letter Group

Dear <Name of patient>

I am writing to you because I note from our records that you have been taking <Name of BZD> for some time now. Recently, family doctors have become concerned about

this kind of medication when it is taken over long periods. Our concern is that the body can get used to these tablets so that they no longer work properly. If the tablets are stopped suddenly, a few people experience withdrawal effects. Research shows that repeated use of the tablets over a long time may actually cause anxiety and sleeplessness and that the tablets can be addictive.

I am writing to ask you to consider cutting down on your dose of these tablets and perhaps stopping them at some time in the future. The best way to do this is to cut down very gradually on your tablets (for example, if you take three tablets, reduce to two and a half tablets; or if you take one tablet divide it in half). You should make these changes slowly over a period of two to four weeks. In this way, you might be able to make a prescription last longer.

Once you have cut down, you might be able to think about stopping them altogether. Most people even feel better when they are off their tablets.

If you would like to talk to me personally about this, I would be glad to see you in the surgery.

Yours sincerely

Dr{Name of GP}