Reducing therapist contact in cognitive behaviour therapy for panic disorder and agoraphobia in primary care: global measures of outcome in a randomised controlled trial

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SUMMARY

Background. *Panic disorder, with and without agoraphobia, is a prevalent condition presenting in general practice. Psychological treatments are effective but are limited by restricted availability. Interest has grown in methods by which the efficiency and thus availability of psychological treatments can be improved, with particular emphasis on reduced therapist contact formats.*

Aim. *To evaluate the relative efficacy in a primary care setting of a cognitive behaviour therapy (CBT) delivered at three levels of therapist contact: standard contact, minimum contact, and bibliotherapy.*

Method. *A total of 104 patients were randomly allocated to receive standard therapist contact, minimum therapist contact or bibliotherapy, with 91 patients completing treatment. All patients received an identical treatment manual and were seen by the same psychologist therapist. Outcome was reported in terms of brief global ratings of severity of illness, change in symptoms, and levels of social disruption. These brief measures were chosen to be suitable for use in general practice and were used at treatment entry and endpoint.*

Results. *The standard therapist contact group had the strongest and most comprehensive treatment response, showing significant differences from the bibliotherapy group on all, and the minimum therapist contact group on some, endpoint measures. Some reduction in efficacy was therefore found for the reduced therapist contact groups.*

Conclusion. *The standard therapist contact group showed the greatest treatment efficacy in the present study. As it was of notably shorter duration than many other current formulations of CBT, it represents a useful and efficient treatment for panic disorder and agoraphobia in primary care.*

Keywords: panic disorder; agoraphobia; cognitive behaviour therapy; randomised controlled trial.

Introduction

PANIC disorder, with or without agoraphobia, is a prevalent condition that presents predominantly in primary care,[1] and causes considerable distress and heavy use of primary care services.[2] Both pharmacological and psychological treatments are efficacious in the treatment of panic disorder,[3] with cognitive behaviour therapy (CBT) showing an advantage in the longer term.[4] Unfortunately, psychological treatments such as CBT are not widely available in the primary care setting, partly owing to the current lack of available trained staff to deliver these treatments.[5] It has been suggested[6] that future research should focus on developments in treatment delivery to increase the availability of psychological treatment resources for panic disorder patients in primary care, with particular emphasis on treatments involving reduced therapist contact. Several recent studies have investigated the efficacy of reduced therapist contact psychological treatments for panic disorder and agoraphobia; however, methodological shortcomings make it difficult to draw firm conclusions. Several studies have investigated reduced therapist contact treatments only, or have compared these with a no-treatment or waiting list control group.[7-10] This design does not permit a comparison of reduced therapist contact treatments with more standard levels of therapist contact which is of more immediate relevance to the practising clinician. Other studies have varied the method of treatment delivery used beyond simply the amount of therapist contact given.[11,12] Patients received written instructions and interacted with therapists and computers. The influence of therapist contact alone is confounded in such study designs. Many previous studies have been conducted in specialist hospital or academic settings despite the fact that panic disorder presents predominantly in the primary care setting. It is not clear if the findings of such research are applicable to the majority of patients seen in primary care. Most studies in this area report outcome in terms of standardised assessment scales, such as the Hamilton Anxiety Scale[13] or the Fear Questionnaire.[14] The use of such scales permits normative comparisons and the calculation of clinical significance of change according to established criteria.[15] However, such scales are time-consuming to use and are not ideal for use in the primary care setting.

The need for more brief global assessment measures in clinical trials that are more applicable to the primary care setting is now recognised.[16,17] Brief ratings of global symptom severity and global improvement following treatment have been employed in one previous study on psychological and pharmacological treatments for panic disorder;[6] these showed strong positive correlations with more traditional rating scales.[18] This study also employed brief ratings of the impact of treatment on social functioning.

The present study attempts to overcome the methodological problems using previous research on therapist contact in CBT for panic disorder. The study reports on the relative efficacies of a standard therapist contact CBT plus bibliotherapy, a reduced therapist contact CBT plus bibliotherapy, and bibliotherapy alone

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Submitted: 7 October 1999; Editor's response: 27 March 2000; final acceptance: 5 July 2000.

used in the treatment of panic disorder with or without agoraphobia. The study was conducted in the primary care setting. Outcome is reported in terms of global measures of outcome and social functioning, more suitable for use in general practice. Outcome in terms of more traditional rating scales is reported elsewhere.[19]

Methods

Subjects

Patients were referred by general practitioners (GPs) from 26 general practices in the Forth Valley Health Board area of Scotland and seen for all sessions in their local general practice health centre or surgery. Following initial assessment and referral by their GP, patients were seen for assessment prior to treatment group randomisation and thereafter for treatment by the same clinical psychologist (DS). Randomisation was conducted according to a computer-generated randomisation schedule, with individual allocations unavailable until after initial assessment. Treatment end-point assessments were conducted by an independent clinical psychologist (KP) and patients were instructed not to discuss their treatment with the blind endpoint assessor.

The study was given ethical approval by the Forth Valley Health Board Ethics of Research Committee. Patients provided written consent and conformed to the following entry requirements: panic disorder with or without agoraphobia according to Diagnostic and Statistical Manual of Mental Disorders (DSM III-R)[20] criteria; a minimum score of 15 on the Hamilton Anxiety Scale;[13] a maximum score of 20 on the Montgomery Asberg Depression Rating Scale;[21] symptoms lasting at least three months; between 18 and 70 years of age inclusive; and no psychological treatment for panic disorder and agoraphobia received in the six months prior to entry to the study.

Many patients attend for psychological treatment while continuing to take concurrent psychotropic medications. There has been considerable debate as to the most appropriate means of controlling for such concurrent medication in treatment outcome study design.[22] In pragmatic research designs where treatments should reflect wider clinical practice as closely as possible, it is usually accepted that stabilisation of psychotropic use during the study period is adequate. The current study was designed to replicate clinical practice as closely as possible. The use of concurrent psychotropic medication was not therefore an exclusion criterion in the present study. Any patients taking concurrent psychotropic medications were required to have taken them for two months prior to study entry, and to continue taking them as prescribed throughout the study period.

A total of 132 patients were referred; 28 patients did not meet the study criteria and were not entered. A total of 104 patients entered the study and 13 patients dropped out during treatment. Patients withdrawing early owing to effectiveness or ineffectiveness of treatment, receiving at least 42 days treatment, and who provided full endpoint data, were included in the final analysis as 'defined completers'. This methodology avoids an unnecessarily stringent intent-to-treat analysis as well as the positive bias inherent in a 'full completers only' analysis. A total of 91 'full completers' and 'defined completers' comprised the study group. A flow diagram of study participants is given in Figure 1 and demographic details of the sample in Table 1.

Treatment

All patients received the same CBT and all received identical treatment instructions, the same written treatment manual being supplied to all patients. The CBT entailed both gross exposure and behavioural and cognitive panic management techniques. Treatment emphasised the alteration of the action tendencies associated with panic attacks and the hypervigilant and avoidant information processing and behaviours typical of panic disorder and agoraphobia. Patients were encouraged to confront their panic attacks — during exposure outings if necessary — and to attempt to replace behavioural and cognitive avoidances with more approach-centred actions. This approach to CBT was similar to that of Barlow and co-workers,[23] and was identical to that used in previous studies at the Anxiety and Stress Research Centre, University of Stirling.[6,24] The CBT was delivered at three levels of therapist contact:

1. *Standard contact*. Patients in the standard contact condition received the standard treatment manual and eight sessions of 45 minutes' duration over 12 weeks with sessions at Days 0, 7, 14, 28, 42, 56, 70, and 84; a total of six hours' therapist contact.
2. *Minimum contact condition*. Patients in the minimum contact condition received the treatment manual and six sessions, with sessions involving assessments (at Days 0, 42, and 84) being 30 minutes' duration and the other sessions (at Days 7, 21, and 63) being 10 minutes' duration; a total of two hours' therapist contact.
3. *Bibliotherapy*. Patients in the bibliotherapy condition received the treatment manual and assessment sessions at Days 0, 42, and 84. The one hour and 30 minutes of therapist contact in this condition was for assessment only, with treatment instruction provided solely by the treatment manual.

Measures

Severity of illness was measured using the global symptom severity scale.[25] This seven-point scale gives a range of clinical severity from 1 ('normal') to 7 ('extreme'). Ratings were assigned by the psychologist therapist (DS) at Day 0 and by the independent assessor (KP) at Day 84.

Change in symptoms was measured using the clinical global improvement scale.[25] This seven-point scale rates symptom change on a range of 1 ('very much improved') to 7 ('very much worse'). Ratings were assigned by the psychologist therapist (DS) and independently by patients at Day 84.

Social functioning was measured using the Sheehan Disability Scale (SD).[26] This scale assesses disruption to lifestyle and comprises three 10-point sub-scales on which patients self-rate disruption to work, social life, and family or home life. Patients rated these on Days 0 and 84.

Statistical analysis

Two-factor analysis of variance with a between-subjects factor, treatment group, and a within-subjects factor assessment point were conducted where appropriate. Simple effects one-way analyses of variance were used to investigate between-group differences, with post hoc Scheffe tests used to detect significance of between-group differences. Within-group comparisons of pre- and post-treatment scores were conducted using paired two-tailed *t*-tests.

Results

There were no statistically significant differences between treatment groups on any clinical or demographic measures at entry, nor were there any statistically significant differences in the proportion of patients taking any psychotropic medication at the start of treatment.

Table 1. Demographic features of 'completers' sample (n = 91).

	Standard (n = 31)	Minimum (n = 31)	Bibliotherapy (n = 29)
Mean age (years)	35	39.4	40.5
Mean duration of current episode (months)	26.8	44.3	38.2
Concurrent non-psychotropic medication (number of patients)	10	10	9

Table 2. One-way ANOVAs, two-tailed t-tests, and means (SD) for psychologist ratings of global symptom severity pre- and post-treatment.

	Standard (n = 31)	Minimum (n = 31)	Bibliotherapy (n = 29)	F	Scheffe (P< 0.05)
Global symptom severity					
Pre-treatment (Day 0)	4.37 (0.68)	4.33 (0.77)	4.15 (0.76)	0.84 (NS)	–
Post-treatment (Day 84)	2.22 (1.56)	3.12 (1.11)	3.61 (1.26)	8.09 (P<0.001)	1–2, 1–3[a]
Two-tailed t-test	8.15 (P<0.0001)	5.88 (P< 0.0001)	2.13 (P<0.05)		

[a]1 = standard contact; 2 = minimum contact; 3 = bibliotherapy; NS = not significant.

Table 3. One-way ANOVAs and means (SD) for psychologist and patient ratings of clinical global improvement at treatment endpoint.

	Standard (n = 31)	Minimum (n = 31)	Bibliotherapy (n = 29)	F	Scheffe (P<0.05)
Psychologist clinical global improvement	1.77 (1.58)	2.5 (0.95)	3.26 (1.02)	10.61 (P<0.0001)	1–3
Patient clinical global improvement	1.7 (0.83)	2.12 (1.03)	3.14 (1.19)	14.71 (P<0.0001)	1–3, 2–3[a]

[a]1 = standard contact; 2 = minimum contact; 3 = bibliotherapy; NS = not significant.

Table 4. One-way ANOVAs, two-tailed t-tests, and means (SD) for Sheehan Disability Scale, pre- and post-treatment.

Sheehan Disability Scale	Standard (n = 31)	Minimum (n = 31)	Bibliotherapy (n = 29)	F	Scheffe (P<0.05)
Work					
Pre-treatment (Day 0)	6.94 (3.31)	6.00 (3.49)	5.71 (3.19)	1.30 (NS)	–
Post-treatment (Day 84)	2.19 (2.45)	4.06 (3.43)	4.42 (3.29)	4.56 (P<0.01)	1–2, 1–3
Two-tailed t-test	6.86 (P<0.0001)	2.06 (P<0.05)	1.85 (NS)		
Social life					
Pre-treatment (Day 0)	6.56 (3.01)	5.66 (3.28)	5.74 (2.97)	0.919 (NS)	–
Post-treatment (Day 84)	2.09 (2.65)	3.31 (3.05)	4.33 (3.48)	3.884 (P<0.05)	1–3, 2–3
Two-tailed t test	6.47 (P<0.0001)	2.65 (P<0.01)	3.03 (P<0.01)		
Home life					
Pre-treatment (Day 0)	5.03 (3.23)	5.39 (3.36)	5.45 (3.29)	0.171 (NS)	–
Post-treatment (Day 84)	2.06 (2.70)	2.93 (3.01)	4.37 (3.31)	4.292 (P<0.01)	1–3, 2–3
Two-tailed t test	3.87 (P<0.001)	3.26 (P<0.01)	1.26 (NS)		

[a]1 = standard contact; 2 = minimum contact; 3 = bibliotherapy; NS = not significant.

Severity of symptoms

Table 2 presents the means and standard deviations (SDs) for the psychologists' ratings of global symptom severity pre- and post-treatment. Analysis of variance revealed significant group effects (F = 3.23 for [2,85] d.f.; P<0.05), time effects (F = 89.28 for [1,85] d.f.; P<0.001), and interaction effects (i.e. group x time) (F = 13.12 for [2,85] d.f.; P<0.001), indicating differential effects between groups. No significant differences existed between groups at the start of treatment. Post-treatment, the standard therapist contact group showed significantly lower ratings of global symptom severity than the minimum therapist contact and bibliotherapy groups, which did not differ from each other. All three groups showed significant reductions in global symptom severity pre-to-post-treatment, most notably for the standard therapist contact and minimum therapist contact groups.

Change in symptoms

Means and SDs for psychologist therapist and patients ratings of change in symptoms at treatment endpoint are given in Table 3. Between-groups analysis showed significant differences for psychologist therapist ratings with the standard therapist contact group showing significantly lower ratings following treatment, and thus greater improvement, than the bibliotherapy group. For patients ratings of change in symptoms following treatment, both the standard therapist contact and minimum therapist contact groups showed significantly lower ratings than the bibliotherapy

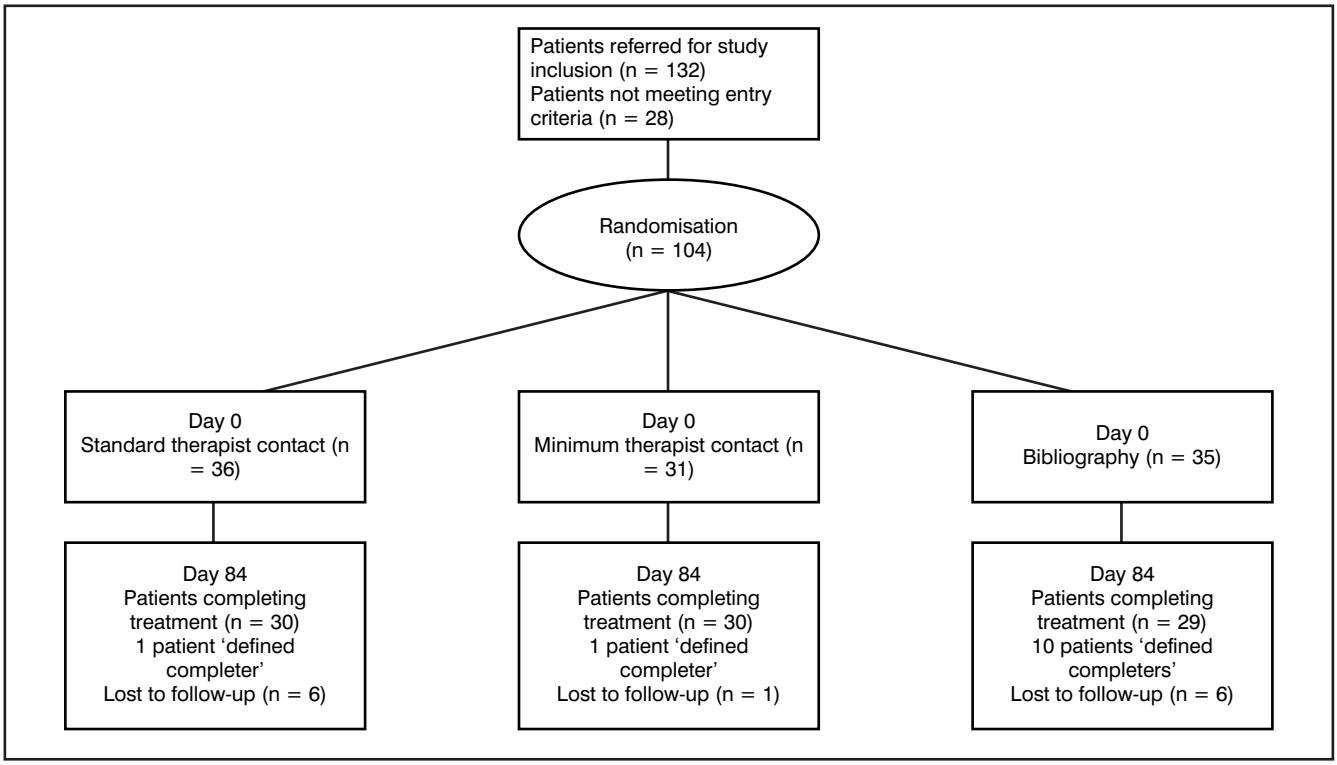

Figure 1. Flow diagram of study participants.

group but did not differ significantly from each other. There was considerable agreement between the ratings of the psychologist therapist and the patients (Pearson's coefficient of correlation r = 0.86; P<0.001).

Sheehan Disability Scale (SD)

The means and SDs for scores on this scale pre- and post-treatment are given in Table 4. Analysis of variance for the work scale revealed a significant time effect (F = 32.87 for [1,87] d.f.; P<0.001) and interaction effects (i.e. group x time) (F = 5.86 for [2,87] d.f.; P<0.01). The social life scale also revealed significant time effects (F = 41.67 for [1,87] d.f.; P<0.001) and interaction effects (i.e. group x time) (F = 4.14 for [2,87] d.f.; P<0.01). The home life scale revealed a significant effect for time only (F = 24.23 for [1,87] d.f.; P< 0.001).

None of the groups differed significantly on ratings of disruption to work, social life or home life pre-treatment. The standard therapist contact group showed significantly lower ratings of disruption to work post-treatment than both the minimum therapist contact and the bibliotherapy groups, which did not differ from each other. Both the standard therapist contact and the minimum therapist contact groups showed significantly lower ratings of disruption to social life and to home life post-treatment than the bibliotherapy group but did not differ significantly from each other. All groups showed a significant reduction in scores pre-to-post-treatment on social life while only the standard therapist contact and the minimum therapist contact groups showed significant reductions in pre-to-post-treatment scores on the work and home life scales.

Discussion

The present study compared the efficacy of a standard therapist contact CBT for panic disorder and agoraphobia with minimum therapist contact and bibliotherapy variations of the treatment. An attempt was made to standardise the CBT across treatment groups with all patients receiving the same written treatment manual. The same psychologist therapist delivered all the treatments. Thus the only variable that fluctuated across treatment groups was the amount of therapist contact received. To increase the ecological validity of findings, the study was conducted in primary care. Treatment outcome was expressed in terms of brief global measures suitable for use in general practice that covered clinically relevant aspects of treatment, such as global severity, global improvement, and the social impact of the disorder. The results of this study suggest that such relatively simple measures are capable of indicating differential outcomes between groups. Identical brief global measures were found to have reasonable discriminatory powers in a previous treatment outcome study in a primary care sample.[6]

Current results indicated that the bibliotherapy group showed the weakest treatment response. While the bibliotherapy group did show significant pre-to-post-treatment reductions in global symptom severity and significant reductions in rated disruption to social life following treatment, ratings for disruption to work and home life did not show any significant reduction following treatment. This represents only a partial response to treatment and validates the use of ratings of the impact of the disorder and subsequent treatment on social functioning in treatment outcome research of this type. The minimum therapist contact group occupied an intermediate position, showing significant pre-to-post-treatment changes on all measures. The minimum therapist contact group also showed a response that was significantly superior to that of the bibliotherapy group on the patient-rated measure of clinical global improvement, and ratings of disruption to social life and home life post-treatment. However, the minimum therapist contact group did not differ from the bibliotherapy group on post-treatment ratings of global symptom severity, therapist-rated clinical global improvement or disruption to work. This again suggests an incomplete treatment response. The standard therapist

contact group showed the strongest and most comprehensive treatment response, differing significantly from the bibliotherapy group on all post-treatment measures and from the minimum therapist contact group on global symptom severity and rated disruption to work. This latter finding for the work sub-scale of the Sheehan Disability Scale is potentially important. A reasonable expectation of a treatment is that it will return patients to normal levels of social functioning. The standard therapist contact group was the only treatment group to show comprehensive and unequivocal change on all three sub-scales of the Sheehan Disability Scale.[26] Given the above results it would appear that there is some loss of treatment efficacy when levels of therapist contact are reduced to those of the minimum therapist contact and bibliotherapy groups.

There are points that should be borne in mind when considering the results of this study. First, although the same therapist delivered all treatments and all patients received the same treatment manual, no further checks on treatment delivery were made. Checks should be made in future studies to ensure that no 'therapist by contact level' interactions have occurred. The psychologist therapist also rated clinical global improvement at treatment endpoint. Independent ratings of global symptom severity at treatment endpoint were, however, provided by the independent assessor (KP) and patients provided independent self-ratings of clinical global improvement at treatment endpoint that showed strong agreement with the psychologist therapist's ratings (Pearson's correlation coefficient $r = 0.86$; $P<0.001$). In the current study, there were no statistically significant differences between groups in the proportions of patients taking psychotropic medications during the study; the relatively small sample size employed, however, did not permit the investigation of possible medication by treatment group interactions. Larger studies on this topic are required. Lastly, although follow-up data were collected for the more traditional outcome measures reported elsewhere,[19] follow-up findings were not collected for the global measures employed in the current study. This should be considered in future research.

Results from this study suggest that the standard therapist contact CBT employed here is a viable treatment for panic disorder and agoraphobia as assessed by the brief global measures used here. There would also appear to have been some fall-off in treatment efficacy as levels of therapist contact were reduced. A final point on levels of therapist contact: the standard therapist contact group in this study received a total of six hours' therapist contact. This is substantially less than the 20 hours of therapist contact employed in the standard therapist contact conditions of other recent studies on CBT for panic disorder,[27,28] and certainly less than the average treatment time of 42 hours for CBT packages in a recent survey of therapists.[29] The standard therapist contact treatment group in the present study might therefore be more appropriately titled 'brief CBT'. Indeed the therapist contact time of six hours employed as a standard treatment at our centre is similar in duration to brief treatments employed in other recent research.[30] The findings of efficacy across all the measures for the standard therapist contact group in the present study are all the more relevant for this. This also suggests that the minimum therapist contact condition employed in this study represents a particularly stringent test of the reduced therapist contact paradigm. This caveat aside, this study reinforces the efficacy of CBT treatments for panic disorder and agoraphobia in primary care and that treatment outcome can be viably assessed by brief global measures more appropriate to general practice. Results also indicate that at least some degree of therapist contact is required to maintain the efficacy of the CBT as employed here. It would appear, however, that the very high levels of therapist contact employed in much previous research are not required. CBT treatments with levels of therapist contact similar to the standard therapist contact condition in this study may therefore be used in wider clinical practice and the efficiency of treatment delivery enhanced accordingly.

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Acknowledgements

The study was conducted while the first author was based at the Anxiety and Stress Research Centre, University of Stirling. The authors would like to thank the GPs who supported the study and of course the patients who agreed to take part.

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