A controlled trial of internet-based cognitive-behavioural therapy for panic disorder with face-to-face support from a general practitioner or email support from a psychologist

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Introduction

Panic disorder (PD) is one of the most common anxiety disorders in the Australian community, but is consistently undertreated. In any 12-month period, approximately 2% of Australians are afflicted by PD; however, the majority (61%) of people with PD with/without agoraphobia do not seek or receive professional assistance.\(^1\)

Clinical trials have demonstrated that cognitive-behavioural therapy (CBT) is the most effective treatment for PD, and recent findings suggest that CBT confers longer-term benefits than selective serotonin reuptake inhibitor (SSRI) alone or CBT and SSRI in combination.\(^2\)–\(^4\) Multi-element CBT treatment protocols for PD result in panic-free status for 75–95% of patients, with improvements maintained for at least two years.\(^5\)–\(^7\) Importantly, CBT is also uncompromised by co-morbid depression,\(^8\) or the transfer from research to clinical treatment settings.\(^9\)

Despite the demonstrated efficacy of CBT, a lack of access to specialist mental health services and their high cost impede provision of this best-practice treatment. Access to mental health services is also limited in the UK and Ireland.\(^9\)\(^,\)\(^10\) People residing in rural and remote areas are particularly disadvantaged by the shortage of mental health services.\(^11\) In Australia the accessibility of mental health services is likely to improve with the federal government’s recent changes to the healthcare system which enable general practitioners (GPs) to refer patients to eligible psychologists for a limited number of reduced-fee consultations. Nevertheless, many people will be unable to afford the reduced fee or ongoing consultations, and inaccessibility due to geographic isolation will remain a significant problem.

Partly as a consequence of the historical difficulty in accessing mental healthcare, most people seeking assistance for a mental illness first consult their GP.\(^13\) Indeed, between one-quarter and one-half of general practice patients have a mental health problem.\(^14\),\(^15\) Seeking assistance from a GP has several advantages, including the provision of rapid and affordable access to comprehensive healthcare without the stigma often associated with attending specialist psychological or psychiatric services. Compared to other healthcare professionals, GPs are accessible, large in number and can be seen at little or no direct cost to the consumer.\(^16\)

Nevertheless, there are considerable shortfalls in the provision of mental healthcare within this setting, with skill limitations and time constraints being the prominent difficulties.\(^15\),\(^17\) Furthermore, many patients who present with sufficient disturbance...
Despite the recent call for internet-based mental health treatment and practitioner support within primary care, most published research on primary care internet interventions has focused on physical health-related behaviours. There is some evidence that self-help treatments in the form of written or audio-behavioural or cognitive-behavioural materials, delivered in primary care, confer clinical benefits. However, the methodological shortcomings of several such studies have been noted, as have contrary results. Furthermore, a literature search failed to reveal published research on the effectiveness of internet-based CBT programmes delivered by GPs, for the treatment of panic disorder.

Responding to this evidence gap in the literature, this study investigated the effectiveness of PO with face-to-face assistance provided by a GP (PO-GP), compared to PO with email assistance from a psychologist (PO-P), for treating PD, with or without agoraphobia. This study is one of the first to directly compare two different ways of delivering internet-based CBT for PD, and provides new information about the effectiveness of an internet-based mental health intervention applied to a primary care setting. If PO-GP is found to be as effective as PO-P, this programme will serve as a model for the implementation of evidence-based CBT programmes in primary care. It was predicted that the PO-GP would be as effective as PO-P for treating panic disorder, with or without agoraphobia.

Method

Recruitment

The study was advertised to the general public via Australian mental health websites and local and national media. Interested individuals were directed to the panic online website to self-register for the study. The study was also promoted directly to GPs via several BOiMHC-accredited mental health training programmes in Victoria and South Australia. This served the dual purpose of recruiting GPs to participate as treating GPs in the PO-GP group, and/or to encourage referral of patients to the study. GPs who indicated an interest in participating in the programme were contacted by telephone and registered for the study. All GPs who registered were given access to the website and sent written materials about the study. Considerable time was also spent corresponding with registered GPs about their involvement in the research. A research officer (also a registered
psychologist) either met with each GP or, if the GP preferred, discussed the research protocol via telephone. During this correspondence the research officer explained the PO programme components and the expected role of the GP and patient in the use of PO.

Participants and therapists

A total of 65 individuals with PD (78% of whom were agoraphobic) participated in the study. The PO-GP group comprised 34 participants with panic disorder (29 with agoraphobia), including 25 females and nine males (mean age = 37.91 years, standard deviation (SD) = 10.88 years). The PO-P group comprised 31 participants with panic disorder (22 with agoraphobia) including 23 females and eight males (mean age = 42.00 years, SD = 11.03 years). Data pertaining to the duration of panic disorder were obtained for 28 participants in the PO-GP group and 25 participants in the PO-P group, with a mean duration of 58.08 (SD = 66.70) and 59.07 (SD = 112.65) months, respectively. Of the participants in the PO-GP group, eight were taking antidepressants and four were taking benzodiazepines. Of those assigned to the PO-P group, 16 were taking antidepressants and two were taking benzodiazepines.

One-hundred and thirty-two GPs from Victoria and South Australia registered to participate as therapists in the PO-GP group. All GPs were accredited by the General Practice Mental Health Standards committee and were therefore eligible to provide FPS under the BOiMHC initiative. Of the GPs, 37 actively referred and treated participants in the study. The first and second authors provided initial training for the GPs to use PO, and regular consultative support via telephone and email for the GPs during the project.

Seven psychologists (six female and one male) from Monash University’s Department of General Practice, Victoria, were recruited as therapists for the PO-P group and/or assessors for both groups.

Inclusion and exclusion criteria

Criteria for inclusion were a primary diagnosis of PD (with or without agoraphobia), according to criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), as assessed by the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV). Panic disorder with or without agoraphobia was considered to be the primary diagnosis when its severity was greater than any secondary diagnosis on the clinician’s nine-point severity rating scale in the ADIS-IV.

Exclusion criteria included the presence of a seizure disorder, stroke, schizophrenia, hyperthyroidism, alcohol or drug dependency, organic brain syndrome, heart condition or chronic hypertension. All participants were between the ages of 18 and 64 years and Australian residents; they spoke English fluently, and agreed not to undertake any other type of therapy or self-help procedure during the study. Participants taking medication for anxiety or depression were only included if they had been stabilised on this medication for at least 12 weeks but continued to experience panic symptoms and met criteria for a diagnosis of PD. All participants and GPs were consulted about the need for patients to refrain from starting medication (or altering medication dosages) while taking part in the study. Those taking medication were requested to inform us of any changes to medications. However, in no instances were the researchers contacted for this reason. A total of 29 participants, including 18 in the PO-GP condition and 12 in the PO-P condition were taking medication during the period of participation.

Measures

Assessment included clinical interviews administered by a psychologist over the telephone, and self-administered online questionnaires. Validated paper-based panic questionnaires were recently shown to produce equivalent outcomes when administered via the internet.

ADIS-IV

The ADIS-IV was used as a clinical diagnostic tool to determine a primary diagnosis of PD, with or without agoraphobia. The ADIS-IV is a semi-structured clinical interview schedule designed to permit differential diagnosis among the anxiety and mood disorders, and screen for other major disorders (e.g., substance abuse, psychosis, somatoform disorders). It has good-to-excellent reliability and validity, with inter-rater reliability of $r = 0.72$ for the diagnosis of PD.

Panic Disorder Severity Scale (PDSS)

The PDSS was used to assess panic frequency and severity. The PDSS has excellent inter-rater reliability on all scale items ($r = 0.74–0.87$) and good validity.
Anxiety Sensitivity Profile (ASP)
The 60-item ASP measures fear of anxiety-related sensations, based on beliefs that they have harmful consequences. Respondents rate, on a seven-point Likert scale, the extent to which they agree that the sensations described would lead to something bad happening. The coefficient alphas for the six scales range from 0.88 to 0.94, and the overall scale has high test–retest reliability.

Depression Anxiety Stress Scales (DASS)
The DASS comprises three 14-item self-report scales which measure levels of depression, anxiety and stress. Respondents rate the extent to which particular symptoms were experienced in the last week, using four-point Likert scales. Lovibond and Lovibond reported alpha coefficients of 0.91 for depression, 0.84 for anxiety and 0.90 for stress.

Treatment Credibility Scale-Modified (TCS-M)
The TCS-M is a five-item questionnaire measuring perceived treatment credibility on a 0 (not at all) to 10 (very much) rating scale. Participants rated the credibility of the treatment they were allocated to after reading the rationale and description of the treatment. The five items were summed to derive a treatment credibility score ranging from 0 to 50 (low to high credibility).

WHO-Quality-of-Life-BREF (WHO-QOL-BREF)
The WHO-QOL-BREF comprises 26 items, each pertaining to one of four subdomains: physical health, psychological health, social relationships and environment. Each item is rated on a five-point Likert scale. This tool has good internal consistency and validity.

Design
A natural groups design was employed whereby people who learned of the programme and the research study independently (e.g. via media, web surfing) were recruited into the psychologist email assist (PO-P) group, while those referred to the programme by their GP were recruited into the face-to-face GP-assist (PO-GP) group. GP were subsequently telephoned by one of the psychologists who explained the study and screened participants for PD. If it appeared probable that the person would fit DSM-IV criteria for PD, he/she was emailed the explanatory statement and consent form, which they completed via return email. Subsequently, a full clinical diagnostic assessment using the ADIS-IV was conducted by the psychologist via telephone, taking approximately 90 minutes. Upon a primary diagnosis of PD (with or without agoraphobia), eligible participants completed the battery of online questionnaires. The psychologist then emailed the participant with a username and password and instructions on how to access the PO site. Participants were requested to utilise either their email therapist or GP (depending on group allocation), and all therapists and GPs were notified when their patient had completed assessments and was eligible to commence treatment. Participants found to be ineligible for the study were advised of the reason and referred to alternative services as appropriate.

Procedure
Procedures of this study were approved by the Monash University Human Research Ethics Committee. Potential participants who registered online or contacted the researchers upon referral from their GP were subsequently telephoned by one of the psychologists who explained the study and screened participants for PD. If it appeared probable that the person would fit DSM-IV criteria for PD, he/she was emailed the explanatory statement and consent form, which they completed via return email. Subsequently, a full clinical diagnostic assessment using the ADIS-IV was conducted by the psychologist via telephone, taking approximately 90 minutes. Upon a primary diagnosis of PD (with or without agoraphobia), eligible participants completed the battery of online questionnaires. The psychologist then emailed the participant with a username and password and instructions on how to access the PO site. Participants were requested to utilise either their email therapist or GP (depending on group allocation), and all therapists and GPs were notified when their patient had completed assessments and was eligible to commence treatment. Participants found to be ineligible for the study were advised of the reason and referred to alternative services as appropriate.

Post-treatment assessments at the end of week 12 included the ADIS-IV interview via telephone and the same battery of online questionnaires. The psychologists did not provide any treatment to participants for whom they conducted the interview and questionnaire assessments.

Panic Online (PO)
PO comprised an introductory module, four learning modules and a relapse-prevention module. The programme included treatment methods commonly used in standard CBT for PD, including instructions for controlled breathing, progressive muscle relaxation, cognitive restructuring and interoceptive and situational exposure.

The programme contained standardised information and guidance that did not vary according to participant input. Downloadable audio material (for both tense–relax and passive progressive muscle relaxation) was available, and sequenced photographic slide shows of two gradual-exposure in vivo exercises (going to the supermarket and driving a car) were provided. PO also included a stress-management programme comprising six learning modules on coping with daily stresses, time and anger management, tuning into one’s thoughts, relaxation, and social connectedness, as in Richards, Klein and Austin’s (2006) study.

Panic Online with psychological assistance (PO-P)
Once a participant was allocated to the PO-P group, they were assigned a treating psychologist.
Psychologist–participant interaction occurred via email, enabling the therapist to provide support and feedback to the participant, and guide him or her through the programme according to their individual needs. There was no limit to the frequency with which participants could email their psychologist, although the psychologist initiated contact at least once per week (and usually more frequently) and responded to all client emails within a 24-hour period.

**Panic online assisted by GPs (PO-GP)**

Once allocated to the PO-GP group, the assessing psychologist asked participants to make an appointment with their GP for the first consultation. The assessor then contacted the participant’s GP to inform him/her that the participant could commence treatment. GP–participant interaction occurred face to face, enabling the GP to provide support and feedback to the participant, as well as guide him or her through the programme according to their requests and needs. The GPs and participants were encouraged to consult on a regular basis for the 12 weeks of the trial, and participants were requested to use PO in the interim periods between consultations.

Participants in both conditions utilised PO in their place of residence.

**Attrition**

The attrition rate was 12.9% (4/31) for the PO-P group and 26.5% (9/34) for the PO-GP group, with an overall attrition rate of 20% (13/65). Fisher’s exact chi-square test revealed no significance between group difference for attrition $\chi^2(1, n = 65) = 1.84, P > 0.05$. Analyses also revealed no differences between completers and non-completers on age, sex, medication use and all of the baseline questionnaires.

**Data treatment and analysis**

Intention-to-treat analyses were used, with the pre-assessment scores for participants who discontinued during treatment ($n = 13$) carried forward and used in the post-treatment assessment. Dependent variables that were non-normally distributed were transformed (DASS subscales and panic attacks in last month) using a square root transformation to satisfy normality assumptions.

One-way analyses of variance (ANOVA) were conducted on all pre-treatment measures to check for significant differences between-group differences. No significant differences were found. In addition, no significant difference was found between the two groups for age ($F(1,62) = 2.08, P = 0.15$), sex ($\chi^2(1, n = 65) = 0.13, P > 0.05$) or frequencies of participants in the two treatment conditions for participants who were taking medication ($\chi^2(1, n = 65) = 2.63, P > 0.05$).

To test whether participants in the two conditions were significantly improved at post-treatment assessment, three repeated measures of multivariate analyses of variance (MANOVAs) were performed. The first examined PD parameters and included the following measurements: panic attacks per month, clinician-rated PD severity, interference and distress, taken from the ADIS-IV and the PDSS total score. The second included the three DASS subscales, and the third included the four WHO-QOL-BREF subdomains. A repeated measures ANOVA was conducted to analyse group differences in ASP scores. This was analysed separately as it was the only cognitive measure. An independent groups $t$ test was conducted to assess treatment credibility.

Results of evaluation of normality assumptions, homogeneity of variance–covariance matrices and linearity were satisfactory. Additionally Bartlett’s test of sphericity was conducted to confirm that the dependent variables in the MANOVA groupings were correlated at the $P < 0.05$ level.

**Results**

Table 1 displays means and standard deviations for measures at each assessment phase across treatment conditions.

**Treatment credibility**

An independent samples $t$ test revealed no significant differences between groups for perceived treatment credibility, $t(56) = 1.53, P > 0.05$.

**Panic parameters**

For the panic parameters grouping (panic attacks in last month, PDSS and PD severity, interference and distress) the MANOVA revealed a significant main effect for time, $F(5,43) = 17.78, P < 0.01$ (partial $\eta^2 = 0.67$, power = 1.0). There was no significant main effect for group, $F(5,43) = 0.76, P > 0.05$ (partial $\eta^2 = 0.08$, power = 0.25), nor a significant effect for group × time, $F(5,43) = 0.82, P > 0.05$ (partial $\eta^2 = 0.09$, power = 0.26). The main effect for time was due to a
### Table 1: Means and standard deviations (SD) pre- and post-treatment across groups

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reduction in mean scores on all panic parameters for both groups.

Negative effect
For the negative effect grouping (DASS subscales), the MANOVA indicated a significant main effect for time, \( F(3,61) = 19.68, P < 0.01 \) (partial \( \eta^2 = 0.49 \), power = 1). There was no significant main effect for group, \( F(3,61) = 1.01, P > 0.05 \) (partial \( \eta^2 = 0.05 \), power = 0.26), or the interaction for group \( \times \) time, \( F(3,61) = 1.11, P > 0.05 \) (partial \( \eta^2 = 0.05 \), power = 0.29). The main effect for time was due to a reduction in mean scores on each of the three DASS subscales for both groups.

Panic cognition
For ASP scores, a repeated measures ANOVA showed a significant main effect for time, \( F(1,40) = 42.34, P < 0.01 \) (partial \( \eta^2 = 0.51 \), power = 1) due to a reduction in ASP scores for both groups (see Table 1). The main effect for group was not significant, \( F(1,40) = 0.42, P > 0.05 \) (partial \( \eta^2 = 0.01 \), power = 0.08); however, there was a significant group \( \times \) time interaction, \( F(1,40) = 5.38, P < 0.01 \) (partial \( \eta^2 = 0.12 \), power = 0.62). This interaction effect was due to marginally higher pre-treatment ASP scores for PO-P than PO-GP (mean = 3.62 and 3.49, respectively) and lower post-treatment ASP scores for PO-P than PO-GP (mean = 2.02 and 2.74, respectively).

Quality of life
For the QOL subscales, the main effect for time was significant, \( F(4,50) = 9.91, P < 0.01 \) (partial \( \eta^2 = 0.44 \), power = 1.00). However, the main effect for group and the group \( \times \) time interaction were not, \( F(4,50) = 0.97, P > 0.05 \) (partial \( \eta^2 = 0.07 \), power = 0.28) and, \( F(4,50) = 0.15, P > 0.05 \) (partial \( \eta^2 = 0.01 \), power = 0.08), respectively. The main effect for time was due to an increase in mean scores on each of the three QOL domains, for both groups.

PD clinical change
Participants were assessed as having achieved PD clinical change if they had a post-treatment PD severity score of less than four points on the nine-point clinician rating scale of the ADIS. PD clinical change was achieved by 87.1\% (27/31) of the PO-P group participants and 70.6\% (24/34) of the PO-GP group participants. The between-group difference was not statistically significant, \( \chi^2(1, n = 65) = 2.70, P > 0.05 \).

Panic-free status and end state functioning
Panic free-status was defined as having no panic attacks during the month immediately prior to post-treatment assessment. Panic-free status was achieved by 41.9\% (13/31) of the PO-P group participants and 61.8\% (21/34) of the PO-GP group participants. High end-state functioning was defined as being panic free and with a clinician-rated PD severity score of less than four points on the nine-point clinician rating scale of the ADIS. High end-state functioning was achieved by 41.9\% (13/31) of the PO-P group and 29.4\% (10/34) of the PO-GP group achieved high end-state functioning. However, the between-group difference was not statistically significant, \( \chi^2(1, n = 65) = 0.11, P > 0.05 \).

Discussion
The results indicate that participants receiving PO with assistance provided by a GP achieved similar outcomes to those receiving PO with support from a psychologist via email. Given the demonstrated efficacy of PO with psychologist email assistance, this study suggests that accredited GPs, when provided with validated online treatment protocols, can achieve patient outcomes comparable to treatments delivered by clinical psychologists.

The quality of GP-provided mental health care has traditionally been compromised by time constraints and limited training or availability of resources. The treatment applied in the present study provides a model for how GPs may be assisted to provide evidence-based mental health therapies effectively. Internet-based programmes relieve much of the burden from the GP, as therapeutic materials, exercises and activities are delivered directly to the patient, with the GP occupying a coaching and monitoring role, which is more easily integrated within existing general practice models, and potentially sustainable beyond the research setting.

This is the first study to evaluate the use of an internet-based CBT treatment for panic disorder within general practice. Several previous studies of internet-based mental health interventions, with community samples, suffered from high attrition rates. By comparison, attrition was low in the present study. This is likely to reflect the substantial time spent by the researchers communicating with the participants and GPs throughout their involvement in the study.

At present, very few GPs are using electronic mental health resources, despite the fact that they recognise several advantages to doing so, such as high patient acceptance, time efficiency, and perceived high
quality. Results found here however, suggest that GPs may be confident that, in the near future, electronic clinical mental health tools will facilitate their provision of mental health treatments and lead to improved patient outcomes.

It is noteworthy that less than half (28%) of GPs who registered their interest in the study actively referred patients to the CBT programme. This relatively low uptake may indicate reluctance by some GPs to manage their client’s panic disorder via an internet-based treatment tool. However, it is often the case that the GPs choose between several appropriate treatments for mental illnesses in their clinical practice. The internet-based tool evaluated here represents one of several possible treatment options. As with other treatment approaches that are newly introduced into a general practice setting, if internet-based mental health treatments are introduced in future they are likely to take some time to become common practice.

Several methodological considerations and limitations are worthy of discussion. The first of these relate to design and recruitment factors. This study adopted a non-randomised, natural groups design. It is possible that the treatment groups resulting from the two different recruitment routes were non-equivalent in ways that were not obvious from the psychometric measures employed. Furthermore, the GPs involved in the present study had received prior training in FPT, based on cognitive-behavioural principles. Thus, while this research does encourage GPs’ development of FPS skills, future research should also investigate the use of internet-based mental health interventions delivered by GPs without this training.

Another limitation of this study concerns the inclusion of people taking antidepressants and/or anxiolytics. The potential effects of medication were not analysed statistically due to the small numbers of participants taking medication. Nevertheless, medication dosages were stable and all participants experienced clinically significant panic disorder at pre-assessment, suggesting comparability between the two treatment groups prior to the interventions.

Furthermore, in the present study the researchers were unable to control the amount of time spent by GPs providing supportive therapy. Future research should investigate whether the frequency of GP visits, in which supportive therapy is provided to patients undergoing internet-based treatment, affects patient outcomes. Approximately 30% of participants in both treatment conditions achieved high end-state functioning. This rate is encouraging, particularly as many of the participants had suffered from panic disorder for several years, and for many of them agoraphobic symptoms caused considerable functional impairment. Nevertheless, this finding suggests that there is room for improvement of the two interventions. Further research is needed to isolate the mechanisms of change in CBT and internet-based treatment for panic disorder, with a view to more closely targeting these mechanisms in future interventions.

The present study demonstrated that internet-based CBT with GP support produced clinically significant improvements in panic disorder symptomatology, quality of life and end-state functioning. Programmes such as PO provide an innovative opportunity to relieve some of the pressures on our GP workforce. The challenge is to ensure programmes such as PO are integrated into existing models of primary care, in order to increase their availability. If this is achieved it will be a major step towards addressing the issue of accessibility of evidence-based treatments for PD.

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CONFLICTS OF INTEREST
None.

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