Early intervention in panic:
a pragmatic randomised controlled trial

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ABSTRACT

Background. Many people suffer from subthreshold and mild panic disorder (PD) and are at risk of developing more severe PD.

Aims. This study was conducted to evaluate the effectiveness of an early group intervention - based on cognitive behavioural principles - to reduce panic disorder symptomatology.

Method. Participants with subthreshold or mild PD were recruited from the general population and randomised to the intervention (N=109) or wait-listed (N=108). The course was offered by 17 community mental health centres.

Results. In the experimental group 43/109 (39%) participants presented with a clinically significant change on the Panic Disorder Severity Scale - Self Report (PDSS-SR), versus 17/108 (16%) in the control group (OR for favourable treatment response = 3.49; 95% CI=1.77-6.88, p=0.001). The course had also a positive effect on DSM-IV PD status (OR=1.96; 95% CI=1.05-3.66, p=0.037). PDSS-SR symptom reduction was also substantial (between-group standardized mean difference of 0.68). The effects were maintained at 6-month follow-up.

Conclusions. People presenting with subthreshold and mild PD benefit from this brief intervention.
INTRODUCTION

Early intervention in subthreshold or mild panic disorder (PD) is of public interest because it affects a sizeable population segment, is associated with a large burden of disease and generates considerable economic costs to society. Only a few studies have been conducted in early intervention for panic symptoms in adults. The results of these studies suggest that early intervention is a promising option. However, the research lacks generalizability, given the use of a limited sample (i.e., college students and patients with panic attacks seen in an emergency room). The aim of this study was to examine the effectiveness of an early group intervention for panic symptoms, based on cognitive behavioural therapy, and offered by community mental health centres, in a sample of self-referred people presenting with subthreshold or mild PD. To strengthen the trial’s external validity, the present intervention was studied in its natural setting. We hypothesized that the intervention would show superior effects in reducing panic disorder symptomatology, relative to a wait-listed control group with unrestricted access to usual care.

METHOD

Design

We conducted a pragmatic, multi-site, randomised controlled trial of the ‘Don’t Panic’ course versus a wait-listed control group. Measurements were taken at baseline (T0), and at post-test after three months (T1). To monitor effect maintenance over time, the experimental group received an extended follow-up at 9 months after baseline, i.e., 6 months after the end of the course (T2). The randomization took place after administration of the Mini International Neuropsychiatric Interview-Plus (MINI-Plus) and was carried out centrally by an independent third party. A blocked randomization scheme was used, stratified by mental health centre, subthreshold PD versus mild PD, and by presence versus absence of co-occurring agoraphobia. The latter was included because it was assumed that agoraphobia is a prognostically relevant factor for treatment response in PD. This procedure ensured that participants with and without PD or agoraphobia were equally distributed across both trial arms. Power calculations indicated that 129 participants per condition were required in order to detect a difference in symptom reduction, equivalent to a standardized effect size of at least 0.35 in a two-sided test at alpha =0.05 and a power of (1-beta)=0.80. The trial protocol was approved by an independent medical ethics committee (METIGG) and was conducted between September 2005 and July 2007.

Sample

Participants were recruited from the general adult population in the Netherlands. They were eligible if over 18 years of age and presenting with subthreshold or mild panic disorder,
defined as having symptoms of PD falling below the cut-off of 13 on the Panic Disorder Severity Scale-Self Report (PDSS-SR). Exclusion criteria were: severe PD (PDSS-SR ≥ 13), current psychological treatment for PD-related complaints, presence of other severe mental or social problems, suicidal intention warranting treatment or likely to interfere with participation in the group course as assessed by an experienced psychologist during intake. People meeting one of the exclusion criteria were advised to seek regular treatment. If a participant used medication for anxiety or depression (e.g., benzodiazepines or antidepressants), it was agreed to keep medication use stable during the study period. Eligible participants received a complete description of the study, and only entered the trial once informed consent was obtained.

**Recruitment**
Participants were recruited from the general population using a recruitment strategy that is comparable to the strategy normally used by the community mental health centres, such as media announcements, and via banners placed on the internet. There were 17 participating community mental health centres. For screening, the standard procedures employed by the community mental health centres were used. First, people who showed interest received more information about the course and the study. They also had an initial screening interview by telephone to ascertain the presence of panic symptoms. Second, potential participants had an interview with an experienced psychologist from a community mental health centre. In this interview, the inclusion and exclusion criteria as described above were checked. In addition, potential participants were interviewed by trained interviewers from the Trimbos Institute (Netherlands Institute of Mental Health and Addiction) using the MINI-Plus. This was done to assess the DSM-IV PD status as well as possible presence of concurrent agoraphobia, and to exclude people presenting with severe depressive disorder.

**Interventions**
We developed an early intervention for panic symptoms, called the ‘Don’t Panic’ course. The course was based on cognitive-behavioural principles that have been shown to be effective in the treatment of the full-blown disorder. This course was developed specifically for adults. It consisted of 8 weekly sessions of 2 hours each in groups of 6 to 12 participants. The ‘Don’t Panic’ course manual was used by the psychologist and prevention worker offering the intervention and there was an accompanying workbook for the participants. To ensure the integrity of intervention delivery, the course instructors were trained in offering the course and working with the course manual by the Trimbos Institute (i.e., a one-day training programme by P.M.). In addition, they had access to a help desk when questions arose while offering the intervention. Participants were taught to examine their panic attacks and the possible causes, to use techniques to control anxiety levels, and
to develop coping skills. The course included (a) psycho-education on the psychological and physiological nature of anxiety and panic attacks, (b) lifestyle changes to improve their physical condition, (c) stress management to prevent constant tension by learning effective ways to cope with stress, (d) relaxation training to reduce physiological arousal, (e) cognitive restructuring to challenge and correct dysfunctional cognitions about panic and anxiety, (f) interoceptive exposure to reduce the fear of somatic sensations, (g) ‘in vivo’ exposure to reduce agoraphobic avoidance and safety behaviours, and (h) techniques aimed at relapse prevention. Participants evaluated their progress during the course. After three months following completion of the course a booster session was offered to the participants. Each session was structured and encompasses a review of homework assignments, feedback, rehearsals, information about the upcoming topics and practical skills training. The course was extensively pilot-tested before entering the clinical trial stage.\textsuperscript{15}

The control condition consisted of a waiting list. Wait-listed people were free to make use of other interventions for PD. Therefore, the control condition could also be described as care-as-usual (CAU) – with one difference: wait-listed participants knew that they could start the course 1 month after the experimental condition had completed the intervention. Wait-listed people were not kept waiting for the extended follow-up (at 9 months after baseline) for ethical reasons.

**Measures**

We used the PDSS-SR and the MINI-Plus as the primary outcome measures. Severity of panic symptoms was measured with the PDSS-SR\textsuperscript{16,17}. The PDSS-SR generates a total score ranging from 0 to 28, with a higher score indicating more severe panic symptoms. A cut-off score of thirteen discriminates between mild and severe panic disorder.\textsuperscript{9} To assess the DSM-IV panic disorder and agoraphobia status, the MINI-Plus\textsuperscript{8,10} was used. To exclude severe major depressive disorder, the depression section of the MINI-Plus was supplemented with the Sheehan Disability Scale\textsuperscript{18}. Subjects presenting with severe impairments in at least 2 areas of role functioning due to a depressive disorder, were excluded from the study. The interviews were conducted by trained interviewers who received one day’s training from the Trimbos Institute (P.M. and G.W.). For efficiency, the interviews were conducted by telephone; an approach that can be justified from a psycho-metric point of view.\textsuperscript{19,20} The interviewers were kept unaware of the randomisation status of the participants. The following self-rated questionnaires were used as secondary outcome measures. For agoraphobic avoidance the Mobility Inventory (MI\textsuperscript{21,22}) was employed. The subscale for anxiety of the Hospital Anxiety and Depression Scale (HADS-Anxiety\textsuperscript{23,24}) was used to indicate anxiety levels. The Beck Depression Inventory-second edition (BDI-II\textsuperscript{25,26}) was used to assess depressive symptoms. All outcome measures have good psychometric properties. The self-report questionnaires were utilized for all three measurements and completed at home. The MINI-Plus was conducted by telephone at T0 and T1.
**Analyses**

As the primary outcome, we compared the proportion of participants manifesting with a clinically significant change on the PDSS-SR across both conditions. A clinically significant change was defined according to the criteria proposed by Jacobson and Truax\(^27\): a change should move from a dysfunctional distribution to a functional one, and the change should be statistically reliable in the sense that the observed change cannot be attributed to measurement error. While we studied a population with subthreshold and mild PD, we considered scores below one standard deviation of the mean pre-test score on the PDSS-SR as falling within the functional range\(^28\). Participants meeting the Jacobson & Truax criterion were coded 1 (implying favourable treatment response, ‘success’) or else 0 (‘failure’). This binary outcome was used to obtain the Odds Ratio (OR) using the logistic regression model and the numbers-needed-to-be-treated (NNT) using a linear probability model for a binomial outcome (i.e., a generalized linear model for a binomial distributed error-term and using identity as the link function).

We tried to obtain converging evidence for the central clinical outcome by also evaluating the effect on PD status using the MINI/DSM-IV criteria. As indicated, the sample can be divided into two groups: people with relatively mild manifestations of MINI/DSM-IV panic disorder (N=100) and those with subthreshold manifestations not meeting the diagnostic criteria (N=117). The latter group is said to be ‘at risk’ of developing PD. In this group it could be observed how many remained PD-free at T1 (a favourable preventative outcome, ‘success’). However, when attention is paid to the former group presenting with mild PD, a favourable treatment response occurs when a participant is PD-free at T1 (‘success’). This allows a comparison of the proportion of successes across both trial conditions. Again, this yields a binomial outcome with failure coded as 0, and success as 1. In a next step, this binary outcome was used to obtain the OR and NNT as before.

For outcomes on continuous measurement scales, such as the PDSS and the HADS, a Gaussian regression model was used to test the hypothesis of superior effects in the experimental arm as compared to the wait-listed control group. We also calculated standardized between-group mean differences (Cohen’s \(d\) effect size).

To test effect maintenance up to the extended follow-up at 9 months after baseline in the experimental condition, we used a paired-samples T-test to analyse the difference in mean score of the self-report measures in the experimental group from T0 to T1, T0 to T2 and T1 to T2.

All analyses were conducted in agreement with the intention-to-treat (ITT) principle\(^29\), hence all participants were analysed in the condition to which they were randomised, and missing endpoints at follow-up were imputed using a regression model with the best available predictors of outcome and the best predictors for dropout. The first set of predictors is required to obtain the most precise estimates for the missing values; the latter set of predictors is used to correct for bias that may stem from differential loss-to-follow-up associated with T0 variables\(^30\). To provide a more comprehensive picture of the effects of the intervention, the outcomes were
also analysed for intervention completers only (admittedly somewhat arbitrarily defined as participants who attended at least 6 sessions).

In all analyses, we accounted for the clustering of data induced by the multi-site character of the study. Clustering violates the assumption of independence of observations, and may thus affect standard errors and $P$ values. So-called ‘robust standard errors’ and correct $P$ values were obtained using the first-order Taylor-series linearization method. All analyses were conducted with Stata 9.0 (StataCorp LP, College Station, TX, USA, 2005). All tests were conducted using a two-sided significance level of $p=0.05$.

**Figure 1.** Participants’ flow through the study*

* Abbreviations: PDSS-SR = Panic Disorder Severity Scale-Self Report; PD = Panic Disorder; MINI-Plus = Mini-International Neuropsychiatric Interview-Plus.

a Participants can have more than one contraindication.

b Including: somatic problems (n=11).

c Including: practical restraints.

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Interested subjects and telephonic screening
$n = 586$

Other psychiatric symptoms
than panic symptoms
or practical restraints
(work, travelling) $n = 210$

Interview using inclusion and exclusion
criteria and PDSS-SR
$n = 376$

Contraindication by clinician
$n = 129$: psychiatric or social
problems $n = 80$;
PDSS$>12$ $n = 56$;
professional treatment PD $n = 13$;
on-response $n = 21$.

Diagnostic interview MINI-Plus
$n = 222$

DSM-IV Severe mood disorder $n=4$
suicidal $n = 1$

Randomisation after informed consent
$n = 217$

Intervention
$n = 109$

Intervention
not started $n=4$ (4%)  
$>= 6$ sessions completed
$n = 82$ (75%)

Post intervention T1  
diagnostic interview $n = 106$ (97%)  
selfreport measures $n = 96$ (88%)

Waiting list
$n = 108$

T1  
diagnostic interview $n = 106$ (98%)  
selfreport measures $n = 98$ (91%)

Follow-up  
selfreport measures $n = 99$ (91%)
RESULTS

Characteristics of the sample and attrition
A total of 586 persons expressed an interest in the course. During a first screening by telephone, it transpired that 210 of them presented with psychiatric symptoms other than panic related (e.g., related to social phobia or generalized anxiety), or had practical obstacles (work, travel distance) that precluded their participation in the trial. The remaining 376 participants had an interview with an experienced psychologist. A total of 217 participants entered the study and were randomised to the experimental group (N=109) or the control group (N=108) (Figure 1).

The baseline characteristics of the study participants are presented in Table 1.

Table 1. Baseline characteristics of the participants for Total group, Experimental group and Control group*

<table>
<thead>
<tr>
<th></th>
<th>Total group (n=217)</th>
<th>Experimental group (n=109)</th>
<th>Control group (n=108)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>154 (71)</td>
<td>77 (71)</td>
<td>77 (71)</td>
</tr>
<tr>
<td>Mean age, Years (SD)</td>
<td>42 (12.4)</td>
<td>42 (12.9)</td>
<td>42 (11.8)</td>
</tr>
<tr>
<td>Age, Range</td>
<td>20-75</td>
<td>20-75</td>
<td>20-74</td>
</tr>
<tr>
<td>Married/living with partner, n (%)</td>
<td>169 (78)</td>
<td>83 (76)</td>
<td>86 (80)</td>
</tr>
<tr>
<td>Employed (paid), n (%)</td>
<td>151 (70)</td>
<td>75 (69)</td>
<td>76 (70)</td>
</tr>
<tr>
<td>Years of education, mean (s.d.)</td>
<td>14.04 (3.26)</td>
<td>14.07 (3.29)</td>
<td>14.01 (3.25)</td>
</tr>
<tr>
<td>MINI-Plus-Panic Disorder, current, n (%)</td>
<td>100 (46)</td>
<td>50 (46)</td>
<td>50 (46)</td>
</tr>
<tr>
<td>MINI-Plus-Agoraphobia, current, n (%)</td>
<td>135 (62)</td>
<td>68 (62)</td>
<td>67 (62)</td>
</tr>
<tr>
<td>PDSS-SR, mean (s.d.) (range: 0-28)</td>
<td>7.18 (3.23)</td>
<td>7.02 (3.24)</td>
<td>7.35 (3.24)</td>
</tr>
<tr>
<td>HADS-Anx., mean (s.d.) (range: 0-21)</td>
<td>9.54 (3.83)</td>
<td>9.48 (3.94)</td>
<td>9.60 (3.74)</td>
</tr>
<tr>
<td>MI, mean (s.d.) (range: 1-5)</td>
<td>1.96 (0.66)</td>
<td>1.89 (0.62)</td>
<td>2.02 (0.69)</td>
</tr>
<tr>
<td>BDI-II, mean (s.d.) (range: 0-63)</td>
<td>12.46 (7.64)</td>
<td>11.96 (8.01)</td>
<td>12.97 (7.26)</td>
</tr>
</tbody>
</table>

* Abbreviations: MINI-Plus = Mini International Neuropsychiatric Interview-Plus; PDSS-SR = Panic Disorder Severity Scale-Self Report; HADS-Anx. = Hospital Anxiety and Depression Scale, subscale Anxiety; MI = Mobility Inventory; BDI-II = Beck Depression Inventory-second edition.
In the sample, 71% were female. The mean age was 42 years, ranging from 20 to 75 years. Most participants were employed and were living with a partner (Table 1). The experimental and the control group did not differ significantly with regard to socio-demographic and clinical characteristics. Almost 50% met the DSM-IV criteria of (mild) PD at entry to the study, while 62% were diagnosed with agoraphobia. Overall, 194 (89%) participants completed the T1 self report questionnaire, with no significant difference in response rate between both conditions. Completers did not differ significantly from non-completers on any of the baseline variables. Follow-up data of 99 participants (91% of the experimental group) became available at 6 months after completion of the course.

Effects on clinically significant change
The functional range turned out to be a score below 3.95 on the PDSS-SR; this is 4 scale points below the cut-off score of 8 which may discriminate between the presence or absence of current DSM-IV panic disorder\textsuperscript{16,17}. The reliable change on the PDSS-SR appeared to be a pre-post difference of at least 3.85 scale points. We coded for ‘success’ when a reliable pre-post change of 3.85 scale points had occurred and when, in addition, the cut-off value of 4 on the PDSS was crossed. In the experimental group 43/109 (39%) participants, versus 17/108 (16%) participants in the control group presented with a successful outcome: OR=3.49; 95% CI=1.77-6.88, p=0.001; NNT=4.2 under an intention-to-treat analysis. These results compare well with completers-only findings: OR=3.79; 95% CI=1.94-7.41, p=0.001; NNT=3.9.

It was further tested whether there was any difference in the primary outcome between people with subthreshold PD and those with mild PD. A logistic regression analysis revealed no significant difference (OR=0.88; robust SE=0.6755; t=-0.16; p=0.878).

Effects on MINI/DSM-IV diagnostic status
In the experimental group 89/109 (82%) participants presented with a favourable treatment response on the MINI-Plus, compared to 75/108 (69%) participants in the control group (Table 2; OR=1.96; 95% CI=1.05-3.66, p=0.037; NNT=8.2; completers only OR=2.57; 95% CI=1.08-6.02, p=0.034; NNT=6.3).

Effects on panic severity
The course was found to have a beneficial effect on reducing panic severity levels compared to the wait-list control group (PDSS-SR; p=0.004). The mean score on the PDSS-SR at T1 for the experimental group was 3.48 versus 5.77 for the control group. The standardized effect size on the PDSS-SR at T1 was 0.68; from a clinical perspective this can be interpreted as a large effect\textsuperscript{31}. For completers only the mean score at T1 was 3.19 (significant at p=0.002) and the effect size was 0.77.
Table 2. Success on the MINI-Plus, n=217*  

<table>
<thead>
<tr>
<th>PD-status</th>
<th>Experimental (n=109)</th>
<th>Control (n=108)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Subthreshold PD at T0</td>
<td>59</td>
<td>58</td>
<td>58</td>
</tr>
<tr>
<td>Success (stayed PD-free at T1)</td>
<td>51</td>
<td>86%</td>
<td>43</td>
</tr>
<tr>
<td>Mild PD at T0</td>
<td>50</td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>Success (became PD-free at T1)</td>
<td>38</td>
<td>76%</td>
<td>32</td>
</tr>
<tr>
<td>Total success on the MINI-Plus</td>
<td>89</td>
<td>82%</td>
<td>75</td>
</tr>
</tbody>
</table>

* Abbreviations: PD = Panic Disorder; MINI-Plus = Mini International Neuropsychiatric Interview-Plus.

Other outcomes  
The scores for the other outcomes are presented in Table 3.

Table 3. Means and Standard Deviations for Experimental and Control Group at Baseline (T0) and Post-test (T1), and Effect Sizes at Post-test (T1)*  

<table>
<thead>
<tr>
<th>Scale measure</th>
<th>Experimental (n=109)</th>
<th>Control (n=108)</th>
<th>Effect Size*</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDSS-SR (range: 0-28)</td>
<td>T0, mean (s.d.)</td>
<td>7.02 (3.24)</td>
<td>7.35 (3.24)</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>T1, mean (s.d.)</td>
<td>3.48 (3.22)</td>
<td>5.77 (3.54)</td>
<td></td>
</tr>
<tr>
<td>HADS-Anx. (range: 0-21)</td>
<td>T0, mean (s.d.)</td>
<td>9.48 (3.94)</td>
<td>9.60 (3.74)</td>
<td>0.59</td>
</tr>
<tr>
<td></td>
<td>T1, mean (s.d.)</td>
<td>6.26 (3.93)</td>
<td>8.61 (4.00)</td>
<td></td>
</tr>
<tr>
<td>MI (range: 1-5)</td>
<td>T0, mean (s.d.)</td>
<td>1.89 (0.62)</td>
<td>2.02 (0.69)</td>
<td>0.44</td>
</tr>
<tr>
<td></td>
<td>T1, mean (s.d.)</td>
<td>1.67 (0.57)</td>
<td>1.95 (0.70)</td>
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</tr>
<tr>
<td>BDI-II (range: 0-63)</td>
<td>T0, mean (s.d.)</td>
<td>11.96 (8.01)</td>
<td>12.97 (7.26)</td>
<td>0.31</td>
</tr>
<tr>
<td></td>
<td>T1, mean (s.d.)</td>
<td>9.20 (7.89)</td>
<td>11.58 (7.69)</td>
<td></td>
</tr>
</tbody>
</table>

* Abbreviations: PDSS-SR = Panic Disorder Severity Scale-Self Report; HADS-Anx. = Hospital Anxiety and Depression Scale, subscale Anxiety; MI = Mobility Inventory; BDI-II = Beck Depression Inventory-second edition.
*a Between-group effect size (Cohen’s d).
*b Difference in outcome between the experimental group and the control group.
The course was superior to the waiting list condition on all outcomes. The between-group effect sizes for these secondary outcomes ranged from 0.31 to 0.59. For completers only the results of the analyses were comparable.

There was no significant difference in the use of medication between the groups at baseline. In the experimental group 36 (33%) participants used medication at baseline, 3 (3%) started medication during the course and 9 (8%) stopped using medication. In the control group 48 (44%) participants used medication at baseline, 7 (6%) started and 8 (7%) stopped medication in the period between baseline and T1. Therefore, it is unlikely that the present findings can be explained by changes in medication use.

**Effect maintenance at 6-month follow-up**

The difference in mean scores on the self report measures of the experimental group from T0 to T1 and T0 to T2 were all significant at p<0.001. The mean score at T2 on the PDSS-SR (mean=3.48, s.d.=3.42) and the HADS-Anx. (mean=6.13, s.d.=3.81) of the experimental group did not differ significantly from T1 (PDSS-SR: p=0.995, HADS-Anx.: p=0.627). The mean score at T2 on the MI (mean=1.61, s.d.=0.60) and the BDI-II (mean=7.83, s.d.=7.53) were significantly lower than at T1 (MI: p=0.037, BDI-II: p=0.007). The results suggest that the improvement after the course was maintained at 6-month follow-up.

**Acceptability**

After each session, the attendance of the participants was registered and it was ascertained whether they had carried out their homework assignments. On the basis of this information it can be concluded that 4 participants in the experimental group (4%) did not start the course. Reasons for not starting were beginning another course and lack of time because of work. Eighty-two (75%) subjects of the experimental group completed the course (completing the course is defined as attending at least 6 sessions). The main reasons for not completing the course were practical obstacles (work, illness). The mean number of attended sessions was 6.3 sessions. Of the attending participants, 83% had completed their homework for each session, 15% did not complete their homework for 1 session, 1.4% for 2 sessions, 0.5% for 3 sessions and 0.5% for 4 sessions. Therefore, compliance with the course was satisfactory.

The post-test self-report questionnaire of the experimental group provided information about satisfaction with the course (response rate 83%, n=91). The participants evaluated the course positively (organizational aspects, coaching, content, group sessions, and workbook). Asked whether the course had contributed to being better able to manage panic complaints, 88% answered in the affirmative. The participants rated psycho-education about anxiety and panic attacks, changing lifestyle, relaxation training, and cognitive restructuring as most helpful. On a scale ranging from 1 ‘very bad’ to 10 ‘excellent’, the mean rating for the course was 7.8 (range: 5-9, s.d.=0.945). These findings add to the impression that the course is acceptable.
DISCUSSION

Effects on panic symptoms
We hypothesized that the ‘Don’t Panic’ course would be superior in reducing panic disorder symptomatology. The results show that the participants in the experimental group made significantly more improvement on panic symptoms compared to the wait-listed control group on all outcomes. Furthermore, symptoms of depression declined, as measured by the BDI-II. This finding is important because people with panic symptoms may also have higher rates of depressive symptoms\(^32\). To our knowledge this is the first study that shows the effectiveness of an early group intervention for self-referred adults with subthreshold or mild panic disorder. The improvements were maintained over 6 months after the course. These findings are in agreement with previous findings on prevention and early intervention of panic disorder\(^6,7\). The difference between the present sample and clinical samples\(^16,17\) is emphasized by the substantially lower mean degree of severity of panic symptoms as measured with the PDSS-SR at baseline.

Acceptability of the course
The participants who evaluated the course assessed it as positive and helpful. Compliance with the course was satisfactory. These findings suggest the course is suitable and acceptable. This is furthermore supported by the fact that many (about 40%) community mental health centres in the Netherlands now offer the course on a regular basis. In addition, an economic evaluation of the intervention showed that it may be acceptable from a cost-effectiveness point of view\(^33\). The results may be highly generalizable, as the course was examined in its natural setting and the recruitment strategy of the study and the community mental health centres that offer the course are comparable. Another strength of this study was the high response rate.

Limitations
We recognize a number of limitations in this study. First, because of the absence of a placebo control, it is not clear whether nonspecific components of the course, such as social interaction and expectation of gain contribute to the early intervention effect. Future research should use placebo controlled designs to overcome this limitation. Second, the period allocated to studying change in PD status was only 3 months. For ethical reasons the control group received the intervention a few weeks after T1. In future research longer follow-up is recommended to study changes in the incidence of PD. Third, the extended follow-up in the treatment group was only 6 months following the conclusion of the course. Longer follow-up periods are needed to know how long the beneficial effects will persist.
CONCLUSION

Overall, our findings carry the promise that prevention and early intervention through a brief intervention for people with subthreshold or mild PD can be effective. The selected target group is known to be reticent in asking professional help and it is therefore good to see that a low threshold intervention is apparently regarded as accessible and acceptable.

ACKNOWLEDGEMENTS

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REFERENCES


Early intervention in panic

**Introduction**
- Panic disorder is a mental disorder affecting 2% - 3% of the adult population annually.
- It is associated with a large burden of disease, considerable medical consumption and extensive loss of productivity.
- A large population segment suffers from subthreshold and mild panic disorder and is at risk of developing more severe panic disorder.
- This underscores the public health importance of prevention and early intervention of panic disorder.
- The course “Don’t Panic” is an early intervention and can be used as a first step in a stepped-care model in mental health.

**Intervention**
- 8 weekly sessions of 2 hours which contain:
  - psycho-education
  - changing life-style
  - managing stress
  - relaxation training
  - cognitive restructoring
  - interoceptive exposure
  - ‘in vivo’ exposure
  - relapse prevention
- 6 to 12 participants per group

**Study**
- Pragmatic, pre-post, two-group, multi-site, randomised controlled trial
- Setting: 17 community mental health centers in the Netherlands
- Outcome measures:
  - Diagnoses (MINI-Plus)
  - Severity of panic symptoms (PDSS-SR)
  - Symptoms of agoraphobia (MI)
  - Cognitive measure for panic (PAI)
  - Depressive symptoms (BDI-II)
  - Questionnaires to evaluate the course by the participants at posttest
- Analyses: Intention to Treat
- Measurements:
  - Before intervention (T0)
  - After intervention (T1)
  - Follow-up 6 month after intervention (T2)

**Baseline characteristics**
- 217 participants
  - Experimental group (N = 109), control group (N = 108)
  - 71% female
  - 42 years of age (M)

**Results**
- The participants in the experimental group improved significantly more on panic symptoms compared to the wait-listed control group on all outcomes.
- Escalation toward more severe manifestations of panic disorder is avoided.
- Panic symptom levels were much reduced.
- The improvements were maintained over 6 months after the course.
- The participants evaluated the course positively and the compliance was satisfactory.

**Conclusions**
- Early intervention through a brief intervention for people with subthreshold or mild panic disorder can be effective.
- The target group is known to be reticent in asking professional help and it is therefore good to see that a low threshold intervention is apparently regarded as accessible and acceptable.