Randomized Controlled Trial of Adult Therapeutic Coloring for the Management of Significant Anxiety in the Emergency Department

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ABSTRACT

Background: Anxiety and acute distress are significant concerns in the emergency department (ED). Adult coloring books are often utilized as an effective means of relaxation in waiting rooms and newsstands, but there are no reported randomized trials examining their effectiveness as a treatment for anxiety.

Methods: We set out to examine the effectiveness of adult coloring books using a randomized placebo-controlled trial at a university-affiliated tertiary ED. Anxiety was measured using a validated self-reporting score, the Hospital Anxiety and Depression Scale (HADS-A), with a range of 0 to 21. Patients with HADS-A $\geq$ 7 were randomly assigned to either an adult coloring pack (n = 26) or placebo pack (n = 27). The primary outcome measure was the within-patient change in HADS-A scores following 2 hours of exposure.

Results: A convenience sample of 117 patients were screened, and 53 patients were randomized. Characteristics of allocated groups were similar in terms of sex, diagnosis, and ethnicity. A higher proportion of intervention subjects spent $\geq$1 hour engaged with their activity (46.2% vs. 4.0%, p = 0.01). For the primary outcome measure, the mean within-patient decrease in HADS-A score at 2 hours for intervention subjects was 3.7 (95% confidence interval [CI] = 2.4 to 5.1, p < 0.001) versus a decrease of 0.3 (95% CI = –0.6 to 1.2, p = 0.51) in the placebo group.

Conclusions: Among ED patients, exposure to adult coloring books resulted in lower self-reported levels of anxiety at 2 hours compared to placebo.

In recent years the number of emergency department (ED) presentations have significantly increased internationally, leading to prolonged waiting times and overcrowding.[1] Anxiety disorders are the most common psychological disorders and have a high prevalence in the ED.[2] The stressful nature of an unplanned hospital visit may exacerbate underlying anxiety disorders. Further, acute medical illnesses including severe pain and shortness of breath may worsen symptoms of distress.[3–6] Nonpharmacologic treatment of anxiety and distress are well described in the pediatric literature and could represent an avenue for managing distress in adult patients during periods of waiting.[7–9]

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Given that the ED is a stress inducing environment, nonpharmacologic therapy for anxiety in the form of art therapy may be useful. Moreover, the Australasian College of Emergency Medicine has recently put forward an aspirational approach to improving care of patients with mental health disorders. Specifically, the recommendation stated that "the ED should be a place that is safe and supportive for all, not a place that people want to escape from. Long, uncertain waits are unacceptable."[10] Further, there is evidence to suggest that unoccupied time in the ED can increase patients' negative perceptions of their waiting time with a strong association between delays and overall dissatisfaction.[11,12]

Commonly available adult coloring books have been used extensively in the community as an effective strategy for reducing anxiety,[13,14] but have not been formally studied in an ED setting. Art therapy has been hypothesized to be an effective mindfulness strategy that alleviates symptoms of anxiety through cognitive easing.[14,15] Prior observational studies have shown that art therapy can reduce symptoms of anxiety in healthy university students and oncology patients in a hospital setting.[16–19]

Abbing et al.,[20] in their 2018 review of the effectiveness of art therapy on anxiety in adults, identified only three studies with a total of 162 patients and concluded that the small sample size and large heterogeneity within the data set made it impossible to perform a meta-analysis. Many systematic reviews evaluating art therapy as a treatment for anxiety suggest potential benefit but conclude that more well-designed randomized controlled trials (RCTs) are required.[20–23] These reviews acknowledged the anecdotal evidence that art therapists and other health care professionals experience regarding the impact of art therapy in patient care but called for trials that were randomized and placebo controlled to obtain stronger evidence on the efficacy of art therapy.

Art therapy has a low potential risk of harm and represents a simple short-term intervention in a busy ED setting. Furthermore, art therapy requires little staff supervision, explanation, or facilitation and is low in cost, making it an ideal intervention for the busy ED setting. The purpose of this study was to test the effect of adult coloring books on anxiety in the ED. We hypothesized that patients who spent up to 2 hours engaged with adult coloring book images would experience a significant drop in their anxiety compared with patients who were provided with a placebo.

MATERIALS AND METHODS

Study Design and Setting

This study was conducted at Westmead Hospital, a university-affiliated tertiary center in Sydney, Australia. The Westmead Hospital ED receives around 80,000 presentations a year. Ethical approval was obtained through the Western Sydney Local Area Research Ethics Committee (HREC/17/WMEAD/354) and adhered to Australian national guidelines.[24]

This study was a RCT comparing adult coloring books to placebo for the treatment of anxiety in the ED. Patients were approached by investigators from Monday to Friday between 8 AM and 6 PM. ED staff were made aware that a "study on anxiety" was occurring and were invited to flag patients for screening. From April 2018 to January 2019, convenience sampling occurred based on the rostered availability of two lead investigators. Patients were asked if they would be willing to participate in a research study related to nonmedical therapy and anxiety in the ED. Following written consent, a validated score, the Hospital Anxiety and Depression Scale (HADS-A) anxiety subscale, was used for screening. The HADS-A was assessed again at 2 hours for patients who were randomized.

Selection of Participants

All patients in the ED treatment area were potentially eligible for the study. Potential patients were flagged as being "anxious" by senior medical officers (residents and consultants), triage nurses, or an ED social worker who then referred them to the research team. For inclusion in the trial it was necessary for participants to be ED patients with "moderate-severe anxiety" (HADS-A $\geq$ 7). Patients were required to be able to provide informed written consent. Patients were excluded if they were age < 16 years, were unable to provide informed consent, were a perceived aggression risk, had a past history of violence, or were Glasgow Coma Score < 15. Figure 2 describes the flow of participants for selection into the trial. The investigators noted that a proportion of the subjects approached for the trial simply declined to participate even prior to being screened for eligibility. Potential reasons for this have been expanded on in the discussion section of this paper.

Interventions

Participants in the intervention arm were provided with a "coloring pack," which included 10 standardized adult

mindfulness coloring book images and 36 pencils from the "Milan Colored Pencils in Tin" set. The selection of 10 coloring pages from adult art books was based on images described in the prior art therapy literature including mandalas, buildings, and fictitious animals.[14,16] Control subjects were provided with a "placebo pack" containing a Bic pen and 10 sheets of A4 paper and were instructed to draw or write freely. The placebo pack was chosen as an active control to provide these patients with an activity and thus avoid comparing the intervention with an inactive control.

Measurements

There are various validated self-reporting tools for quantifying anxiety including the HADS-A.[25,26] Further, the HADS-A has been validated in various languages and groups of patients including in the ED.[27–29] Our review of the literature noted that the HADS-A has an equivalent validity for the screening of anxiety disorders as other more time consuming scales.[29,30] Previous studies have identified various cut points of ≥7 (scale = 0–21) as being representative of significant anxiety.[31,32] Therefore, a cut point of ≥ 7 was selected as the main inclusion criteria.

Outcomes

The primary outcome measure was the within-patient change from baseline HADS-A score following 2 hours of therapy (Figure 1). Demographic data collected included age, sex, ethnicity, and prior use of art therapy. Secondary measures included postintervention survey questions quantifying the value of the therapy and engagement with the treatment packs. Engagement was a patient reported estimate of the length of time engaged with the trial packs. Additionally, intervention subjects were asked if they would "recommend the coloring" to other patients (Likert scale = 1–5).

Power Calculation

An observational pilot study of 15 patients was conducted by the investigators as an internal quality assurance project at the Westmead Hospital ED. This study estimated the standard deviation (SD) of the within-patient change in HADS-A score over 2 hours was 2.3. For a conservative sample size calculation, we assumed the SD of the within-patient change in HADS-A following 2 hours of exposure to therapy would be 3. Therefore, a sample size of 48 patients (24 per arm) would have an 80% power to detect a difference of 2.5 or more in the mean change of HADS-A for the intervention group compared to the placebo group (two-sample t-test, 5% two-sided significance level). To account for an anticipated 10% dropout rate, a total sample size of 52 patients was finalized.

Randomization and Blinding

Sealed study packs (n = 56) were produced containing half placebo and half coloring materials. Allocation of study pack numbers occurred by the generation of consecutive random numbers by a statistician. Following consent, patients were screened, and those meeting the inclusion criteria were allocated randomization group by taking a pack blindly from a sturdy box. Blinding was limited given the clear visibility of both the intervention and the placebo but allocation concealment was maintained during the 2 hours of exposure to the activities.

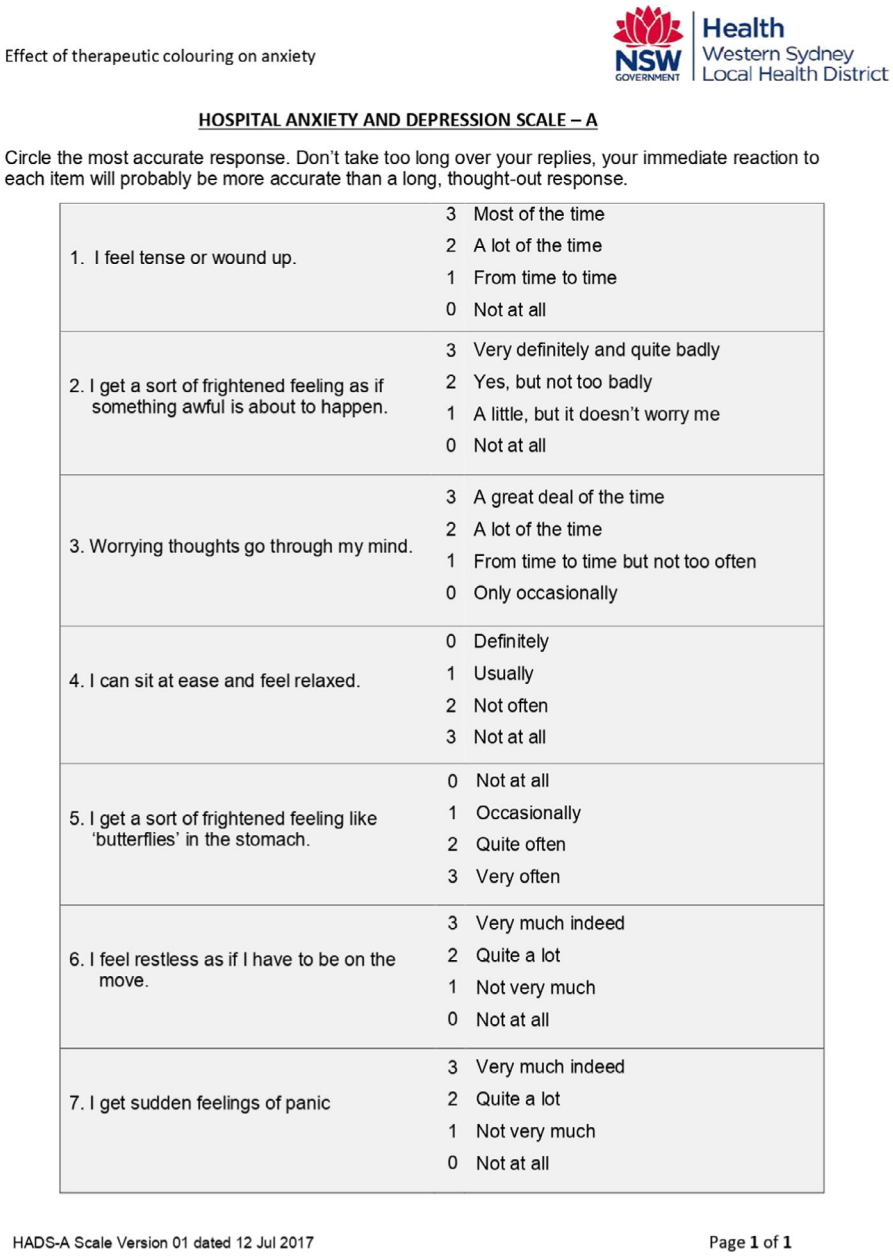
Data Analysis

Data were analyzed using IBM SPSS (V24). The mean and SD were used to summarize continuous variables. Frequencies and percentages were used for categorical variables. A two-sample t-test was used to test for differences in the distribution of continuous variables between intervention and control groups. For comparative analysis, mean differences are reported together with 95% confidence intervals (CIs). Chi-square or Fisher's exact tests were used as appropriate to test for association between categorical variables. Two-tailed tests with a 5% significance level were used throughout.

RESULTS

Over 9 months, 117 ED patients aged 16 to 80 years were consented and screened. Sixty-four patients were excluded (Figure 2). Included patients (n = 53) were randomized to either intervention (n = 26) or placebo (n = 27). Baseline characteristics of the groups including sex, age, ethnicity, prior exposure to art therapy, and diagnosis were similar (Table 1). There was a significant difference in length of engagement with the respective activities provided (p = 0.01). Further, 37.0% of participants allocated to placebo engaged with the allocated activity for less than 5 minutes compared to nil in the intervention group.

Table 2 summarizes the distribution of the HADS-A scores at baseline and following 2 hours of therapy. Table 2 also reports on the primary outcome measure



Effect of therapeutic colouring on anxiety

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HOSPITAL ANXIETY AND DEPRESSION SCALE – A

Circle the most accurate response. Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

1. I feel tense or wound up.	3 Most of the time 2 A lot of the time 1 From time to time 0 Not at all
2. I get a sort of frightened feeling as if something awful is about to happen.	3 Very definitely and quite badly 2 Yes, but not too badly 1 A little, but it doesn't worry me 0 Not at all
3. Worrying thoughts go through my mind.	3 A great deal of the time 2 A lot of the time 1 From time to time but not too often 0 Only occasionally
4. I can sit at ease and feel relaxed.	0 Definitely 1 Usually 2 Not often 3 Not at all
5. I get a sort of frightened feeling like 'butterflies' in the stomach.	0 Not at all 1 Occasionally 2 Quite often 3 Very often
6. I feel restless as if I have to be on the move.	3 Very much indeed 2 Quite a lot 1 Not very much 0 Not at all
7. I get sudden feelings of panic	3 Very much indeed 2 Quite a lot 1 Not very much 0 Not at all

HADS-A Scale Version 01 dated 12 Jul 2017 Page **1** of **1**

Figure 1 Hospital Anxiety and Depression Scale (HADS-A) anxiety subscale.

(within-patient change in HADS-A from baseline to 2 hours). For the primary outcome, the mean within-patient decrease in HADS-A score after 2 hours of intervention therapy was 3.7 (95% CI = 2.4 to 5.1, $p < 0.001$). The change in HADS-A score at 2 hours in intervention subjects was significantly greater ($p < 0.001$) than the mean placebo group change of 0.3 (95% CI = –0.6 to 1.2, $p = 0.51$).

Although, the HADS-A scores did not differ significantly at baseline ($p = 0.22$), the intervention group had higher mean HADS-A scores than the placebo group at baseline. At 2 hours, the intervention group had significantly lower HADS-A scores when compared with controls (mean difference = 3.4, 95% CI = 1.9 to 5.0, $p = 0.03$). A general linear model was used to adjust for the imbalance at baseline. The mean difference between groups at 2 hours adjusted for the baseline HADS-A score was 3.2 (95% CI = 1.6 to 4.7, $p < 0.001$).

The box plot (Figure 3) illustrates the distribution of the primary outcome measure (i.e., the within-patient decrease in HADS-A score from baseline to 2 hours). It appears that the within-patient changes observed in the placebo group were evenly distributed above and below the reference line at zero—corresponding to no significant change in reported anxiety.

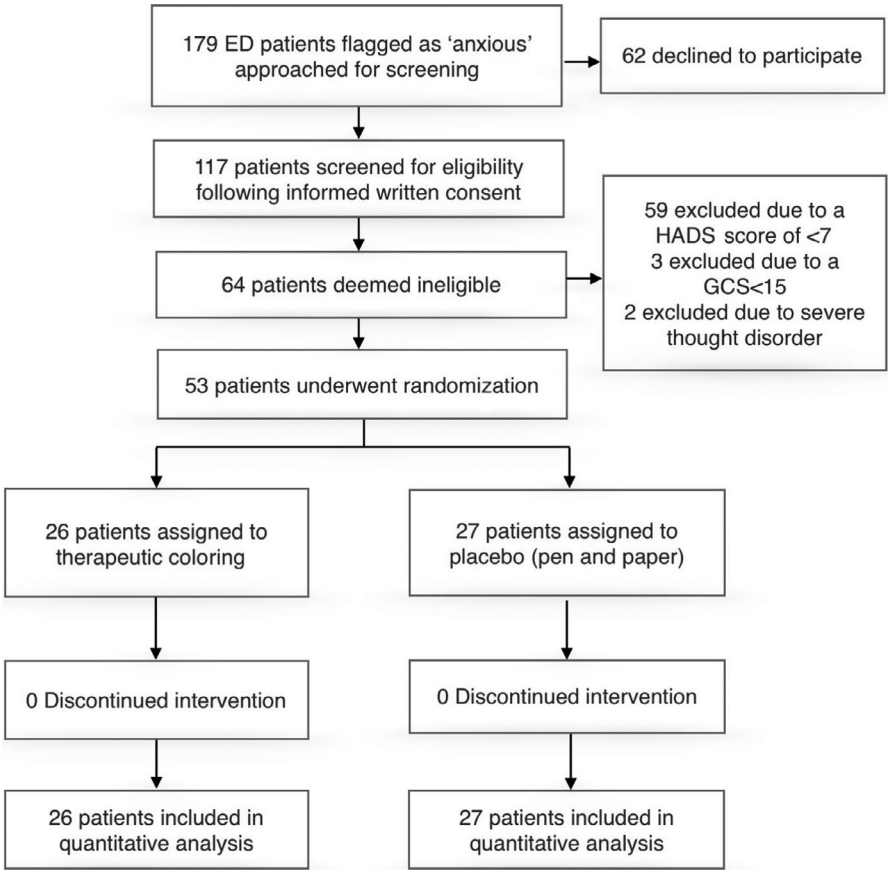

Figure 2 Flow diagram. GCS = Glasgow Coma Scale; HADS = Hospital Anxiety and Depression Scale.

Table 1
Participant Characteristics

	Intervention (n = 26)	Control (n = 27)
Age (years)	32 (±12)	34 (±15)
Male	6 (24.0)	8 (29.6)
Prior use of art therapy	3 (11.5)	2 (7.4)
Diagnosis		
Psychiatric	12 (46.2)	12 (44.4)
Medical	5 (19.2)	8 (29.6)
Unknown	9 (34.6)	7 (25.9)
Ethnicity		
Caucasian	18 (69.2)	16 (59.3)
Asian	6 (23.1)	4 (14.8)
Middle Eastern	2 (7.7)	5 (18.5)
Aboriginal/Torres Strait Islander	0 (0)	2 (7.4)
Minutes used resource		
<5	0 (0)	10 (37.0)
5–60	14 (53.8)	13 (48.1)
60–120	12 (46.2)	4 (14.8)

Data are reported as mean (±SD) or n (%).

Table 2
Primary Outcome Measure (Within-patient Change in HADS-A After 2 Hours)*

	Intervention (n = 26)	Control (n = 27)	p-value
Baseline HADS-A scores	13.1 (±3.3)	12.0 (±3.2)	0.22
2-hour HADS-A scores	9.3 (±3.3)	11.7 (±4.1)	0.03
Decrease in HADS-A from baseline to 2 hours*	3.7 (±3.3)	0.3 (±2.3)	<0.001

Data are reported as mean (±SD).
HADS-A = Hospital Anxiety and Depression Scale.

By contrast, all except two patients in the intervention group showed an improvement in their HADS-A score after 2 hours of therapy.

The 26 patients allocated to the intervention group were asked if they would recommend coloring (Likert scale of 1 to 5 with 1 being "would not recommend" and 5 being "would recommend") as a measure of patient satisfaction with the coloring activity. Ten of these patients scored a 5, eleven scored 4, four scored 3, and only one patient scored 1. The average satisfaction score on this scale was 4.2

DISCUSSION

In this RCT we demonstrated a marked reduction in reported anxiety at 2 hours in the coloring therapy

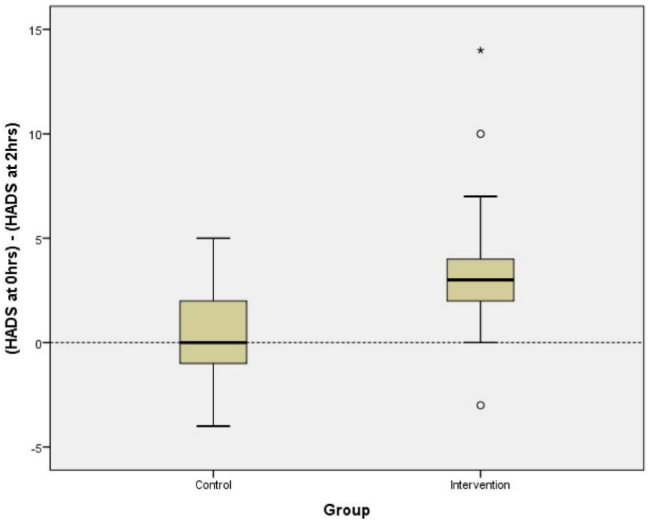

Figure 3 Box plot of within-patient decrease in Hospital Anxiety and Depression Scale (HADS-A) score at 2 hours.*

group. The mean reported difference between groups at 2 hours adjusted for the baseline HADS-A score was 3.2 (95% CI = 1.6 to 4.7, $p < 0.001$). Close to half of the patients of the intervention group engaged for over 60 minutes compared to only 15% of the placebo group suggesting that the art therapy was engaging. Further, the majority of patients in the intervention were highly likely to recommend the experience to other patients. Therefore, in selected patients, art therapy represents a simple patient-centered intervention that confers benefit through distraction leading to short-term stress reduction. These findings might be due to the fact that the task of coloring is thought to be an activity that creates a state of mindfulness even in a noisy environment.[16,21]

In terms of generalizability and veracity of the findings, the groups were similar at baseline and the fragility index of the primary outcome measure is low. This short-term effect is important because ED environments are increasingly overcrowded, with a lack of access to inpatient hospital beds leading to long ED stays.[1,10] Finding reliable strategies to reduce anxiety over these long wait times is likely to have a future benefit. We note that our cohort was heterogeneous in terms of diagnosis, sex, and ethnicity with the most common reason for presentation to ED being a mental health complaint (Table 1). The mixed study population suggests that the results could be applied to any heterogeneous group of patients in an acute hospital setting.

Importantly, we did not ask or assess the patients for mitigating factors that could be causing their acute anxiety. Waiting times, overcrowding, previous adverse experiences, or intercurrent illnesses could all contribute to severe distress.[33] While art therapy represents an opportunity for better ED care at a low cost, we should not assume that a universal provision of this therapy would be either appropriate or effective. Qualitative research on patient experiences with art therapy have revealed that a natural resistance to engagement in art therapy may evoke negative experiences for the patient.[34] This may include frustration, fear of failure, and production of negative feelings during or after the art-based experience.[35]

LIMITATIONS

The main limitations of this study were the relatively small number of patients enrolled and the lack of blinding. Further, given the study was carried out in a single center, caution must be used in extrapolating the results to other settings. Additionally, the intervention and measurement of effect size occurred over a 2-hour period. While this correlates with the length of a typical ED waiting time there is no evidence that the therapeutic effect would be sustained beyond 2 hours. In terms of blinding, the lack of overall blinding was an unavoidable aspect of the study that may have led to bias.[36] Care was taken to minimize bias by clearly predefining the inclusion criteria, randomizing patients with the aid of computer-generated tables and maintaining allocation concealment. To minimize response bias, we ensured that participants received standardized instructions and were blinded to the intent of the study.[37] To minimize interviewer bias and its potential influence on the self-reported anxiety scores, investigators quantifying the HADS-A scores followed a standardized script and underwent training in using self-reporting questionnaires.[36,38] Only three investigators involved in the project administered and recorded HADS-A scores. Using a small number of investigators is likely to have minimized variation in HADS-A score measurement. Another inherent limitation of the study was that patients who had a favorable impression of art therapy could possibly have been more motivated to participate in the trial. As highlighted in Figure 2, a total of 62 of the 179 patients approached for the trial simply declined to participate. Various reasons were cited by patients; common anecdotes included "coloring is not for everyone," "it's for children," or "I am in too much discomfort to engage." While the results of this study should prevent nonpharmacologic treatments for anxiety being

trivialized by health care staff, showing evidence that alternative treatments can work may not overcome the barriers to engagement that we have observed.

CONCLUSIONS

In summary, this randomized controlled trial examined the provision of therapeutic art therapy versus placebo in a heterogeneous group of patients reporting symptoms of significant anxiety. Given the result strongly favoring a reduction in anxiety with the art therapy intervention, we conclude in line with prior observational studies that the use of therapeutic art in the ED is a reasonable strategy for reducing anxiety.[20] This therapy could be used effectively for both medical and psychiatric patients to mitigate stress during periods of waiting in busy acute hospital settings.

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