The Efficacy of Art Therapy on Mental Health Outcomes Among Breast Cancer Patients: The Current State of Evidence Based on Randomised Controlled Trials

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ABSTRACT

Introduction: Breast cancer is the most common cancer among women. Psychosocial distress, in the forms of depression and anxiety, regularly accompanies breast cancer diagnosis and throughout its treatment. Hence, it is important to objectively assess the therapy options that may help this distress. One of the most flexible psychotherapy modalities is the art therapy as it may be incorporated in many settings. The purpose of this systematic review is to determine the efficacy of art therapy (via creative paintings) on the mental health outcomes of female breast cancer patients. **Material and Methods:** Related articles were identified from Medline (OvidSP), ScienceDirect, Pubmed, EbscoHost-Academic Search Premier and Wiley Online Library. Screenings were performed based on the criteria that the study must be a randomised control trial (RCT) that investigated the effect of art therapy in breast cancer. Data were extracted using standardised forms, followed by evaluation of quality of reporting using CONSORT Guidelines. **Results:** Six RCTs were identified. Based on the heuristic synthesis of data extraction results, none of the studies can be considered as studies with acceptable quality, although four of them showed promising results. **Conclusion:** There is inconclusive evidence of the efficacy of art therapy (via creative paintings) for the improvement of mental health outcomes among female breast cancer patients.

KEYWORDS: Art therapy, breast cancer, breast neoplasm, systematic review

INTRODUCTION

Breast cancer is the most common cancer among women and the second commonest cancer in human, accounting for 1.1 million new cases out of 11.5 million cancers cases worldwide in 2004.[1] As in all forms of cancer, a breast cancer diagnosis (and treatment) may cause psychosocial distress to its victims. According to a cohort study in England among 222 women with early stage of breast cancer, nearly 50% of them had depression, anxiety or both in the first year after diagnosis.[2] This annual prevalence dropped to 15% by the fifth year after diagnosis. According to Burgess et al., (2005) the risk factors for depression and anxiety are associated with the characteristic of patients, rather than to the cancer itself or its treatment.[2] In a narrative review by Fann et al., (2008) it was stated that psychosocial interventions (i.e., psychotherapies) have mixed results in term of the improvement of general mood, distress, depression and anxiety among cancer patients.[3] On the other hand, a systematic review by Williams and Dale (2006) found that that there were some evidence of the efficacy of psychotherapeutic interventions on the depressive symptoms among cancer patients.[4]

Among the myriad of psychotherapy modalities, art therapy can be seen as method that primarily focuses on the expressive capabilities of its clients.

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According to one definition, art therapy encompasses the use of different art media, whereby the client can express and work through the issues and problems that require psychotherapeutic intervention.[5] A more thorough conceptual definition by the American Art Therapy Association in their mission statement in 1996 focuses on the healing and life enhancement through creative process of art, which can be seen as a primary form of nonverbal communication of cognition and emotion.[6,7] It can be seen as a modality that create meaning and insight in the process of finding respite from emotional burden or trauma.[8] On the other hand, it should be noted that there are also various approaches in the art therapy -ranging from the eclectic (i.e. nonspecific) approaches as practiced by most therapists to the more obscure psychodynamic approaches that focus in the mysterious realm of the unconscious.[9]

A systematic review by Slayton et al.(2010) based on 35 qualitative and quantitative studies found a varying degree of evidence that art therapy does work in various settings, although most of these studies do not meet the highest standard in efficacy research.[10] A more specific systematic review by Archer et al., (2015) on creative psychological intervention (that includes art, dance, drama and music therapies) concluded that there is promising initial evidence that this form of intervention benefits adult cancer patients in terms of anxiety and depression, quality of life, coping and mood.[11]

Search of electronic databases:
MEDLINE (OvidSP), PubMed, ScienceDirect, Academic Search Premier (EbscoHost), Wiley Online

Identification of abstracts:
MEDLINE=15 PubMed=26 ScienceDirect=12 Academic Search Premier=12 Wiley=19 **Total=148**

Removal of abstracts due to duplicates: 57

Screening of pooled abstracts **Total=91**

Rejection of abstracts based upon selection criteria (**Total=83***):
Not in English: 14
Not related with art therapy and breast cancer: 60
Not original studies: 5
Not randomised controlled trial: 2
Outcome not related to psychosocial distress: 2
*This number is inclusive of 9 ambiguous abstracts that were rejected after the full articles were traced and screened.

Full text articles obtained: 8

Rejection of articles based upon selection criteria (Total=2)
Absence of relevant quantitative outcome: 2

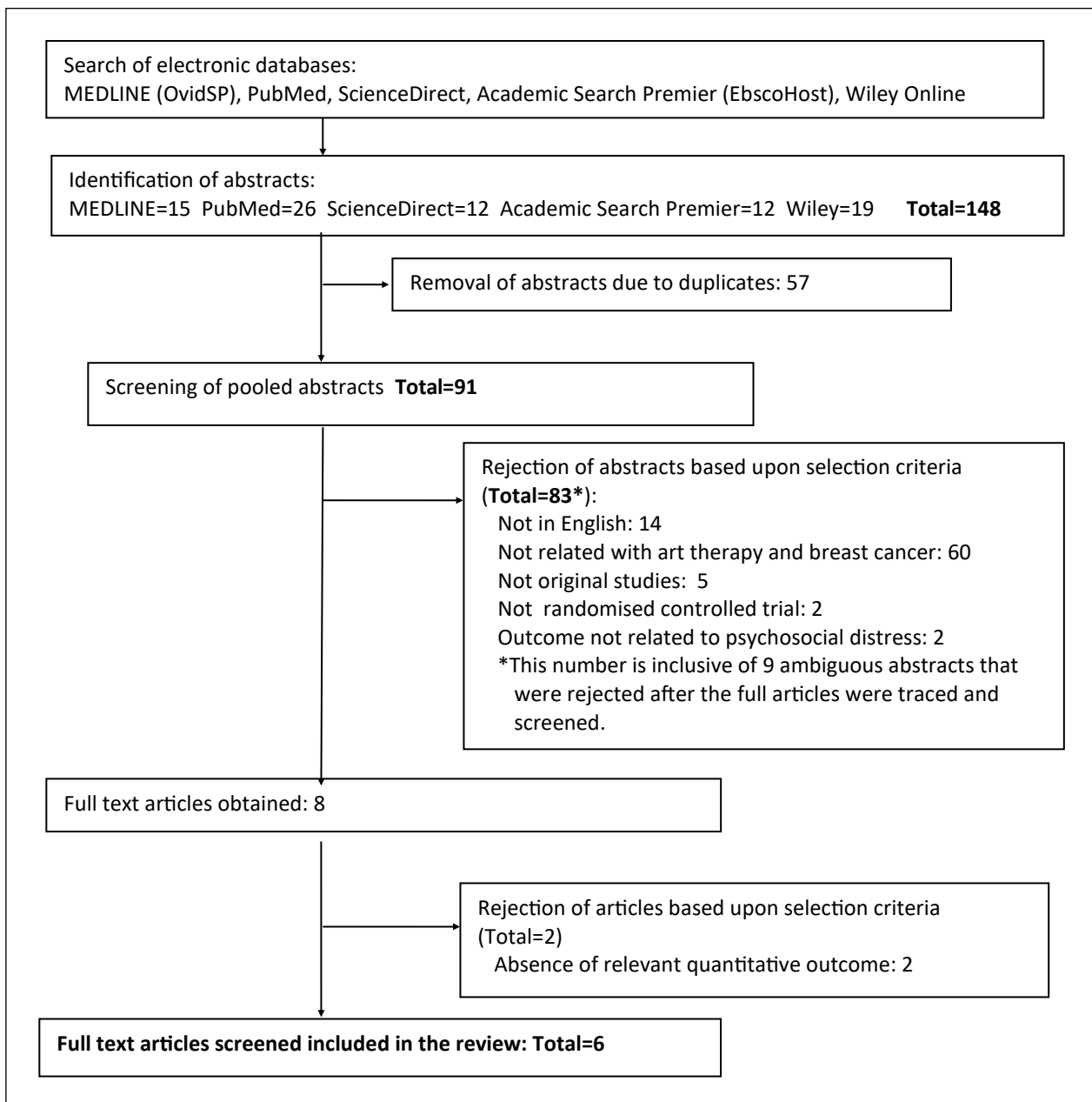**Full text articles screened included in the review: Total=6**

Figure 1: Flowchart to show the selection process of the articles in this review.

Conversely, a systematic review and meta-analysis by Boehm et al.,(2014) concluded that "art therapies" positively affect patients' anxiety, but not depression or quality of life.[12] This systematic review focused on the efficacy of art therapy (via creative paintings) on the mental health outcomes of female breast cancer patients, based only on past randomised controlled trials. The specific designs, results and quality of each of these studies were dissected for the synthesis of coherent conclusion about the current state of evidence.

MATERIALS AND METHODS

Based on current trend to minimise bias in the reviewing process, we followed the recommended steps for systematic review by Needleman (2002).[13] At the same time, we made some minor adjustments to the procedure as to improve the objectiveness of the review.

Study selection

We conducted a systematic electronic search in five databases i.e. MEDLINE [OvidSP], ScienceDirect, Pubmed, EbscoHost-Academic Search Premier and Wiley Online Library; that comprised a publication timeline from the earliest date possible to the end of September 2014. The search strategy included the following terms and Boolean operators: 1) breast cancer*; 2) Art therapy*; 3) 1 AND 2 (abstract/title field only). A total of 148 individual abstracts were identified (Figure 1). In the first stage, screening of abstracts were included in the review based upon these criteria: a) the study reported the effects or association between breast cancer and art therapy; b) it is an original study; c) it is a randomised controlled trial (RCT); and d) written in English. At the same time, abstracts were excluded from the review if: a) the study was related "art-based therapies" that are not under the definition or art therapy in this review (e.g. music, dance and drama therapy); or b) the study did not have any psychological outcomes. Ambiguous abstracts were excluded only after their full papers were traced and screened in the next phase. Any discrepancies in the results of the screening were resolved through a consensus process.

The first stage screening yielded eight abstracts that fulfilled the selection criteria. This phase was followed by tracing the full articles for each abstract electronically. The downloaded articles were then subjected to a second round of screening by two researchers using a standardised electronic form independently. In the second stage, the study would be rejected from the review if: a) the effect of the RCT was not measured using any quantitative mental health-related inventories; or b) the analyses included male breast patients. Again, any disagreements in the screening results were settled by mutual consensus. Through these two-phased screening, only six full articles were finally included in the review (refer Table 1). It should be noted that all these studies were included in this systematic review, regardless of their quality, due to the lack of identified articles. This is contrary to the ideal practice of including only studies with high methodological quality in a systematic review.[20]

Data extraction

To reduce bias, the data extraction procedure for the studies was also done by two researchers. This procedure was performed using three different electronic forms i.e. i) the study design form, ii) the study results form and iii) the study report quality form.

In the study design form, the following information was recorded: a) classification of RCT design (by assignment, proof type and confirmatory/exploratory nature); b) sample characteristics (age, breast-cancer stage, medical treatment state); c) type of art therapy; d) sampling method used, sample and size of each group; e) intervention description in the control and comparison group; f) length of intervention; g) psychological questionnaire used and its measured construct; h) reliability & validity of each psychological inventory used in the study (based on study population and not literature review); i) analysis type (per protocol or intention-to-treat); and j) main outcome measure(s). On the other hand, the study results form required the researchers to record the following information: a) reported descriptive values of main outcome measure(s); b) reported inferential statistical analysis; c) result summary; and d) conclusion of the effect of art therapy in breast cancer cases. During the tabulation of the results, we also recalculated the effect size of the art therapy intervention based on the reported

descriptive results to ensure a clearer conclusion later on.[21]

Finally, the quality of the study report was assessed using two different checklists based upon the Consolidated Standards of Reporting Trials (CONSORT) Statement.[22] The CONSORT Statement checklist was used to assess the quality of the controlled trials in the review, whereas the Strengthening Reporting of Observational studies in Epidemiology (STROBE) checklist was used for the cohort study. The grading of the items in the checklists was created for the purpose of this review to correspond to the following subjective assessments: a) acceptable; b) some minor weaknesses; c) some major weaknesses; d) not acceptable; and e) ambiguous.

RESULTS

Summary of study designs of the included studies
Based on Table I, all the studies were parallel in design, without blinding or placebo-controlled. Besides that, all the studies were done in developed countries. Non-probability sampling was the method to enrol subjects in all these studies. The lowest sample size was 37[19] and highest number of sample size was 191.[18] Besides that, baseline characteristics between the intervention group and control group were poorly described in most of the studies - some of them even showed evidence of imbalance in age.[16,17,19] There was no significant difference of outcome measures between the intervention and control groups at pre-intervention period in all the studies. Fours studies excluded subjects with psychiatric illness,[14, 16, 17, 19] whereas the other two did not state this important exclusion criteria.[15,18] None of the studies provided the reliability and validity of the measurements inside the study itself (i.e. all were based on literature).

In terms of the art therapy intervention, four studies [14,16,17,19] used the phenomenological method as described by Betensky (1995),[23] whereby the five weekly sessions were divided into the following: a) one session involving visualisation of feelings as analogue of drawings; b) one session involving creation of a life-size body image to express the different feelings in her body using shapes and colours; c) two free-painting sessions; and lastly by d) one session where reflection was done by the patient to summarise her creative journey. Two

studies used non-specified art therapy procedure in combination with meditation.[15,18] The length of intervention for these two studies ranged from four weekly sessions[15] to eight weekly sessions.[18]

Summary of results of the included studies
Due to the variety of outcome measures in the six studies, we have clustered the outcomes into three main domains of mental health outcome; a) positive psychology domain (Coping Resource Inventory[14] and Emotional Approach Coping Scale[15]); b) mental illness domain (Profile of Mood States[15] and Symptom Check List-90[17,18]); and quality of life domain (WHOQOL-BREF[16,19], QLQ-BR23[16] and SF-36[18]). Based on Table II, art therapy group has significantly better mental health outcomes compared to control group in four different studies.[15-17,19] For the mixed art-therapy-and-meditation study by Puig et al.,(2006)[15] it was shown that there was significant improvement mood after four weeks post-intervention, whereby its effect size on depression was large (Cohen's d: 0.83) and its effect size on anxiety was medium (Cohen's d: 0.59). For the studies using Betensky's method, positive significant results can only be seen in three studies, in terms of ; a) significant general distress improvement after four months post-intervention with small effect size (Cohen's d: 0.03)[17]; and b) significant improvement of quality of life after 6 months post-intervention with small (Cohen's d: 0.13)[16] to large (Cohen's d: 1.05)[19] effect sizes.

None of the studies showed significant results for the positive psychology domain, in terms of coping. As a whole, the Cohen's d effect size of art therapy (compared to control) on each domain of mental health outcomes ranged as follows; a) positive psychology domain: 0.02-0.63; mental illness domain: 0.03-0.83; and quality of life: 0.03-1.05. Due to the heterogeneity of the designs, we did not proceed with a meta-analysis to prevent misleading synthesis of varied quantitative outcomes.

Summary of quality of the included studies
Referring to Table III, none of the six studies fulfilled the minimum assessment category of 'some minor weaknesses' in all 27 items in the methods and results section of the CONSORT statement checklist. For example, none of the study described the statistical calculation to justify their sample size. On top of that, randomisation procedure was

poorly reported in most of the studies (except Svensk et al., (2009),[16] and most importantly, there was also lack of blinding and placebo control in all the studies. These weaknesses caused the studies to be open to criticism for selection and experimenter biases that may skewed the results.

Table I: Evidence Table for the Study Design of Past Studies on the Effect of Art Therapy In Breast Cancer Patients

Study	RCT Design	Sampling and sample characteristics	Art therapy intervention description	Control/ comparison group(s) description	Length of Intervention	Relevant main outcomes and their psychometric properties

Oster et al. (2006) [14]	Parallel/ superiority/ confirmatory	• Purposive sampling among 41 Swedish women with primary non-metastatic breast cancer who were undergoing radiotherapy (median age: 59).
		• Exclusion of women with dementia or severe psychiatric illness.
		• Stratified randomisation done (based on postoperative chemotherapy status)—intervention group (n=20) versus control group (n=21)
		• Baseline characteristics:
		  • Comparison in terms of age, breast cancer stage and medical treatment state were not described.
		  • Outcome measures were not different between the 2 groups.
			Individual art therapy session once a week during radiotherapy using phenomenological method (as described by Betensky):
			• First session: visualisation of feelings as analogue drawings.
			• Second session: made a life-size body image to express different feelings in her body through shapes and colours
			• Third and fourth session: paint whatever.
			• Fifth session: reflection (a summary of her creative journey)
				Procedure in control group was not described	Once a week for 5 weeks during patients radiotherapy treatment.	• Measurement of the following scales at 0 month (pre intervention), 2 months and 6 months post intervention period:
						1. Coping ResourcesInventory to measure changes in coping resources - 5 domains: cognitive, social, emotional, physical, and spiritual, philosophical. (Reliability and validity in the study no described)

Puig et al. (2006) [15]	Parallel/ superiority/ exploratory	• Purposive sampling among 39American women who were 18 years and above and have been diagnosed with Stage I or Stage II breast cancer within 12 months prior to the study.
		• Not stated whether there was exclusion of women with dementia or severe psychiatric illness.
		• Randomisation done—intervention group (n=20) versus control group (n=19)
		• Baseline characteristics:
		  • Comparison in terms of age, breast cancer stage and medical treatment state were not described.
		  • Outcome measures were not different between the 2 groups.
			Individual counselling session that involved:
			• semi-structured creative art therapy experiences, where creative freedom was encouraged in order to facilitate and explore the woman's emotional expression, spirituality, and psychological well-being state
			• Guided meditation to help with exploration of spiritual themes
				Delay of individual counselling session over 4 weeks (i.e. the similar intervion to intervention group would only start after the intervention group finished its sessions)	4 individual therapy over 4 weeks-- 60 minutes for each session	• Measurement of the following scales after 4 weeks of intervention period:
						1. Emotional Approach Coping Scale to assess emotional expression--processing emotion and expressing emotion. (Reliability and validity in the study no described)
						2. Expressions of Spirituality Inventory to measure spirituality. (Reliability and validity in the study were not described)
						3. Profile of Mood States to measure mood disturbance score

Con't

Svensk et al. (2009)[16]	Parallel/ superiority / exploratory	• Purposive sampling among 42 Swedish women with non-metastatic breast cancer who were undergoing post-operative radiotherapy.
		
		• Exclusion of women with dementia or severe psychiatric illness.
		
		• Randomisation done—intervention group (n=21) versus control group (n=20)
		
		• Baseline characteristics:
		  • median age for intervention group (59 years) was higher than control group (55 years).
		  • Comparison of breast cancer stage and medical treatment state not described.
		  • Outcome measures were not different between the 2 groups.
			Individual art therapy using phenomenological method (as described by Betensky). The aim of the intervention was to (1) offer time and space for expression and reflection; (2) give support in the process of restoring body image; and (3) reduce stress and supporting agency.	Procedure in control group was not described.	5 weeks during patients' radiotherapy treatment (frequency of session per week was not stated)	• Measurement of the following scales at pre-intervention, 2 months and 6 months post intervention:
						1. WHOQOL-BREF to identify Quality of Life and general health - 4 domains physical health, psychological health, social relationship and environment. (Reliability and validity in the study were not described)
						2. EORTC Quality of Life Questionnaire [(QLQ)-BR23]to identify Quality of Life in breast cancer patients. (Reliability and validity in the study were not described)

Thyme et al. (2009)[17]	Parallel/ superiority / exploratory	• Convenience sampling among 143 Swedish women with non-metastatic breast cancer who were undergoing post-operative radiotherapy (41 participated).
		
		• Exclusion of women with preexisting physical or psychiatric illness
		
		• Matched randomisation done (by age and adjuvant therapy)—intervention group (n=20) versus control group (n=21)
		
		• Baseline characteristics:
		  • median age for intervention group (59 years) was higher than control group (55 years).
		  • Subgroup in both group intervention and control who had (i) chemotherapy and radiotherapy (n=9 and n=10, respectively) and (ii) hormone treatment (n=7 and n=10, respectively)
		  • Comparison of breast cancer stage was not described
		  • Outcome measures were not different between the 2 groups.
			Individual sessions of individual art therapy using phenomenological method (as described by Betensky): First session: visualisation of feelings as analogue drawings towards a word. Second session: made a body image and encourage to paint in colour and forms within. Third and fourth session: paint whatever. Fifth session: reflection	No psychological intervention in control group.	Once a week for 5 weeks during patients radiotherapy treatment.	• Measurement of the following scales at pre-intervention, at 2-month and 4-monthpost intervention:
						1. Structural Analysis of Social Behaviour to measure perceived self-image - clusters are divided into attachment clustersgroup and disruptive clusters group. (Reliability and validity in the study were not described)
						2. Symptom Check List–90 to measure perceived symptoms-- In this study only General Severity Index and the subscales of Depression, Anxiety, and Somatization were used. (Reliability and validity in the study were not described)

Con't

Monti et al. (2013) [18]	Parallel/ superiority/ confirmatory	• Sampling method not described.
		
		• Among 191 American women with primary or recurrent breast cancer, who received diagnosis between 6 months to 3 years prior to enrolment in the study.
		
		• Not stated whether there was exclusion of women with dementia or severe psychiatric illness.
		
		• Randomisation done— intervention group (n=93) versus control group (n=98)
		
		• Baseline characteristics:
		  • Both groups were comparable in terms of age (both: 56+ years) and breast cancer stage.
		  • Comparison of medical treatment state was not described.
		  • Outcome measures were not different between the 2 groups.
		*There exist a third wing of added comparison group that did not receive any treatment programme— this group will not be discussed in this review as it was not part of the randomisation procedure.
			Mindfulness-based Art Therapy:
			
			• Specific art therapy tasks complementing the Mindfulness Based curriculum by providing an additional nonverbal mode of identifying and organizing internal and external representations of stressors and related emotions. The Mindfulness Based Curriculum involved a variety of mindfulness meditation techniques that were taught during the programme including body scan, awareness of breathing, awareness of emotions, and mindful yoga, walking, eating and listening.
				Breast cancer support group educational programme
				
				• To provide breast cancer patients with support and resources to maximize quality of life. Most sessions included an expert speaker on a topic (such as navigating long-term care, diet and fitness or coping with cancer recurrence), and there was time in each group for sharing and supportive exchanges.
					8 weeks programme	• Measurement of the following scales at week-1, week-9 (week-1 post-intervention) and week-36 (week-28 post intervention):
						1. Symptom Check List-90 to measure perceived symptoms-- In this study General Severity Index and the subscales of Somatization, Obsession, Interpersonal sensitivity, Depression, Anxiety, Hostility, Phobic, Paranoid, and Psychotic symptomswere used. (Reliability and validity in the study were not described)
						2. Medical Outcomes Study Short-Form Health Survey (SF-36) to measure health-related quality of life.

Oster et al. (2014) [19]	Parallel/ superiority/ exploratory	• Purposive sampling among 37 Swedish women who were breast cancer survivors(post-operative radiotherapy) and had participated in a previous study (Oster et al. 2006).
		
		• Exclusion of only women with dementia or severe psychiatric illness.
		
		• Randomisation done— intervention group (n=18) versus control group (n=19)
		
		• Baseline characteristics:
		  • Median age for intervention group (66.5 years) was higher than control group (61 years).
		  • Comparison of breast cancer stage and medical treatment state not described.
		  • Outcome measures were not different between the 2 groups.
			Individual art therapy session once a week during radiotherapy (specific method was not described in this article—have to be refered to Oster et al (2006))	Procedure in control group was not described.	Once a week for 5 weeks during patients' radiothe-rapy treatment	• Measurement of the following scales at 2 months, 6 months and 5-7 years post intervention:
						1. WHOQOL-BREF to identify Quality of Life and general health - 4 domains physical health, psychological health, social relationship and environment. (Reliability and validity in the study were not described)
						
						Note: The Coping Resource Inventory result that was reported in this article was a repetition of the result in the article by Oster et al. (2006).

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Study	Positive Psychology Domain Outcome(s)	Mental Illness Domain Outcome	Quality of Life Domain outcome	Conclusion
Oster et al. (2006) [14]	Coping Resource Inventory Mean Total Score: • After 2 months post-intervention: • Intervention Group: 257.2 (±28.7) • Control Group: 233.6 (±44.1) • $p=0.050$ [Cohen's d: 0.63] • After 6 months post-intervention: • Intervention Group: 256.3 (±25.9) • Control Group: 240.0 (±34.9) • $p=0.098$ [Cohen's d: 0.53]			As a whole, there was no difference of efficacy between the art therapy group and control group in terms of coping resource,
Puig et al. (2006) [15]	Emotional Approach Coping Scale after 4 weeks: • Intervention Group: Not reported • Control Group: Not reported • $p>0.05$	Profile of Mood States (Relevant constructs) after 4 weeks: • Depression-dejection mean: • Intervention Group: 20.66 (±4.74) • Control Group: 26.34 (±8.48) • $p<0.05$* [Cohen's d: 0.83] • Tension-anxiety mean: • Intervention Group: 17.31 (±5.01) • Control Group: 20.32 (±5.24) • $p<0.05$* [Cohen's d: 0.59]		There is evidence of efficacy of art therapy in terms of mood improvement (depression and anxiety constructs) after 4 weeks post-intervention. However, there was no improvement difference in terms of emotional coping resource.
Svensk et al. (2009) [16]			WHOQOL-BREF Mean Overall Score: • After 2 months post-intervention: • Intervention Group: 75.0 (±21.5) • Control Group: 72.6 (±15.6) • $p>0.05$ [Cohen's d: 0.13] • After 6 months post-intervention: • Intervention Group: 85.0 (±12.6) • Control Group: 67.5 (±20.0) • $p=0.003$* [Cohen's d: 1.05]	There is evidence of efficacy of art therapy in terms of quality of life improvement after 6 months post-intervention.
Thyme et al. (2009) [17]		Symptom Check List-90 Mean General Severity Index: • After 2 months post-intervention: • Intervention Group: 0.32 (±0.31) • Control Group: 0.40 (±0.31) • $p>0.05$ [Cohen's d: 0.26] • After 4 months post-intervention: • Intervention Group: 0.19 (±0.16) • Control Group: 0.34 (±0.28) • $p<0.05$* [Cohen's d: 0.03]		There is evidence of efficacy of art therapy in terms of general distress (i.e. general severity of psychiatric symptoms) improvement after 4 months post-intervention.
Monti et al. (2013) [18]		Symptom Check List-90 Adjusted Mean General Severity Index: • After 1 week post-intervention: • Intervention Group: 0.72 • Control Group: 0.65 • $p>0.05$ • After 28 weeks post-intervention: • Intervention Group: 0.69 • Control Group: 0.68 • $p>0.05$	SF-36 Adjusted Mean (General Health): • After 1 week post-intervention: • Intervention Group: 62.56 • Control Group: 65.21 • The main effect significance level was not reported. • After 28 weeks post-intervention: • Intervention Group: 62.98 • Control Group: 65.05 • The main effect significance level was not reported.	Ambiguous conclusion in terms of general distress and quality of life improvement for art therapy if compared to control.

Con't

| | | | WHOQOL-BREF Mean Overall Score: After 2 months post-intervention: Intervention Group:78.8 (±14.7) Control Group: 66.7 (±22.8) p=0.078 [Cohen's d: 0.63] After 6 months post-intervention: Intervention Group: 85.0 (±12.6) Control Group: 67.5 (±20.0) p=0.003* [Cohen's d: 1.05] After 5-7 years post-intervention: Intervention Group: 77.8 (±24.1) Control Group: 75.0 (±19.2) p=0.52 [Cohen's d: 0.13] | Art therapy was shown to be effective after 6 months post-intervention for quality of life. However this effect did not extend beyond 5 years. |
| Oster et al. (2014)[9] | | | | |

*: Significance at level of p<0.05 (two-tailed)

Table III: Quality of methods and results reported in studies included in the review (based on CONSORT Statements).

Section	Item in CONSORT	CONSORT Checklist	Status in article					
			Oster et al. (2006)[14]	Puig et al. (2006)[15]	Svensk et al. (2009)[16]	Thyme et al. (2009)[17]	Monti et al. (2013)[18]	Oster et al. (2014)[19]
METHODS								
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	C	A	A	A	A	A
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	A	A	A	E	E	E
Participants	4a	Eligibility criteria for participants	A	A	A	A	A	A
	4b	Settings and locations where the data were collected	B	E	A	A	B	B
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	B	B	A	A	A	B
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	B	B	A	A	A	A
	6b	Any changes to trial outcomes after the trial commenced, with reasons	B	C	A	B	E	C
Sample size	7a	How sample size was determined	D	D	D	D	D	D
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA	E	B	C	NA	NA
Randomisation:								
Sequence generation	8a	Method used to generate the random allocation sequence	B	C	A	E	B	C
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	A	C	A	E	A	C

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	B	C	A	E	B	C
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	D	C	C	C	B	C
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	D	C	C	C	B	C
	11b	If relevant, description of the similarity of interventions	C	C	C	B	A	E
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	A	A	A	A	A	A
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	A	A	A	A	A	A
RESULTS								
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	B	B	A	A	A	E
	13b	For each group, losses and exclusions after randomisation, together with reasons	B	B	A	A	A	A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	B	B	A	A	A	A
	14b	Why the trial ended or was stopped	D	A	A	A	A	A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	D	B	A	A	A	A
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	B	A	A	A	A	A
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	A	B	A	B	A	A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA	NA	NA	NA	A	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA	NA	NA	NA	A	A
Harms	19	All important harms or unintended effects in each group	B	C	C	C	C	C

Evaluation of quality:
A: Acceptable ; B: Some minor weaknesses; C: Some major weaknesses; D: Not acceptable; E: Ambiguous; NA: Not applicable

DISCUSSION AND CONCLUSION

Through a careful review of the current literature, we found that there is a serious lack of good quality RCT studies in answering whether art therapy (via creative paintings) is worth the while to be done among breast cancer patients. One of the issues that predominated in this systematic review is the heterogeneity of the multiple types of outcomes for mental health. This prevents a cohesive conclusion to be drawn. For example, an improvement of mood does not automatically means that the quality of life will also improve. The use of weighted outcome (i.e., selecting the main outcome) for mental health measurements may be problematic. This is due to the inherent subjective nature of psychological-based outcomes that may have different significant phenomenological significance for each separate individuals. The phenomenological view towards mental health was elegantly summarised in a review by Aho (2008)[24] as a world that "is not understood mechanistically as an aggregate of real physical objects in causal interaction, but, rather is the meaning of being".

The current systematic review suffers from several limitations that cannot be avoided due to the lack of resources. Firstly, we cannot effectively control for the effect of publication bias.[25] However, there is a lack of statistical evidence to conclude the publication bias (e.g. absence funnel shape pattern of Forest Plot) as we did not manage to convert the systematic review into a meta-analysis.[26] Hence, future systematic reviews on this topic should strive for a single primary mental health outcome measure during data extraction that would help the synthesis of studies to be done as a proper meta-analysis. All of this will be possible if there are more original RCTs on this topic in the coming years. Besides that, future researchers should use and decide on a "gold standard" quantitative measurement of the most important mental health outcome for such studies. They should also try to use a "gold standard" comparative treatment group, such as Cognitive behavioural therapy (CBT). Via these two last suggestions, a future systematic review will be more conclusive than the current one.

There is inconclusive evidence of the efficacy of art therapy (via creative paintings) for the improvement of mental health outcomes among female breast cancer patients. The main reason for this inconclusiveness is primarily due to the lack of studies with acceptable quality, rather than the lack of evidence itself as there were four studies with promising results. Hence, we found no strong reason to recommend the adoption of art therapy as a therapy of choice for the treatment of psychosocial distress among breast cancer patients in the public health setting for now.

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