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META-ANALYSIS OF THE EFFECTS OF THE EDUCATIONAL AND COUNSELING INTERVENTIONS ON MENTAL ADJUSTMENT AND QUALITY OF LIFE IN BREAST CANCER

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ABSTRACT

Background: Education and counselling are widely used independently or as supplementary components in the psychosocial interventions. However, there is a certain level of ambiguity if used separately. In this analysis, we attempted to answer the following question; "Does the education and counseling support improve of the adjustment to cancer in women diagnosed with breast cancer?"

Methods: An online search was undertaken in 12 databases for the longitudinal studies for the period from January 2007 to March 2018. The effects of the interventions on the adjustment to breast cancer, were calculated based on the results of the mental adjustment and quality of life (QoL). Three distinct periods were examined; baseline, three months, and six months. The methodological quality, risk of bias, publication bias, and attrition rate were examined. Meta-analysis was carried out using Review Manager 5.3 with the results graphically presented.

Results: A comprehensive systematic review was conducted for 5,464 titles, of which 22 studies fulfilled the inclusion criteria, however 14 studies completed the data and included in the qualitative synthesis; included 3,419 patients. The mean of overall attrition rate in both groups was 14.37% (SE= 2.87, median= 12.28). In mental adjustment, the total mean differences for the three trials were statistically significant 0.40 (0.24 to 0.57). For the QoL, the mean differences of the three trials were statistically non-significant 0.18 (-0.48 to 0.84).

Conclusion: The educational and/or counseling interventions can be beneficial and useful for patients to adapt with the breast cancer, however, it is less effective on the QoL.

Keywords: mental adjustment, quality of life, education, counseling

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1.0 Background

Breast cancer is the most commonly diagnosed cancer found in women (Cancer, 2015; Ferlay et al., 2015), about 24% of all new cancer cases (Bray et al., 2018). Further, it is a chronic life-threatening illness that greatly impacts all spheres of women's life (Aydiner et al., 2016). The burden of breast cancer remains extraordinarily stressful experience for the majority of women (Compas & Luecken, 2002). It makes them prone to psychological disturbances, reduce the quality of life and hopeful about the future (Avis et al., 2005; Bayram et al., 2014; Kwan et al., 2010), and leaves dramatic and adverse effects on their life (Hull et al., 2016). Being diagnosed with breast cancer is likened to facing death in the face (Cozaru et al., 2014).

Numerous types of psychosocial interventions have quickly emerged during the last few decades having one primary goal; to mentally and physically adapt to the illness and its implications. Psychosocial interventions are categorised as; psycho-educational interventions, complementary therapies, psycho-pharmacologic interventions, mindfulness-based and psycho-therapy interventions (Council, 2004; Stanton & Bower, 2015; Tao et al., 2015). Psychoeducation, as an evidence-based practice, is one of the most effective practices that has arisen in clinically established trials and communal settings. The adaptability of the model incorporates illness-specific information and resources for handling similar circumstances. Also, psychoeducation has vast conceivable possibilities to treat many forms of illness and difficulties in life (Lukens & McFarlane, 2004). The psycho-educational model consists of four components; patient education, behavioural training, coping skills training and supportive counselling (Fawzy, 1999; F. I. Fawzy & Fawzy, 2011).

According to Lazarus and Folkman theory, the patient acknowledges the stress events by utilising available resources internally and external support (Friedman. S, 2002). Providing education and counselling regarding their cancer, accordingly, can also help to improve the utilisation of resources and enhance their sense of control (Lyons & Chamberlain, 2006). Nonetheless, education and/or counselling are considered to be the most cost-effective intervention models (Mandelblatt et al., 2008). Previous studies have suggested that patient education and/or counselling ensures that patients have sufficient knowledge and understanding to make informed choices, and to improve their sense of control (M'Imunya et al., 2012; Sánchez et al., 2015; Sherman et al., 2012), which may positively impact their health status and QoL (Coon & Mitterer, 2014).

Education and/or counselling are widely used to complement psychosocial interventions albeit in some studies they are reported to be used separately. Although, there is a certain degree of ambiguity concerning the effectiveness of the intervention if used by separately. To the best of the author's knowledge, no review has been undertaken to assess whether breast cancer women educational or counseling support (separately or in combination) facilitates their adaption to breast cancer. So, in this analysis, we attempted to answer the question "Does the educational and counseling interventions improve the adjustment and quality of life in the breast cancer women? Therefore, the purpose of this analysis was to evaluate the effects of educational and/or counseling interventions on the mental adjustment and quality of life in the breast cancer patients.

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2.0 Method

2.1. Search strategy

A comprehensive and Meta-analysis search was conducted according to PRISMA guidelines for published and non-published studies (i.e. articles, theses, and dissertations) between January 2007 and March 2018. The search process consisted of twelve online databases (refer Figure 1); published literature (Medline (via PubMed), Science Direct, Web of science, Springer, Cochrane library, Scopus database, and EBSCOhost (CINAHL), Psychology and Behavioral Sciences Collection, and Cochrane central register of controlled trials). Also, Gray literature (Google Scholar, ProQuest Dissertations and Theses Global, UPM medical library, and UM medical library) and Arabic studies (AL MANHAL, WHO, Saudi Medical Journal and Alexandria Journal of Medicine).

Certain search terms were used linked to breast cancer, namely; quality of life; adjustment; coping; counselling; counselling; education; psychoeducational; psychoeducation. The search criterion included breast cancer [Title]) AND (quality of life [Title/Abstract] OR adjustment [Title/Abstract] OR coping [Title/Abstract])) AND (counselling [Title/Abstract] OR counseling [Title/Abstract] OR education [Title/Abstract] OR Psychoeducational [Title/Abstract] OR Psycho-education [Title/Abstract]). Next, the selected studies were screened based on the titles and abstracts, followed by an assessment of the entire text based on the inclusion and exclusion criteria. Lastly, reference lists in the included studies were also used to identify additional publications.

2.2. Study selection

Detailed inclusion criteria were drafted by author (A. A), and to assess the eligibility along with expert guidance from two supervisors (M.H.J and H.B.K). Titles and abstracts of all entries were vetted by one reviewer (A. A) followed by two additional reviewers (A. A and F. A) independently vetting the text in all selected articles to confirm whether or not the inclusion criteria had been achieved and to ensure any issues, disagreements were resolved through practical discussion.

In this review, the study designs eligible for inclusion included randomised and quasi-randomised controlled trials (RCTs). Furthermore, the searches were limited to studies written in English and Arabic languages. The participants were all female, diagnosed with primary breast cancer stages I, II and III and sample sizes with fewer than ten participants were excluded. Moreover, articles were also excluded that focused on specific groups, namely; specific age, race, or income level, etc. The interventions were defined as patient education and/or counselling breast cancer patients. Accordingly, interventions incorporating cognitive or behavioural approaches, physical activities, psycho-therapeutic, and complementary medicine interventions were excluded. The control conditions were defined as waiting list, hospital routine care, or with no intervention. Also, the studies included at least one of the following outcomes, namely; stress, adjustment, or QoL and were assessed based upon multiple time intervals; baseline, three months and six months.

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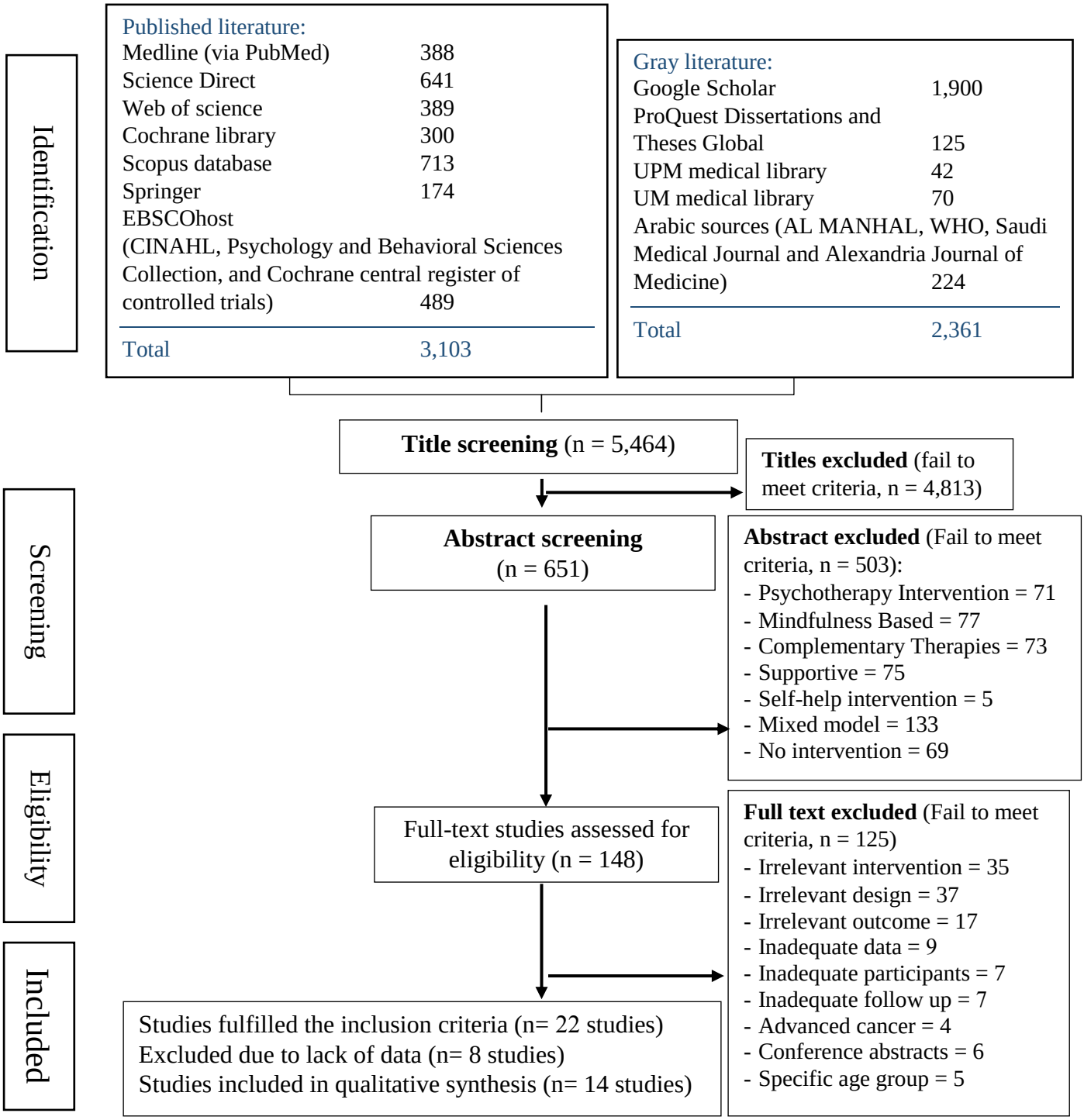

Figure 1: PRISMA flow diagram explaining the methodology to select the eligible studies

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2.3. Assessing the quality of eligible studies

The quality of the eligible studies was evaluated independently scored by two reviewers (A. A and F. A). any variance or noted differences amongst the reviewers were resolved quickly by (H. B).

2.3.1. Methodological Quality Assessment

CONSORT 2010 checklist was used to evaluate the quality of the RCTs articles (Pandis et al., 2017; Schulz et al., 2010), while TREND statement was used to evaluate the quasi-RCTs (Des Jarlais et al., 2004). Each item's score ranged between 0 and 2 "0 = 'no description', 1 = 'inadequate description' and 2 = 'adequate description", where all item scores were then totalled. The score for each study, represented as a percentage, was calculated for easier interpretation and comparison. (Augestad et al., 2011; Jacobsen et al., 2007). Lastly, all individual criteria were weighted equally (Knobloch et al., 2011).

2.3.2. Assessing the risk of bias

Cochrane RoB 2.0 tool was used to evaluate the risk of bias in the RCTs (J. P. T. Higgins & Altman, 2008), and the ROBINS-I tool was employed to assess the risk of bias in the Quasi-RCTs (Sterne et al., 2016). Both tools were employed to assess the possibility of potential risk bias, or distortion of facts, that could threaten the study's internal validity (Jüni et al., 2016). The RoB tool focuses on six distinct domains, namely; "random sequence generation, performance bias, allocation concealment, detection bias, attrition bias and lastly the reporting bias". The criteria for assessing bias for each domain, was based on the following principles; "low risk of bias = minimal risk for all domains, unclear = insufficient information or partial concern in one item, high risk of bias = high risk of bias for any primary domains" (J. P. Higgins et al., 2011; J. P. T. Higgins & Altman, 2008; Viswanathan et al., 2012). The ROBINS-I tool incorporates seven domains; "confounding bias, selection bias, classification bias of the interventions, bias resulting from deviations in terms of the anticipated interventions, bias due to missing data, bias due to outcome measurements, and bias in the selected result". The signalling questions and the assessment of the risk(s) regarding bias were based on the guidance provided by ROBINS-I (Jüni et al., 2016; Sterne et al., 2016; Thomson et al., 2018). Also, the risk relating to bias in the RCTs studies was summarised graphically using the RevMan 5.3 software.

2.3.3. Publication bias assessment

Publication bias was evaluated using a funnel plot, created by the RevMan 5.3 application in accordance with the 'Cochrane Handbook for Systematic Reviews of Interventions'. The effect estimate mean differences (MD) from each study in the analysis was scattered against a measure of standard error (SE). The vertical line represents the average standardised mean differences. Standard error is essentially a function of the sample size, you can see that the smallest standard error (studies with the largest sample size) is placed on the top of the Y-axis. Publication bias is not evaluated for less than ten studies. Notably, if publication bias is observed, a 'bite' out of the funnel will be evident (J. P. Higgins, 2011; Lau et al., 2006; Sterne et al., 2011).

2.3.4. Assessment of the attrition rate

Attrition is a potential threat to internal and external validity in longitudinal studies (Behaghel et al., 2009; Cook et al., 2002; Friedman et al., 2015). The differences between the groups regarding attrition were measured using the overall attrition rate, differential attrition and the relative attrition (RA). The overall attrition rate was estimated as the part or proportion of the sampled item(s) allocated at random to the study groups where the outcome data are unavailable. Notwithstanding, the differential attrition rate is "seen as the variation in attrition rates of the intervention and control groups". High rates of attrition overall could be considered appropriate when the disparity of the attrition rate is minimal or low. Likewise, the contrary is correct as well (Deke et al., 2015). The WWC guideline has suggested that the overall allowable attrition is 20 % and the allowable differential attrition is 7 % (WWC, 2011). The RA rate is calculated by "dividing the attrition as found in the intervention group with the attrition in the control group". Accordingly, if the attrition in both groups are equal, this will then imply that the RA is one. As well, if the RA is smaller than one, this will imply that the attrition is less in the experimental compared to the control arm. Likewise, if the RA is more than one, this implies that the attrition is more in the experimental group (Heneghan et al., 2007). DerSimonian and Laird random-effects models were used in RevMan to estimate a pooled relative attrition with a 95 % confidence interval.

2.4. Data extraction

In this review, the data were independently extracted by two reviewers (A. A and F. A), disagreements were resolved by discussion. A Microsoft Excel worksheet was used to extract the relevant data (quantitative or qualitative) on the characteristics associated with each of the studies (authors, year, setting, study design, sample size, measurement tools). Moreover, the information was extracted, and the characteristics of the intervention programs in the qualified studies including the type, route/path of administration, number of sessions, follow-up and therapist. Results related to adjustment to cancer and QoL were also extracted along with conclusions describing the effectiveness of the intervention (see Table 1).

2.5. Data analysis

Review Manager (RevMan) version 5.3, was used to analysis and present the data graphically. To describe the data and to facilitate the comparison amid the groups, the percentage, Mean ($\bar{x}$), Standard Deviation (SD), and median were employed. A p-value less than 0.05 was judged to be statistical significance. Furthermore, to assure uniformity, baseline test results (T1), and post-intervention test results (T2 and T3) were utilised to estimate the effect size. The mean for each variable and subscales scores were combined using the calculator in RevMan (The Cochrane Collaboration, 2014), and the standard deviation (SD) was combined (i.e. pooled) using Cohen's formula within the group (Cohen, 1988). Next, heterogeneity was tested using the chi-square (χ^2, or Chi^2), I^2, and df tests among the combined study results (J. P. Higgins, 2011). The fixed and random effect statistical models were used as an option for analysis. The mean difference (MD) was employed to evaluate the variations amid the comparison groups at the confidence interval 95 % for continuous outcomes. The publication bias was assessed for QoL but could not be used for adjustment to cancer, due limited studies incorporated in each analysis.

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3.0 Results

3.1 Studies characteristic

Of the 22 eligible studies, 14 studies were included in the analysis, where 8 studies were excluded due to lack of data. The studies were undertaken in South Korea, Germany, Canada, Turkey, Netherlands, Denmark, USA, Norway, Australia, Iran, Egypt, Malaysia, Pakistan, Sweden, Thailand and Finland. A total number of participants was 3,419 women, the average number of participants per trial was 149, ranged between 40 and 408. The sessions were conducted weekly or biweekly, via seven different models, namely; individual person-to-person, telephone one-to-one, group face-to-face, group discussions, audio, video and using printed materials. The intervention types included six studies related to education and counselling support, 12 studies related to education, two studies related to psycho-education, one study on inter-peer support, one discussion study, and one psychosocial intervention study. The interventions were then provided to patients in different illness trajectory phases; 3 interventions at the diagnosis stage, 11 interventions undergoing treatment, and 9 interventions at the survival phase. The control groups included breast cancer patients receiving the usual care or standard hospital care plus informational materials. Further characteristics are provided in Table 1.

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Table 1: Overview of included studies (characteristics of reviewed studies)

Author/ year	Setting	Study design / Sample size / Illness trajectory phase	Tools	Intervention			Dependent variable: outcomes	Conclusion
				Type / Models of intervention delivery	Sessions / follow up	Therapist		
Kim, Choi (48)	South Korea / University Hospital in Seoul/ South Korea	Pre- and post-test RCT/ 31 intervention & 36 control / undertreatment	EORTC QLQ-C30	Educational & counselling / face-to-face & telephone interviews	7 sessions / 9 weeks	Physician and nurse	**QoL**: Significant effect.	The program improved the QoL over time in the intervention group.
Dastan and Buzlu (49)	Turkey / Istanbul University School of Medicine	A pre-test-post-test experimental control group design/ 44 intervention & 44 control / undertreatment	Mini MAC Scale	Educational & counselling / group face-to-face interviews & brochures	8 sessions/ 6 Months	Psychiatrist and nurse	**Adjustment**: Significant effect in fighting spirit (p = 0.006) and Significant effect in avoidance/denial (p = 0.001).	The intervention caused positive changes in the adjustment levels in breast cancer patients.
Boesen, Karlsen (50)	Denmark/ Herlev Hospital, University of Copenhagen	RCT / 102 intervention & 103 control / undertreatment	Mini MAC Scale & EORTC QLQ-C30	Psycho-education / group face-to-face sessions	14 sessions / 12 month	Physician, nurse, psychologist, physiotherapist, dietician and social worker	- **QoL**: No statistically significant effects of the intervention after one month or six months. - **Adjustment**: No statistically significant effects of the intervention after one month or six months, except anxious	The intervention did not enhance the QoL or mental adjustment in primary breast cancer patients.

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Author/ year	Setting	Study design / Sample size / Illness trajectory phase	Tools	Intervention			Dependent variable: outcomes	Conclusion
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							preoccupation, was significant (P = 0.04) at T1 (one month).	
Sandgren and McCaul (51)	USA / Telephone session	RCT / 88 intervention & 53 control / undertreatment	PSS scale, avoidance subscale from the coping response, and FACT-G Scale	Education/tele-phone interviews	5 sessions/ 13 months	Nurses	**Stress**: Statistically significant difference between the groups noted. **Adjustment**: Decrease in coping scoring in both groups, but the statistically significant difference between them was only six months. **QoL**: There was an increase in the QoL in both groups, but the statistically significant difference between them was at six months only.	Improvement in stress, coping and QoL in both groups. Improvement due to educational intervention was more until reaching sixth months compared to the control group.
Bredal, Kåresen (52)	Norway / Department of Oncology, Oslo University Hospital	RCT / 185 intervention & 182 control / At diagnosis	Mini MAC Scale	Education/group face-to-face interviews	5 Sessions / 12 month	Psychologist and oncology nurse	**Adjustment**: There was a significant improvement on adaptive coping with breast cancer in the short-term but was not	While the results were limited, intervention improved in the short-term, but

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Author/ year	Setting	Study design / Sample size / Illness trajectory phase	Tools	Intervention			Dependent variable: outcomes	Conclusion
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							found to be effective in the long-term.	not in the longer-term, for adaptive coping.
Sharif, Abshorshori (53)	Iran / Nemazee Hospital, Shiraz in Fars province	RCT / 50 intervention & 50 control / Survival period	EORTC QLQ-C30 and QLQ-BR23	Education/group face-to-face interviews	4 sessions/ 3 months	Psychologist and oncologist	**QoL**: Significant effects for the peer-educator program regarding the QoL	Overall, in the intervention group breast cancer patients benefited immensely from peer-led education in improving QoL.
Park, Bae (54)	South Korea / Medical Centre in Korea	An experimental longitudinal design /25 intervention & 25 control / undertreatment	FACT-B questionnaire	Psycho-education / one-on-one telephone interviews	6 sessions/ 3 months	Oncology nurses	**QoL**: There were significant effects for the psychoeducational program on the QoL.	Psycho-educational program positively affected overall QoL plus psychological symptoms experienced amongst breast cancer survivors.
David, Schlenker (55)	Germany / Online / University	Experimental design 2 x 2 repeated	EORTC QLQ-C30	Counselling/ one-on-one email	Online via email / 2	Unstated	**QoL**: Overall, no significant effect for the intervention, except	Limited benefits of online counselling via

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	Hospital Tübingen	measures design / 69 intervention & 64 control / Survival period			months		global health (0.012), social functioning (P = 0.023) and emotional functioning (P = 0.01) the QoL.	e-mail on the QoL. Reported positive effects on global health and the social/ emotional functional domains of QoL.
Björneklett, Lindemalm (56)	Sweden / Central Hospital in Västerås, Sweden	RCT / 191 intervention & 191 control / at diagnosis	The EORTC QLQ-C30 and BR23	Psychosocial / group face-to-face	7 sessions / 12 months	Oncologists, social workers, a psychologist, art therapist, a dietician and massage therapists	**QoL**: No significant intervention effects on HRQOL (compared with controls).	Program intervention did not affect HRQOL over time; the positive effects in HRQOL were due to the time in both the intervention and control groups.
Grunfeld, Julian (57)	Canada / Nine tertiary care cancer centres \ cancer clinic	Multicentre, randomised trial / 200 intervention & 208 control / survival period	SF-36 questionnaire	Education / one-on-one face-to-face interviews & provided a binder	One session/ 12 months	Nurse	**QoL:** Not statistically significant or any clinically observed differences between the groups regarding QoL.	SCP program was no better than hospital standard care regarding QoL.
Admiraal, van	Netherlands /	RCT, parallel-	EORTC	Patient education /	10	Psychologists,	**QoL:** No statistically	The

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der Velden (58)	University Medical Centre Groningen and Martini Hospital	group study / 69 intervention & 70 control / Survival period	QLQ-C30 & QLQ-BR23	group face-to-face interviews / telephone interviews / e-mail / leaflets	sessions/ 12 weeks	nurses, oncologists, pastoral worker, and patient advocate	significant effects of the intervention on the QoL except for the domain of global health (p 0.01).	ENCOURAGE program did not affect the QoL. Information from the current study could add further improvement to the program.
Beatty, Oxlad (59)	Australia / Flinders Medical Centre Department of Medical Oncology	RCT / 20 intervention & 22 control / Survival period	PTSD Scale, COPE scale, & EORTC QLQ-C30	Self-educated / one-on-one face-to-face interviews & self-help workbook & tape	Unstated / 6 months	Oncologist and research nurse	**Stress**: No significant effects of the intervention, the main significant effect was regarding time p = 0.003. **Adjustment**: Significant effects of the intervention noted on all coping domains except for the planning domain. **QoL**: No statistically significant effects regarding the intervention found on the QoL, except for the domain of social	There was a positive effect regarding intervention on coping domains, except for the planning domain. For stress, there was a nil effect for intervention. Impact of the intervention noted on QoL for social function and cognitive functioning.

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							functioning [F (1,35.32) = 4.47, p = 0.042] and cognitive functioning (p = 0.003).	
Tabrizi, Radfar (60)	Iran / Omid Cancer Center, Urmia University of Medical Sciences	RCT / 41 intervention & 40 control / under treatment	EORTC QLQ-C30	Supportive-expressive / group face-to-face interviews	12 sessions/ 8 weeks	Physicians and nurses	**QoL**: There was statistically significant differences between the groups (F = 19.8, p = 0.002). More effects on global QoL (effect size = 0.59), for future perspectives (effect size = 0.51), emotional functioning (effect size = 0.35) and social functioning (effect size = 0.31).	Intervention is effective on QoL in the intervention group. However, the intervention requires additional evaluation via a more extensive study, with other types of cancer.
Meneses, McNees (61)	USA / Regional Cancer Centre and Private Oncology offices located in the	Longitudinal, recurrent measures & research design / 27 intervention and 26 control / survival	Breast Cancer Survivors (QOL-BC)	Education & support/group face-to-face interviews, telephone interviews, written & audiotape materials	8 sessions / 6 months	Nurse	**QoL**: The Experimental section observed noticeable improvement in overall QoL (p = 0.013). Significant differences observed in the overall QoL amid the	The BCEI program improved overall QoL in the experimental group compared to the control group at the

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	Southeast region	period					experimental and wait control groups at the third month and sixth month.	third month and sixth month.
Budin, Hoskins (62)	USA / Medical centres in the New York City metropolitan area	RCT / 59 intervention & 58 control / undertreatment	PAIS Scale, Self-rated Health subscale (SRHS), the BCTRI, and (PAL-C) Scale	Education and Counselling/group face-to-face and telephone interviews	Unstated / 6 months	Nurse	**Adjustment**: Results indicated patients receiving intervention experienced lesser side effects, less severity, and increased levels of psychological well-being compared to patients receiving only standard care in the control group.	The patients in the intervention group indicated enhanced (higher/better) adjustment regarding psychological & physical side effects, and psychological well-being compared to the control group.
Salzer, Palmer (63)	USA / Online interactions	RCT / 51 intervention & 27 control / Under treatment	FACT-B questionnaire	Internet peer support (education) / one-on-one online interactions	Unstated / 12 months	Unstated	**QoL**: The Time × Condition interaction was found to be significant (P = 0.004; F = 6.09; df = 76). The control and experimental groups differed at 4 months (d = 9.17; P = 0.05; t =	The results indicated that Internet-based education interactions (control condition) have better scores for the longer-term

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							1.98; df = 76; ES = 0.48) and 12 months (d = 10.89; p = 0.03; t = 2.21; df = 76; ES = 0.55); at both time points, better scores observed for the control group.	(4 and 12 months) of the Internet-based peer-to-peer interactions (intervention condition).
Elshamy (64)	Egypt/ Oncology Center, Mansoura University Hospital	Quasi-RCTs / 32 intervention & 32 control / At diagnosis	EORTC QLQ-C30	Education program / unstated	7 Sessions/ unstated	Oncology nurses	**QoL**: No statistically significant effects for the intervention regarding the QoL.	Education intervention assisted in preparing patients for chemotherapy and helped to improve their ability to cope with their illness.
Loh, Packer (65)	Malaysia / University of Malaya Medical Centre	Quasi-RCTs / 89 intervention & 128 control / survival period	DASS-21 scale & SF-36 questionnaire	Patient-education / group interaction	4 sessions/ 12 weeks	Qualified senior occupational therapist	**Stress**: Significant differences noted amid the groups on stress (P = 0.003) **QoL**: Significant differences observed amid groups regarding QoL (p = 0.001)	The intervention decreased the level of stress. Enhanced QoL for women diagnosed with breast cancer. Helped to

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								improve self-management, medical, emotional and other tasks.
Schou, Ekeberg (66)	Norway / Ulleval University Hospital	Quasi-RCTs / 94 intervention & 71 control / undertreatment	EORTC QLQ-C30	Support & information / group face-to-face interviews	3 sessions / 12 months	Physician and nurse	**QoL**: No statistically significant effects regarding the intervention on the QoL, except appetite loss (P = 0.04)	QoL did not improve following the intervention.
Sajjad, Ali (67)	Pakistan / Karachi Institute of Radiotherapy and Nuclear Medicine (KIRAN) hospital	Quasi-RCTs / 29 intervention & 28 control / undertreatment	FACT-B questionnaire version 4	Education/individual face-to-face interviews, written and telephone interviews	6 sessions/ 8 months	Nurse with supervision by a clinical oncologist	**QoL**: Significant improvement in overall QoL, p-value < 0.05	The intervention significantly improved patients' QoL.
Wonghongkul, Sawasdisingha (68)	Thailand / at Maharaj Nakorn Chiang Mai hospital, Thailand	Quasi-RCTs / 33 intervention & 33 control / Survival period	QoL breast cancer questionnaire	Educative-supportive program group sessions / Lecture, videotape, discussion and practicum	4 sessions/ 3 months	Nurses, doctors and survivors	**QoL**: No significant effects noted in the intervention program on the QoL. Variances amid the groups (F = 5.313, p = .025) and in the groups (F = 6.682, p = .002) were due to	The Education-Support Program did not improve the overall score for QoL. The QoL in both the experimental

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Author/ year	Setting	Study design / Sample size / Illness trajectory phase	Tools	Intervention			Dependent variable: outcomes	Conclusion
				Type / Models of intervention delivery	Sessions / follow up	Therapist		
							the period in the control group which were far better than in the intervention group. No interaction observed amid the effect of treatment and effect of time (F Wilk's Lamba = .763, p = .471).	and control groups decreased over time.
Salonen, Tarkka (69)	Finland / Oncology Clinic of Tampere University Hospital	Quasi-RCTs / 181 intervention & 178 control / undertreatment	The QLI-CV and EORTC QLQ-BR23	Education and support/one-on-one face-to-face and telephone interviews	Unstated / 6 months	Physiotherapist	**QOL**: Statistically significant variations found amid the intervention and control groups in arm symptoms (P = 0.011). Significant clinical variance in sexual functioning and emotions towards losing hair.	Results indicated no improvements in the intervention group in the QoL scores except in arm symptoms. Clinically improved sexual functioning and emotions towards the loss of hair.
Wu et al. (2018)	Taiwan / Cancer	A randomised, controlled	EORTC QLQ-C30 and	Education & support / group face-to-face	Six sessions	Nurse	**QOL**: Statistically significant differences	Face-to-face PEI for breast

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Author/ year	Setting	Study design / Sample size / Illness trajectory phase	Tools	Intervention			Dependent variable: outcomes	Conclusion
				Type / Models of intervention delivery	Sessions / follow up	Therapist		
	Medical Centre-southern Taiwan	study / 20 intervention & 20 control / survival period	QLQ-BR23 questionnaires	interview sessions	/ 20 weeks		noted in last follow-up amid groups in status of health (global) (P = < 0.001), physical function (P = 0.025), cognitive function (P = 0.002), queasiness and vomiting (P = 0.018), constipation (P = 0.038), body image (P = 0.037), future perspective (P = < 0.001), and breast symptoms (P = < 0.035). the remaining domains were statistically non-significant.	cancer patients is potentially useful towards QoL improvement pre and post-chemotherapy.

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3.2 Critical appraisal of the selected studies

3.2.1 The methodological quality assessment

As shown in Table 2, there was 22 eligible studies were included in this review. The average quality score was 66.44 % (SD = 9.4; median = 66.7 %, ranging between 51 % and 85 %).

Table 2: Critical appraisal of the included studies

Author/ year	Design	Attrition assessment					Quality assessment %[3]	Risk of bias [4]
		% in Intervention	% in control	Overall %	Differential Attrition[1]	Relative Attrition (RA)[2]		
Kim	RCT	3.23	16.67	10	13.44 / Concerning	Attrition in Intervention < control < control 0.19	72.7	High
Dastan	RCT	13.6	13.6	13.64	0 / Unlikely to problem	Equivalent : 1	68.2	Unclear
Boesen	RCT	12.75	5.83	9.29	6.9 / Not likely to be a problem	Attrition in Intervention > control / 2.19	74.2	Unclear
Sandgren	RCT	13.64	7.55	10.59	6.1 / Not likely to be a problem	Attrition in Intervention > control / 1.81	66.7	Unclear
Bredal	RCT	12.97	15.38	14.18	2.4 / Not likely to be a problem	Attrition in Intervention < control / 0.84	75.8	Unclear
Sharif	RCT	0	0	0	0 / Not likely to be a problem	Equivalent : 1	59.1	High
Park	RCT	0	8	4	8 / Concerning	Attrition in Intervention < control / 0.20	59.1	High
David	RCT	55.07	46.9	51	8.2 / Concerning	Attrition in Intervention > control / 1.17	59.1	High
Björneklett	RCT	17.8	20.4	19.11	2.62 / Not likely to be a problem	Attrition in Intervention < control / 0.87	77.3	Low
Grunfeld	RCT	23.5	29.8	26.7	6.3 / Not likely to be a problem	Attrition in Intervention < control / 0.79	75.8	Low
Admiraal	RCT	15.7	11.6	13.7	4.12 / Not likely to be a problem	Attrition in Intervention > control / 1.36	65.2	High
Beatty	RCT	25	9.1	17.05	15.9 /	Attrition in	56.1	High

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Author/ year	Design	Attrition assessment					Quality assessment %[3]	Risk of bias [4]
		% in Intervention	% in control	Overall %	**Differential Attrition[1]**	**Relative Attrition (RA)[2]**		
					Concerning	Intervention > control / 2.75		
Tabrizi	RCT	0	0	0	0 / Not likely to be a problem	Equivalent : 1	78.8	Low
Meneses	RCT	0	0	0	0 / Not likely to be a problem	Equivalent : 1	65.2	Unclear
Budin	RCT	13.8	32.2	23	18.4 / Concerning	Attrition in Intervention < control 0.43	71.2	High
Salzer	RCT	19.6	14.8	17.2	4.79 / Not likely to be a problem	Attrition in Intervention > control / 1.32	51.5	Unclear
Wu et al.	RCT	0	0	0	0 / Not likely to be a problem	Equivalent : 1	74.2	Unclear
Elshamy	Quasi-RCT	3.03	3.13	3.08	0.1 / Not likely to be a problem	Attrition in Intervention < control / 0.97	56	Moderate
Sajjad	Quasi-RCT	13.8	10.7	12.25	3.08 / Not likely to be a problem	Attrition in Intervention > control / 1.29	59	Moderate
Loh	Quasi-RCT	24.72	39	32	14.34 / Concerning	Attrition in Intervention < control / 0.63	85	Low
Salonen	Quasi-RCT	38.12	48.3	43.22	10.19 / Concerning	Attrition in Intervention < control / 0.79	58	Moderate
Wonghongkul	Quasi-RCT	9.1	6.1	7.6	3 / Not likely to be a problem	Attrition in Intervention > control / 1.5	69	Moderate

[1] Differential Attrition rate is the variation in attrition rates of the intervention and control groups
[2] Relative Attrition is calculated by dividing the attrition as found in the intervention group with the attrition in the control group
[3] Quality assessment: CONSORT 2010 checklist was used to evaluate the RCTs articles, and TREND statement was used to evaluate the quasi-RCTs
[4] Risk of bias: Cochrane RoB 2.0 tool was used to evaluate the RCTs, and the ROBINS-I tool was used to assess the Quasi-RCTs

In the RCTs, the poorly reported items that might threat the studies' validity, such as; the blinding criterion were reported in only 11.8 % of studies. Also, 41.18 % of studies failed to mention who implemented the randomisation, allocation suppression of concealment was reported in 47 % of studies, and 34 % of studies failed to mention the technique employed to

produce the random allocation sequence. In addition, eight studies failed to mention the approach utilised to determine the sample size, and six studies were partially mentioned. Furthermore, only three studies discussed the calculation of the sample size, and consequently, this may threaten the external validity of the studies. Moreover, some domains were poorly reported in studies, such as; none of the 17 studies provided information concerning the registration number, and only 58.8 % of studies provided a list of limitations in their studies. Regarding quasi-RCTs, poorly reported items that could threaten or limit the studies' validity included; blinding items (16.7 %), the assignment method (22.2 %), sample size determination (33.3 %), baseline data (50 %), statistical methods (56.3 %), and participant flow (58.3 %).

3.2.2 Risk of bias assessment

Random Controlled Trials (RCTs): The risk of bias for all the RCTs studies had been assessed, and assessments summarised for each study in Table (2) and illustrated in Figure (2). Overall, three studies met the criteria for "low risk of bias" (Björneklett et al., 2012; Grunfeld et al., 2011; Tabrizi et al., 2016), seven studies were classified as "unclear" (Boesen et al., 2011; Bredal et al., 2014; Dastan & Buzlu, 2012; Meneses et al., 2009; Salzer et al., 2010; Sandgren & McCaul, 2007; Wu et al., 2018), and seven studies were classified as "high risk of bias" (Table 2) (Admiraal et al., 2017; Beatty et al., 2010; Budin et al., 2008; David et al., 2011; Kim et al., 2017; Park et al., 2012; Sharif et al., 2010). Moreover, the domains were treated as low risk of bias 58.8 %, unclear 34.3 % and "high risk of bias" 6.9 %.

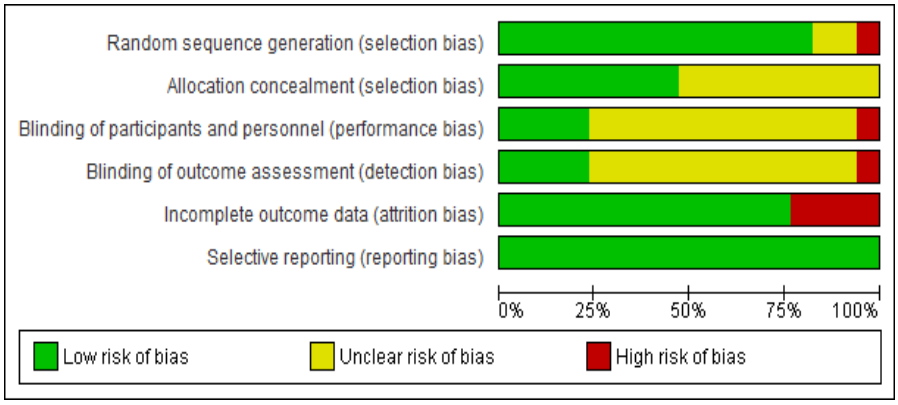

Figure 2: Review of the authors' assessments concerning each risk related to bias. Represented as percentages for all included studies

The blinding domain of participants and researchers was least mentioned in the studies. In fact, four articles reported implementing the blinding of the participants and research team, and one study reported that blinding was not applied to either the research team or the participants. Therefore, this may lead to increasing the incidence of performance and detection bias. Also, 53 % of studies failed to report applying allocation concealment following randomisation. Therefore, these findings may lead to increasing the incidence of selection bias. Notably, the differential attrition rate between groups was concerning in four studies which may lead to bias in estimating the intervention constrain or limit the external validity of the findings in the eligible studies, (Figure 3).

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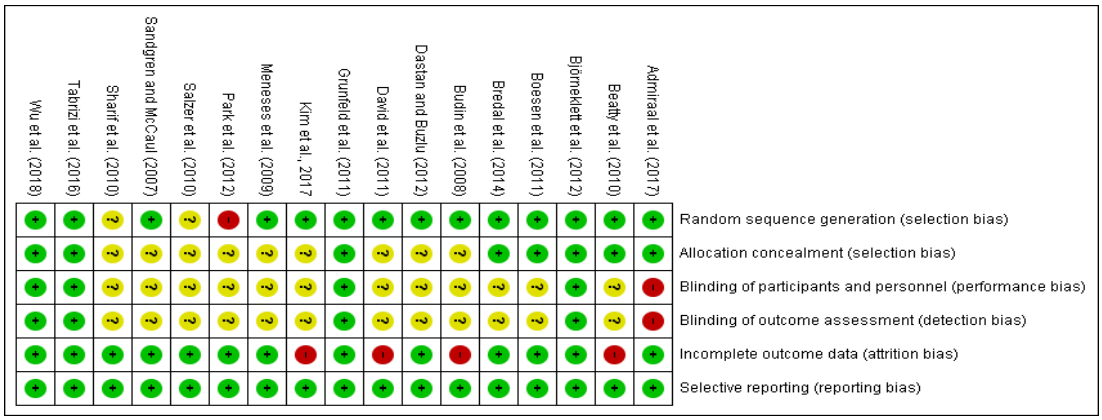


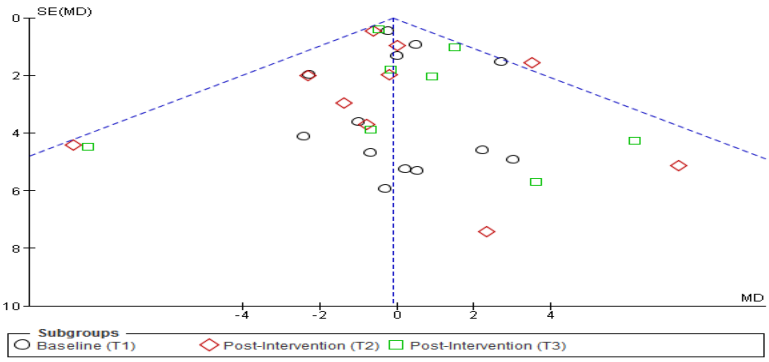
Figure 3: Risk of bias summary: Review of the authors' judgements about each risk of bias item for each included study.

Quasi-experimental Study (quasi-RCTs): The risk of bias has been assessed in the quasi-RCTs studies (see Table 2). The results reported that one study had "a low risk of bias", four studies had "a moderate risk of bias", and one study had a substantial, "serious risk of bias".

3.2.3 Publication bias for QoL:

A funnel plot was constructed to visualise potential publication bias (see Figure 4). Accordingly, it revealed that most of the studies were scattered within the upper and middle area of the graph, to both sides of the line estimate of effect. Notably, the lower area of the funnel is empty, indicating that the data of this meta-analysis is mostly derived from large studies or more specific studies that have relatively low standard error. One study for the intervention group in T3 was out of line. However, visually inspecting the plot did not display significant potential publication bias in the analysis of intervention and control groups.

Figure 4: Funnel plot to assess publication bias for studies examining the effectiveness of educational and counselling support in female breast cancer patients during the trials; T1, T2 and T3, QoL.



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3.2.4 The difference in attrition rates between groups

As observed in Table 2, the average attrition rate was 13.72 % (SE = 2.84; median = 13.62) in the experimental groups and was 14.75 % (SE = 3.09; median = 10.7) in the comparing groups. Further, the average of overall attrition rate was 14.37 % (SE = 2.87, median = 12.28). Moreover, the differential attrition was concerning in four studies (David et al., 2011; Kim et al., 2017; Loh et al., 2013; Salonen et al., 2009), however, the overall differential attrition between the groups was 5.56 (SE = 1.17; median = 4.12). The overall RA rate amongst the groups was 0.88 (95 % CI, 0.76 to 1.03, P = 0.12).

3.3 Effect of the educational and counseling support model on the QoL

Figure (5) illustrates that there were 13 studies included in this analysis, involving 1,536 participants. The overall heterogeneity was moderate: $Tau^2 = 0.62$; $Chi^2 = 43.55$, df = 32 (P = 0.08); $I^2 = 27$ %. The heterogeneity was low in T1; $Tau^2 = 0.00$; $Chi^2 = 6.11$, df = 12 (P = 0.91); $I^2 = 0$ %. While it was moderate in T2 and T3. The heterogeneity in T2: $Tau^2 = 4.48$; $Chi^2 = 27.93$, df = 11 (P = 0.003); $I^2 = 61$ %, if excluded Sharif's article (Sharif et al., 2010), the heterogeneity will decline to be; $Chi^2 = 19.34$, df = 10 (P = 0.04); $I^2 = 48$ %. As well, in T3: $Tau^2 = 0.80$; $Chi^2 = 9.36$, df = 7 (P = 0.23); $I^2 = 25$ % (refer Figure 5).

The random effects analysis gave the large effect size in T2 = 0.74 (95 % CI, -1.15 to 2.62); Z = 0.77 (P = 0.44)). Moreover, the effect size in T3; 0.21 (95 % CI, -1.11 to 1.52); Z = 0.31 (P = 0.76). However, the P value > 0.05, failed to reject the null hypothesis. Notably, this effect size between the intervention and control was statistically not significant. Whereas, in T1; -0.00 (95 % CI, -0.72 to 0.71); Z = 0.01 (P = 0.99). The effect size in all subgroups was statistically not significant; 0.36 (95 % CI, -0.14 to 0.87; Z = 1.40 (P = 0.16). Overall, the random effect meta-analysis gave the effect size for all subgroups = 0.18 (95 % CI, -0.48 to 0.84; Z = 0.53 (P = 0.60)). Hence, P value > 0.05, failed to reject the null hypothesis, the differences were not statistically significant.

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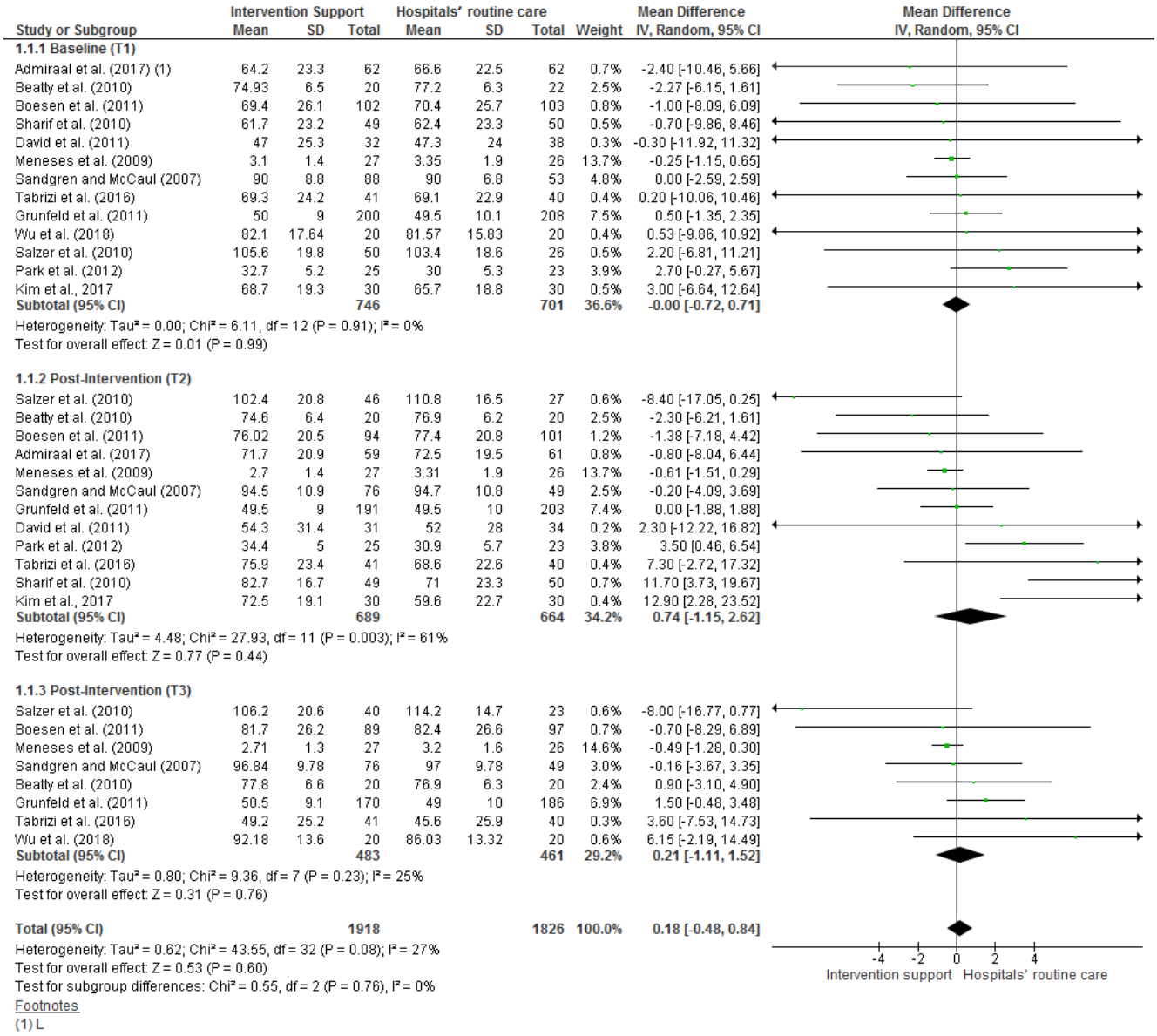
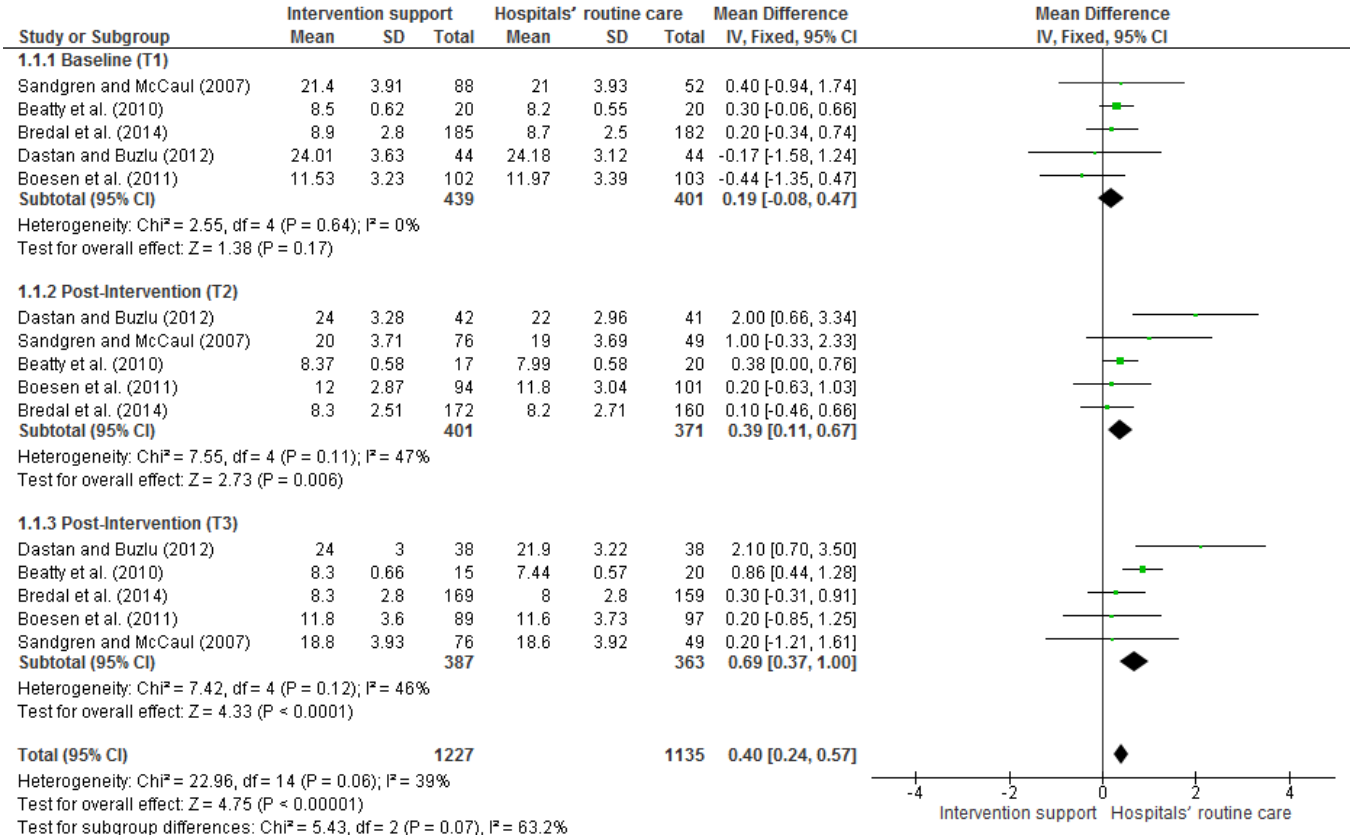


Figure 5: Forest plot: Educational and counseling support versus the hospitals' routine care, outcome; QoL.

3.4 Effect of the educational and counseling support model on the mental adjustment:

As shown in Figure 6, there were five studies included in this analysis involving 752 participants. The heterogeneity was low in the baseline Chi² = 2.55, df = 4 (P = 0.64); I² = 0 %, while it was moderate in both T2 and T3. In T2: Chi² = 7.55, df = 4 (P = 0.11); I² = 47 %, and T3: Chi² = 7.42, df = 4 (P = 0.12); I² = 46 %. Overall, the heterogeneity between subgroups was moderate Chi² = 22.96, df = 14 (P = 0.06); I² = 39 % (refer Figure 5).

Figure 6: Forest plot: Intervention group vs control group, outcome; adjustment to cancer.



The effect size in T_2 and T_3 was statistically significant, while, the effect size in T_1 was statistically not significant (at baseline survey); the fixed effects analysis gave the large effect size in T3 = 0.69 (95 % CI, 0.37 to 1.00; Z = 4.33 (P < 0.001)). In the baseline T_1; 0.19 (95 % CI, -0.08 to 0.47; Z = 1.38 (P = 0.17), and in post-intervention T_2; 0.39 (95 % CI, 0.11 to 0.67; Z = 2.73 (P = 0.006). Overall, the fixed effects meta-analysis gave a summery effect measure for all subgroups = 0.40 (95 % CI, 0.24 to 0.57; Z-value = 4.75 (P = 0.007). Therefore, P value < 0.05, rejected the null hypothesis, and the differences were significant.

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4.0 Discussion

A comprehensive systematic review of educational and/or counseling interventions in breast cancer was undertaken in this study, focussing on adjustment to cancer and QoL. The time of diagnosis is the most stressful period (Waring, 2000), where there were a few of studies focused on patients at the time of diagnosis. The majority of studies (13 studies) examined the impact of the interventions on the QoL, whereas only five studies evaluated the adjustment to cancer.

The average attrition rate was 14.37 %, the differential attrition between the groups was unlikely to constitute a problem 5.56. The RA rate amongst the groups was 0.88, therefore, the attrition in the control groups was observed to be more compared to the intervention group attrition. Relative similar findings have been reported in a systematic review by Jassim, Whitford (2015). They conducted reported that the dropouts and withdrawals were 12.7% in both groups (Jassim et al., 2015). In another study was conducted in North America with 519 patients, the authors reported that the attrition rate was 10% (Christy et al., 2011). However, Brandao et al. (2017) found that the average of attrition rate in the 34 studies was 22.88; SD=15.31(Brandao et al., 2017). In addition, Sheill et al., (2019 conducted a systematic review, they reported that the average of attrition rate 24% (Sheill et al., 2019).

Concerning the effectiveness of the educational and/or counseling interventions in the breast cancer, this analysis provided an overview of current literature. The results indicated that the education and counseling interventions had an effects in improvement of the mental adjustment and QoL in breast cancer patients. However, these improvements were statistically significant in the mental adjustment, while were statistically non-significant in the QoL.

In the current analysis, the findings indicated that the educational and/or counseling interventions had a positive effect on the QoL comapred with control groups, and at the first three months more than the six months of interventions, but these effects statistically non-significant. However, the results revealed that there were three studies revealed that the differences in the effect size between groups were statistically significant; (Kim et al., 2017; Park et al., 2012; Sharif et al., 2010). In contrast, no study indicated that there is a statistically significant difference between groups in the QoL in the six months of intervention.

Similar results were found in a meta-analysis conducted by Matsuda et al. (2014). The analysis revealed that there was no statistically significant differences between groups in the QoL in breast cancer patients (Matsuda et al., 2014). In another systematic review, the analysis has shown similar results too. The authors did not found significant effects for the psychoeducational intervention on the QoL in the breast cancer (Galway et al., 2012).

As well as, Myrhaug et al. (2018) reported that the behavioral interventions, stress management techniques, and physical activities were effective on the QoL. While, the educational and information provision interventions were ineffective on the on QoL (Myrhaug et al., 2018). Similar results were reported by Duncan et al. (2017). They reported

that the results educational interventions were equivocal, while the CBT, MBSR and exercise-based interventions were significantly effects on the QoL(Duncan et al., 2017).

On the contrary, some other reviews reported that the psychoeducational interventions significantly effect on the QoL. Bartolo et al. (2019) reported that the psychoeducational interventions improved the QoL, but the effect size was small (Bartolo et al., 2019). As well as, Raingruber (2011) reported that the review appeared positive results on the QoL and improved the psychological disturbance (Raingruber, 2011). Likewise, Loiselle et al. (2010) the multimedia informational interventions significantly prevent deterioration of functional QoL comparing with the control groups (Loiselle et al., 2010).

Regards with the mental adjustment to cancer, the effects of educational and/or counseling interventions have revealed a significant effects on the mental adjustment in the first three months of the intervention and have increased in the six months after intervention comparing to the control groups. However, results in three studies of five appeared the differences were statistically non-significant: Boesen et al. (2011); Bredal et al. (2014); Sandgren and McCaul (2007).

This findings were substantially similar to a systematic review conducted by Myrhaug et al. (2018). They found significantly effects of multidisciplinary psychosocial interventions on the psychological adjustment in cancer patients (Myrhaug et al., 2018). Similar results were found in the systematic review was conducted by Matsuda et al. (2014). They reported that the psychoeducation interventions improve the emotional well-being in breast cancer patients (Matsuda et al., 2014). However, McAlpine et al. (2015) indicated that the educational and supportive interventions were unclear, and the results appeared mixed efficacy (McAlpine et al., 2015).

In addition, Zhang et al. (2018) reported that the information and supports in telephone-based are necessary and should be routinely offered to women diagnosed with breast cancer (Zhang et al., 2018). In an integrative review, Post and Flanagan (2016) evaluated the effect of information and supports interventions through web-based. They reported that the interventions had the inherent ability to meet the needs of breast cancer survivors and potentially overcoming some of the barriers that have been documented towards the implementation of survivorship care (Post & Flanagan, 2016).

Fawzy (1999) suggested education from an experienced professional and the medical specialist may be tremendously helpful in overcoming many of these challenges (Fawzy, 1999). Indeed, counselling will help patients to manage their health problem better and gradually improve their QoL, which usually begins as early as three months and continues to strengthen moving closer to twelve months (Fawzy, 1999; Linn et al., 1982; M'Imunya et al., 2012).

Several limitations have been observed in this review. The review was not able to include relevant literature published in non-English languages, other than in the English language, but the studies included different regions of the countries. As well as, 41 % of studies had a relatively small sample size, fewer than 50 patients per experimental group. Moreover, some of the included studies tended to employ relatively short follow-up periods, therefore, were excluded from the study. Next, regarding the QoL, domains of symptoms were excluded

because they are not included in all the eligible studies. Also, the anxious preoccupation and helplessness-hopelessness domains in the Mini-Mac scale were excluded because they have yielded different results to the other domains. In addition, the analysis was affected by the heterogeneity and diversity in the studies; mainly in the measurement tools, statistical tests and the studies' objectives. Seventh, due to the insufficient nature of the studies that assessed the adjustment to cancer, publication bias was not assessed. Moreover, some studies were excluded from the meta-analysis due to the authors had not response to provide data. Finally, some authors failed to report the value of the standard deviation (SD), therefore in this study, the RevMan Calculator was employed to determine the value of the SD; that may not be precisely equal to the true value of the standard deviation.

5.0 Conclusion

The educational and/or counseling interventions can be beneficial and useful for patients to adapt with the breast cancer. However, it is less effective on the quality of life, in particularly, in the longer-term as the model may not be consistent with the clinical progression of clinical symptoms and cancer treatment side effects that often arise during the disease. Moreover, three important issues are noted. First, only four articles have reportedly implemented the blinding of participants and research team. Further, nearly 50 % of studies failed to report whether they applied allocation concealment after randomisation. Accordingly, these may lead towards increasing the threat to internal validity. Second, the majority of studies were focused predominantly on the QoL more than towards adjustment and stress. Last but not least, the average of overall attrition rate in the reviewed studies was 14.37 %.

Conflict of Interest

The authors declare no conflict of interest exists.

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Author contributions

Conception and design: author 1, author 2 and author 7

Collection and assembly of data: author 1 and author 6

Quality and risk bias assessment: author 1, author 5 author 6 and author 7

Data analysis and interpretation: author 1, author 5, author 6 and author 7

Manuscript writing: All authors

Final approval of manuscript: All authors

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