Efficacy and Safety of N-acetylcysteine in improving Depressive Symptoms of Neuropsychiatric Diseases: A Systematic Review and Meta-Analysis

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Abstract *– Depressive symptoms are prevalent across various neuropsychiatric disorders. N-acetylcysteine (NAC), which has antioxidant and anti-inflammatory properties, has been explored for its potential as adjunctive treatment. This systematic review and meta-analysis evaluated the efficacy and safety of NAC, compared to standard therapy alone, in improving depressive symptom severity, and quality of life in adults with neuropsychiatric disorders. It also aims to identify any adverse effects from taking NAC.* ***Methods:*** *Randomized Controlled Trials (RCTs) involving adults who are diagnosed with neuropsychiatric diseases with depressive symptoms were included. Primary outcomes assessed were changes in depressive symptom scores, psychosocial function, and reported adverse effects.* ***Results****: Of the 10 RCTs included, 8 were eligible for meta-analysis. NAC as an adjunct significantly reduced depressive symptom severity compared to placebo. However, improvements in psychosocial functioning measured by LIFE-RIFT, SOFAS, and Q-LES-Q were inconsistent and not statistically significant. Subgroup analyses showed no significant benefit in bipolar disorder. Post-hoc analysis revealed a significant reduction in MADRS scores among those treated with NAC.* ***Conclusion:*** *NAC significantly reduces depressive symptom scores in patients with bipolar disorder and MDD. However, its impact on quality of life and psychosocial functioning remains inconclusive. Mild adverse effects, such as gastrointestinal and musculoskeletal complaints, were more common in the NAC group.*

Keywords: Neuropsychiatric disorders, N-acetylcysteine, Depressive symptoms, Major Depressive Disorder, Bipolar Disorder, Generalized Anxiety Disorders, Mood disorder

I. INTRODUCTION

N-acetylcysteine (NAC) is an affordable, widely used drug with potential benefits for depressive symptoms. However, evidence on its effectiveness remains limited and mixed. This systematic review and meta-analysis (SR-Meta) aimed to evaluate the current findings. This study aimed to evaluate the efficacy and safety of NAC, alone or with standard therapy, in reducing depressive symptoms in adults (≥18) years old with major depressive disorder (MDD), bipolar disorder (BD), generalized anxiety disorder (GAD), schizophrenia, and obsessive-compulsive disorder (OCD). Specifically, it aimed to (1)assess changes in depression severity and quality of life using validated scales, and (2) Compare adverse effects of NAC with standard therapy.

II. LITERATURE REVIEW

In 2017, over 970 million people worldwide were affected by mental health disorders, with anxiety and depression being the most common (Roberts et al., 2019). Nearly half of depression cases were in Southeast Asia and the Western Pacific (WHO, 2017). Depression contributed to 43 million Years Lived with Disability and is a leading cause of suicide, the second major cause of death among those aged 15-29 (WHO, 2017). Mental disorders stem from complex genetic and environmental factors, including serotonin transporter gene polymorphisms (Navarro-Mateu et al., 2013). In conflict areas, prevalence can reach 22.1% (Charlson et al., 2019). Depressive symptoms, such as persistent sadness, loss of interest, and suicidal thoughts, are seen across mood and other psychiatric disorders. Comorbidity with anxiety is common and linked to worse outcomes and lower quality of life (Al-Asadi et al., 2014, 2015). Among psychiatric symptoms, depression is the strongest predictor of poor quality of life (Tang & Thomas, 2020). To measure treatment outcomes in adults with depressive symptoms, validated tools are used. Depression severity is assessed through clinician-rated scales like MADRS and HAM-D. Quality of life and functioning are evaluated using instruments such as LIFE-RIFT, SOFAS, and Q-LES-Q, which capture broader impacts of psychiatric conditions beyond symptom reduction.

N-acetylcysteine (NAC), a plant-derived antioxidant and glutathione precursor, is used for conditions like paracetamol toxicity and studied for psychiatric use due to its antioxidant, anti-inflammatory, and neurochemical effects (Šalamon et al., 2019; Agrawal & Khazaeni, 2020). It shows promise as an adjunct treatment for mood and psychotic disorders, with some studies noting symptom improvement and reduced antipsychotic side effects (Berk et al., 2008, 2012; Knackstedt et al., 2009). In depression, NAC may regulate dopamine and glutamate pathways (Belujon & Grace, 2017), though results remain mixed. In addition to these beneficial effects, NAC is more accessible commercially since it is inexpensive, tolerable, and has greater bioavailability orally and topically (Mokhtari et al., 2017; Šalamon et al., 2019).

III. MATERIALS AND METHODS

1. **Research Design:** This study utilized SR-Meta design. The research followed the PRISMA guidelines for SR.

2. **Inclusion Criteria:** This SR included randomized controlled trials (RCTs) involving adults (≥ 18 years old) diagnosed with neuropsychiatric disorders, specifically MDD, BD, GAD, schizophrenia, and OCD, presenting with depressive symptoms. Interventions involved NAC, alone or with standard therapy, in any dose or route. Comparators were placebo or standard therapy. Outcomes assessed were depression, severity and quality of life using validated tools.

3. **Information Sources and Search Strategy:** RCTs were identified through electronic searches in PubMed, Cochrane Library, Science Direct, Google Scholar, UpToDate, and HERDIN. Unpublished data were sought by contacting the St. Luke's Medical Center Psychiatry Department and reviewing bibliographies of relevant studies. Search terms included MeSH headings and keywords related to depression, mood and anxiety disorders, schizophrenia, and NAC.

4. **Procedures:** Two researchers independently screened titles and abstracts. Studies were included if they evaluated the efficacy of NAC (alone or with standard therapy) in improving depressive symptoms among adults with specified neuropsychiatric disorders. All team members independently extracted data, resolving disagreements by consensus. Extracted data, such as study design, NAC dosage, control type, outcomes, and conclusions, were entered into RevMan 5.4. Studies involving depression from medical or substance-related causes were excluded. Two members independently assessed the risk of bias for each study, resolving disagreements by

consensus or consulting a third reviewer. We assessed risk of bias by noting whether each study reported the following criteria: randomization, adequate follow-up, intention-to-treat (ITT) analysis, blinding, similarity of baseline characteristics, and equal treatment of groups. The Risk of Bias Tool Version 2 was used to rate each domain as "low," "some concerns," or "high.

5. **Analysis**: RevMan 5.4 was used for all statistical analyses, following Cochrane Handbook guidelines. A fixed-effect model was applied. Depressive symptom improvement was the primary outcome, analyzed as dichotomous data, with post-hoc analysis based on MADRS mean scores. Secondary outcomes included psychosocial function (measured via LIFE-RIFT, Q-LES-Q, and SOFAS scales) and, adverse effects were recorded. Dichotomous outcomes were expressed as relative risk with 95% CI, while continuous outcomes were reported as mean differences with 95% CI. Heterogeneity was assessed via forest plots, chi-square test ($p<0.10$), and I^2 index. No substantial heterogeneity was found, so a random-effects model was not used. Due to limited included studies, funnel plot analysis for publication bias was not feasible. Subgroup analyses were conducted based on disorder type and treatment duration. Sensitivity analysis was not performed due to the limited number of high-quality studies.

IV. RESULTS

A. Description of Studies

Search Outcome: 135 studies were identified from databases. After removing duplicates and excluding articles based on screening titles and abstracts, 31 studies were left for full-text review. Ten studies met inclusion criteria and 8 were included in the meta-analysis. The 2 studies that could not be pooled into a meta-analysis were described narratively. The selection process followed PRISMA guidelines seen in **Figure 1.**

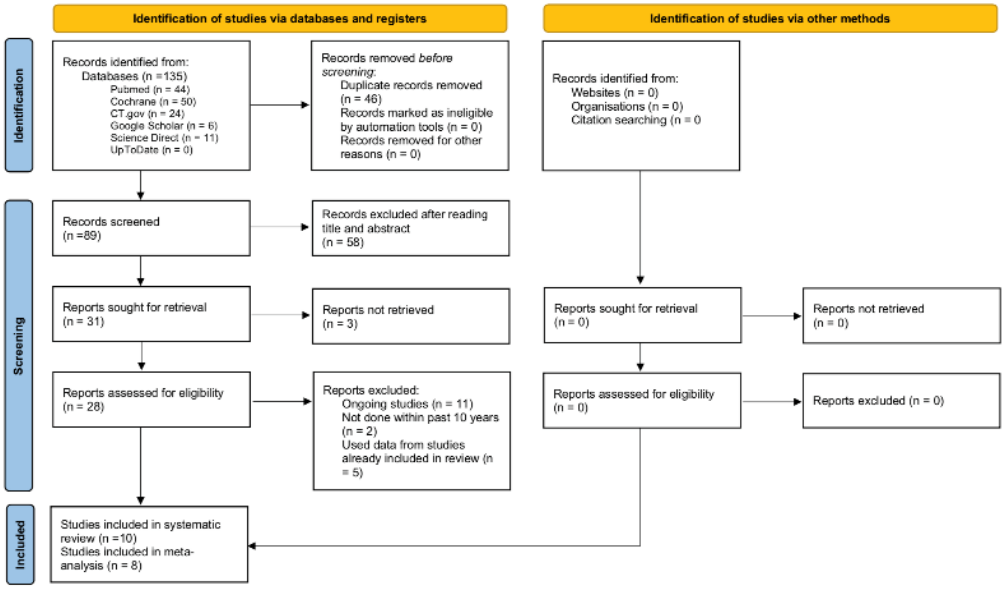

Figure 1. PRISMA Flow Diagram

Included Studies: Table 1 summarizes the included studies, which involved 1,044 adults with sample sizes ranging from 38 to 252. Conditions included bipolar disorder (4), MDD (2), OCD (2), both bipolar and MDD (1), and schizophrenia (1). The included studies used a wide range of validated assessment tools, such as the BDRS, CGI, HAM-D, MADRS, and various quality of life and functioning scales (e.g., SOFAS, Q-LES-Q-SF, LIFE-RIFT, SDS, GAF, WHO-5).

Table 1. Characteristics of included studies

Author, Year	Sample Size	Population	Intervention	Control	Duration
Bauer et al., 2018	38	Bipolar Disorder	NAC 2000 mg/day in addition to current treatment	Sugar pills in addition to current treatment	8 weeks
Berk et al., 2019	181	Bipolar disorder with a current depressive episode	NAC 2000 mg/day per day in addition to existing treatment	Placebo (unspecified)	1 month after
Berk et al., 2012	149	Bipolar disorder with depressive episodes	NAC 2000 mg/day per day in addition to standard treatment	Placebo in addition to standard treatment	24 weeks
Ellegaard et al., 2019	80	Bipolar disorder with a current depressive episode	NAC 3000 mg/day per day in addition to existing treatment	Placebo (unspecified) in addition to existing treatment	24 weeks
Porcu et al., 2018	67	Bipolar depression and MDD	NAC 1800 mg/day in addition to existing treatment	Placebo in addition to existing treatment	12 weeks
Berk et al., 2014	252	MDD	NAC 2000 mg/day in addition to existing treatment (psychotherapy or antidepressant therapy) for 12 weeks	Placebo in addition to current treatment	12 weeks
*Hasebe et al., 2017	121	MDD	NAC 2000 mg/day in addition to existing treatment	Placebo in addition to existing treatment	12 weeks
Grant et al., 2016	66	Skin-picking disorder	NAC titrated from 1200 mg/day to 3000 mg/day over 12 weeks.	Placebo (unspecified)	12 weeks
Sarris et al., 2015	44	Obsessive Compulsive	NAC was titrated from 1000 to 3000 mg/day over 3 weeks in addition	Placebo	16 weeks
*Farokhnia et al., 2013	46	Schizophrenia	NAC given at 1000 mg/day (week 1), then 2000 mg/day, with Risperidone	Placebo, in addition to risperidone	8 weeks

B. Risk of Bias Included in Studies

All studies reported appropriate randomization and comparable baseline characteristics, however, several had limitations in follow-up and in ITT analysis. Only three studies (Berk et al., 2014; Porcu et al., 2018; Grant et al., 2016) fulfilled all criteria. In contrast, five studies (Bauer et al., 2018; Berk et al., 2012; Ellegaard et al., 2019; Sarris et al., 2015; Hasebe et al., 2017) have serious risks of bias because they are missing key methodological elements (Incomplete follow-up or absence of ITT analysis). Assessment of risk of bias can be seen in **Figure 2** below. The studies of Berk et al., 2012, Berk et al., 2014, Berk et. al, 2019, Sarris et al., 2015, and Porcu et al., 2018 were able to comply with all measures and has a low risk of bias. The strengths of the collected studies include randomization, measurement of outcome, and selection of the reported result. Concerns and high risk of bias were seen in five studies in terms of deviations from intended interventions, missing outcome data, and overall bias. Overall, most studies showed low risk of

bias, except for Ellegaard et al., 2019, Grant et al., 2016, Hasebe et al., 2017, and Fahroknia et al., 2013.

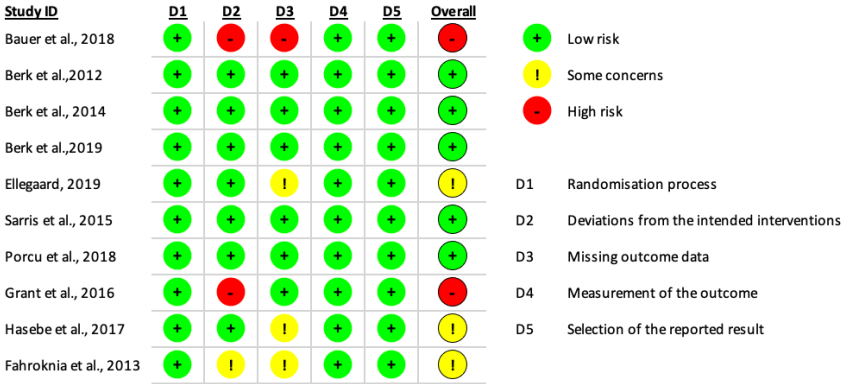

Figure 2. Assessment of Risk of Bias of Included studies

C. Primary Outcome

Two pooled studies (Bauer et al., 2018 and Berk et al., 2014; n=290) showed a significant improvement in depressive symptoms favoring NAC (RR=0.81, CI 0.67–0.98, P=0.03), with no heterogeneity (I^2=0%) as shown in **Figure 3**. Only these two could be pooled; the rest were analyzed narratively. Hasebe et al. (2017) also found a significant reduction in Montgomery–Åsberg Depression Rating Scale (MADRS) scores with adjunctive NAC in MDD. Similarly, Grant et al. (2016) reported decreased Hamilton Depression Rating Scale (HAM-D) scores in patients with skin excoriation disorder. In contrast, Farokhnia et al. (2013), Sarris et al. (2015), and Porcu et al. (2018) found no significant improvements in depressive symptoms with NAC in schizophrenia, OCD, and bipolar disorder, respectively.

Figure 3. Forest Plot using Fixed Effect Model comparing the effect of NAC as main treatment versus placebo on depressive symptoms among neuropsychiatric disease patients

D. Secondary Outcome

Psychosocial Functioning: Three studies (Berk et al., 2012; 2014; 2019) evaluated the impact of adjunctive NAC on psychosocial function and quality of life in patients with bipolar disorder or MDD over 8 to 16 weeks. As shown in **Figure 4**, NAC resulted in a small, non-significant improvement in LIFE-RIFT scores (SMD –0.16, P = 0.14), with no significant effects observed on SOFAS and Q-LES-Q. Heterogeneity across studies was low or negligible.

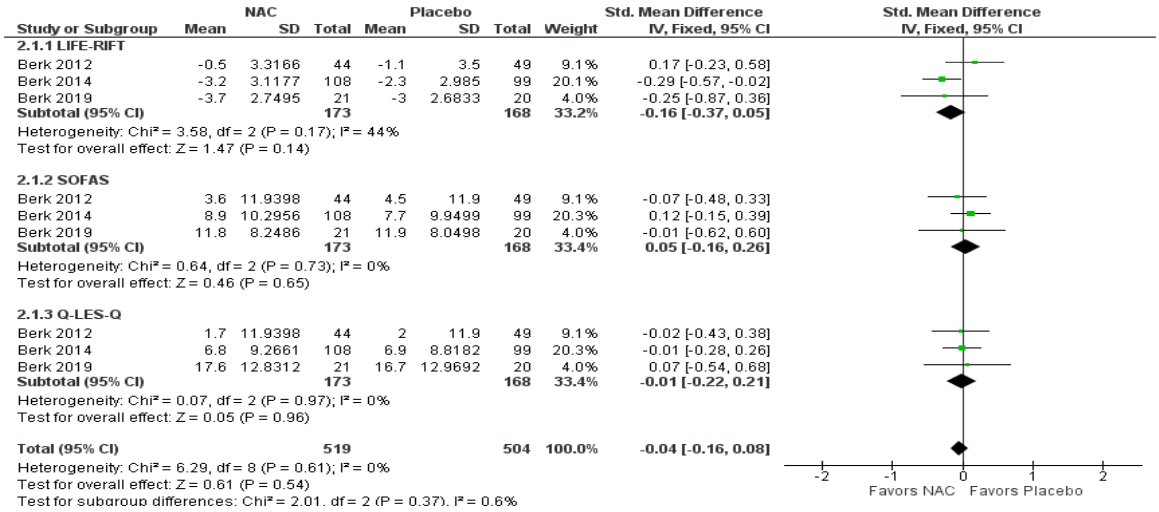

Figure 4. Forest Plot using the fixed effect model comparing the effect of NAC versus placebo in psychosocial function and quality of life.

Adverse Events: As shown in **Figure 5**, adverse events were significantly more common with adjunctive NAC than placebo (RR 1.48, 95% CI 1.21–1.80, P = 0.11), with moderate heterogeneity (I^2 = 49%).

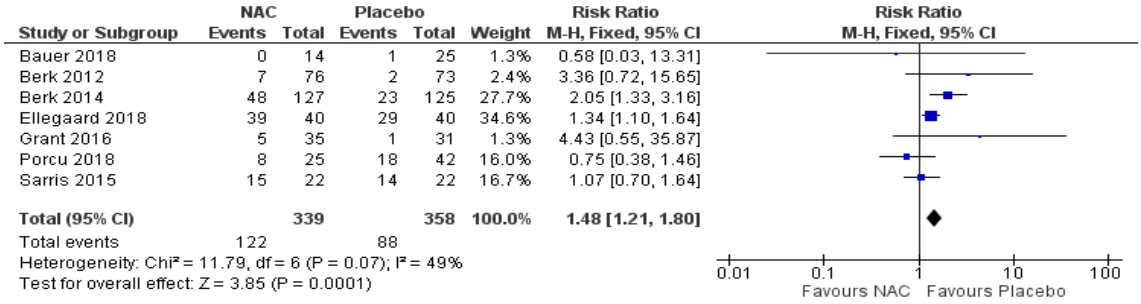

Figure 5. Forest plot using random effect model comparing adverse events among patients who were given NAC as adjunctive treatment and patients who were given placebo

E. Subgroup Analysis

Bipolar Disorder: Subgroup analysis was limited to bipolar disorder (Berk et al., 2012; 2019) due to lack of usable data for other conditions. As shown in **Figure 6**, NAC showed no significant improvement in LIFE-RIFT scores compared to placebo (MD 0.07, P = 0.24), with low heterogeneity (I^2 = 28%).

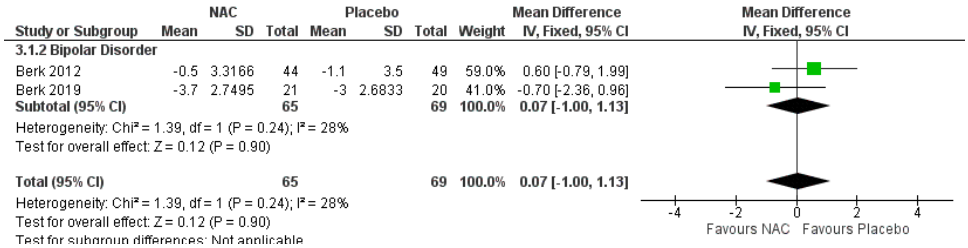

Figure 6. Forest plot using fixed effect model showing the effect of NAC on change in LIFE-RIFT scores on Bipolar Disorder.

Figure 7 shows that NAC had no significant effect on SOFAS scores in patients with bipolar disorder (MD –0.56, P = 0.75), with no heterogeneity (I^2 = 0%).

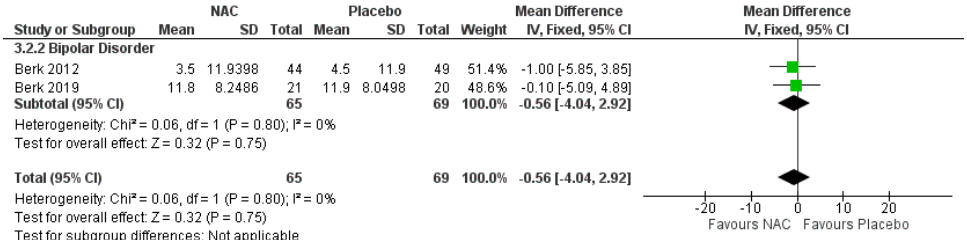

Figure 7. Forest plot using fixed effect model showing the effect of NAC on change in SOFAS on Bipolar Disorder

Figure 8 shows no significant improvement in Q-LES-Q scores with NAC in bipolar patients (MD 0.03, P = 0.99, I^2 = 0%). Similarly, a prior analysis including MDD patients (Berk et al., 2014) found no significant effect (MD –0.10, P = 0.94).

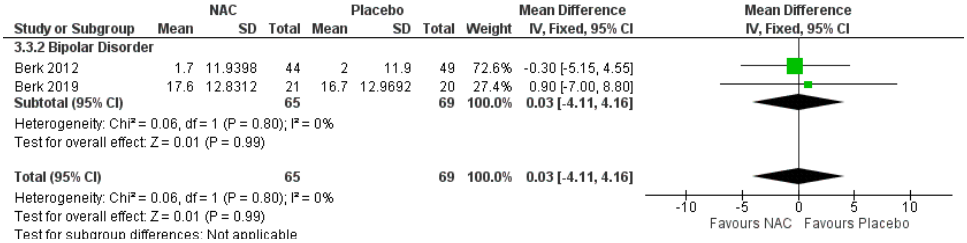

Figure 9. Forest plot using fixed effect model showing the effect of NAC on change in Q-LES-Q scores on Bipolar Disorder

F. Posthoc Analysis

A post-hoc analysis of the changes of MADRS score for four studies (total n=393; Ellegaard et al., 2018; Berk et al., 2012, 2014, 2019) were done. As shown in Figure 17, all studies favored NAC, with a significant pooled reduction in MADRS scores [MD -1.38, 95% CI -1.61 to -1.15, P < 0.00001] and low heterogeneity (Chi2 = 4.30, P = 0.23, I2 = 30%).

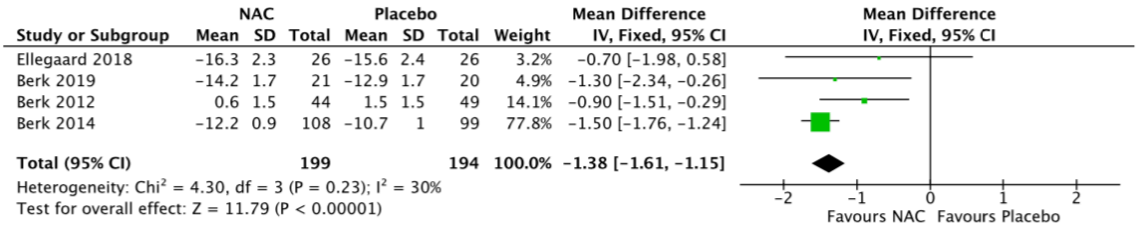

Figure 10. Forest plot using the fixed effect model comparing the effect of N-acetylcysteine and placebo on change in baseline of MADRS scores among patients with neuropsychiatric disorders

V. DISCUSSION

The pooled results from two studies (Bauer et al., 2018; Berk et al., 2014) showed that NAC significantly improved depressive symptom severity in patients with MDD and bipolar disorder (RR = 0.81). This aligns with a post-hoc analysis of four studies (Berk et al., 2012; Berk et al., 2014; Berk et al., 2019; Ellegaard et al., 2018), which reported a mean MADRS score reduction of 1.38, indicating symptom improvement (Muller et al., 2003). NAC may exert this effect by enhancing dopamine release and transport, which are often impaired in depression (Belujon & Grace, 2017). Additionally, its antioxidant and anti-inflammatory properties may reduce inflammation and oxidative stress implicated in depressive states (Berk et al., 2013). However, three studies assessing quality of life and function (via LIFE-RIFT, SOFAS, and Q-

LES-Q) found no significant improvements. This may be due to the studies' focus on mood disorders and the influence of manic symptoms on self-reported measures (Mehta et al., 2014; Sylvia et al., 2017). Nonetheless, Q-LES-Q has shown no major measurement bias in prior assessments (Bourion-Bédès et al., 2015).

In patients with bipolar disorder, NAC showed no significant improvement in functioning or quality of life based on LIFE-RIFT, SOFAS, and Q-LES-Q scores. This contrasts with earlier findings showing functional benefits from adjunctive NAC (Berk et al., 2011). As Porcu et al. (2018) suggest, reduced depressive symptoms do not always translate to improved quality of life.

Adverse events were more frequent in the NAC group than placebo, though generally mild and possibly more relevant in severely ill patients (Berk et al., 2014). Reported side effects included gastrointestinal and musculoskeletal issues such as nausea, heartburn, joint pain, and dizziness (Berk et al., 2019; Ellegaard et al., 2019; Porcu et al., 2018). Given NAC's multiple mechanisms, the exact causes remain unclear, and its safety should not be assumed solely based on its nutraceutical status (Berk et al., 2019).

LIMITATIONS

The study results should be interpreted cautiously, as only two RCTs with a total of 290 participants—one on bipolar disorder and one on MDD—were included in the analysis of the primary outcome. Both studies had high attrition bias. Post-hoc analysis included four RCTs (three on bipolar disorder, one on MDD), but half had poor internal validity (grade D risk of bias). Subgroup analyses for LIFE-RIFT, SOFAS, and Q-LES-Q were also limited to just two RCTs. Additionally, five out of ten included studies had dropout rates over 20%, leading to missing data on NAC's safety and efficacy. Reasons included non-compliance, adverse events, and mental state deterioration. Variability in participants' "usual therapy" and use of different assessment scales also limited result comparability and pooling.

CONCLUSION

Pooled analysis of the two studies showed that NAC combined with standard therapy significantly improves depressive symptoms in patients with bipolar disorder and MDD. This is supported by the findings from Hasebe et al. (2017). Grant et al. (2016) also noted symptom improvement in patients with skin excoriation disorder. However, studies on schizophrenia and OCD showed no significant benefit. NAC did not significantly improve quality of life or psychosocial functioning, including in patients with BD. Mild gastrointestinal and musculoskeletal side effects were more common with NAC than placebo.

RECOMMENDATIONS

Due to the risk of attrition bias in 5 of 8 studies, the authors do not recommend NAC as an adjunct for bipolar disorder and MDD. Further research is needed on its effects in non-mood disorders like GAD, schizophrenia, and OCD, including related conditions under the obsessive-compulsive spectrum.

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