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(REVIEW ARTICLE)

The role of the Mediterranean dietary pattern in the management of depression among adults: A systematic review and meta-analysis of randomized controlled trials

Obianuju Nwosu *

Faculty of Medicine, Health and Life Sciences, Swansea University, Swansea, United Kingdom.

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Abstract

Background: Depression is one of the leading causes of disability and disease burden worldwide, and a substantial gap exists between the global need for mental health care and its provision. Nutritional interventions, such as the Mediterranean diet (MD), have been proposed as accessible, cost-effective adjuncts or alternatives to conventional depression therapies, yet randomised evidence specifically evaluating the whole MD pattern remains scarce.

Aim: To determine the effectiveness of the MD in reducing depressive symptoms among adults globally, and to examine whether this effectiveness varies according to geographical setting.

Methods: A systematic review and meta-analysis of randomised controlled trials (RCTs) was conducted in accordance with the PRISMA 2020 guidelines and a registered PROSPERO protocol. Five databases (MEDLINE, CINAHL, APA PsycInfo, Embase and Scopus) were searched without date restriction owing to the sparsity of relevant RCTs. Methodological quality was appraised using the Cochrane Risk of Bias tool (RoB 2.0). Standardised mean differences (SMD) with standard errors were pooled using a random-effects model in Review Manager 5.4.1.

Results: Seven RCTs (764 randomised participants, 683 completers) met the eligibility criteria; five (438 participants) were pooled in the meta-analysis. Only one study had an overall low risk of bias, while three had some concerns and three had a high risk of bias. The pooled analysis showed a significant improvement in depressive symptoms favouring the MD (SMD = 0.50, 95% CI 0.09–0.90, p = 0.02), with no evidence of statistical heterogeneity (I^2 = 0%, Chi^2 = 0.06, p = 1.00). The effect remained significant after excluding the single high-risk-of-bias study, but became non-significant (p = 0.58) after removing the most heavily weighted trial. Subgroup analysis by geographical setting could not be performed, as all five pooled trials originated from Australia.

Conclusion: There is encouraging, but fragile, evidence that the MD reduces depressive symptoms in adults. The diversity of depressive symptom measurement tools, small sample sizes, short trial durations, and the geographical concentration of the available evidence in a single country limit the strength and generalisability of these conclusions.

Implications for public health and health promotion: Further well-powered, methodologically robust RCTs across diverse geographical and cultural settings, using standardised outcome measures and explicit behaviour-change frameworks, are required before the MD can be confidently recommended within public health nutrition policy for the management of depression.

Keywords: Mediterranean Diet; Depression; Depressive Symptoms; Nutritional Psychiatry; Systematic Review; Meta-Analysis; Randomised Controlled Trials; Public Health Nutrition

* Corresponding author: Obianuju Nwosu; E mail: onyinyechiobianuju@gmail.com

1. Introduction

Depression is one of the leading mental health challenges in public health and a primary global cause of disability, recognised explicitly under Sustainable Development Goal 3.4 on reducing premature mortality from non-communicable diseases (NCDs) and promoting mental health (World Health Organization [WHO], 2017a, 2021). Between 1990 and 2013 the population affected by depression and/or anxiety grew by 50%, from 416 million to 616 million (WHO, 2016), and depression is projected to rank first in the global burden of disease by 2030 (United Nations, 2016). Approximately 280 million people are currently affected, of whom around 92% are adults and women are roughly twice as likely as men to be affected (Priory, 2022; WHO, 2021, 2022b).

Depression interacts bidirectionally with physical health: it is two to three times more prevalent among people with chronic physical conditions, frequently co-occurs with substance use and eating disorders, and is strongly linked with suicide, the fourth leading cause of death among 15–29-year-olds (Read et al., 2017; WHO, 2021). It also carries an enormous economic cost, with depression and anxiety estimated to cost the global economy one trillion US dollars annually (The Lancet Global Health, 2020). Despite the availability of psychological and pharmacological treatments, health systems remain underfunded and under-responsive; only around one-third of people with depression receive formal mental health care, a gap that exceeds 75% in low- and middle-income countries and that was further widened by the COVID-19 pandemic (Moitra et al., 2022; WHO, 2021, 2022a, 2022b). Antidepressants are also frequently reported as ineffective or poorly tolerated, prompting the search for complementary therapeutic strategies (Cuijpers et al., 2020).

Depression shares pathophysiological pathways with several NCDs, including cardiovascular disease, type 2 diabetes, obesity and degenerative conditions, with chronic low-grade inflammation, oxidative stress, gut microbiota disruption and impaired neurogenesis implicated as common mechanisms (Castilho et al., 2020; Marx et al., 2021; Sanchez-Villegas & Martinez-Gonzalez, 2013). Because diet directly influences these same pathways, nutritional psychiatry has emerged as a promising, low-cost and scalable avenue for depression management (Adan et al., 2019; Marx et al., 2017).

The Mediterranean diet (MD) – characterised by a high intake of vegetables, fruits, nuts, legumes, wholegrains, olive oil and fish, moderate wine consumption, and limited red meat and dairy – is among the most extensively researched healthy dietary patterns and has demonstrated cardiometabolic and neuroprotective benefits across diverse populations (Knight et al., 2017; Ventriglio et al., 2020; Woodside et al., 2022). Proposed mechanisms by which the MD may reduce depressive symptoms include anti-inflammatory and antioxidant effects, modulation of the gut microbiota, support for neurogenesis and mitochondrial function, and regulation of the tryptophan–kynurenine pathway (Marx et al., 2021; Sanchez-Villegas & Martinez-Gonzalez, 2013).

Notwithstanding this biological plausibility, the evidence base remains immature and conflicting. Systematic reviews and dose–response meta-analyses of prospective cohort studies (Lassale et al., 2019; Molendijk et al., 2018; Psaltopoulou et al., 2013) report that high MD adherence is associated with a reduced incidence of depression, whereas other meta-analyses (Matison et al., 2021; Shafiei et al., 2019) found no significant association, and a further review (Bayes et al., 2020) reported an ambiguous relationship. Because observational studies cannot establish causal direction (Andrade, 2014), and because no existing systematic review has explicitly synthesised RCT evidence on the whole MD as an intervention for depression (Altun et al., 2019; O'Neill et al., 2022; Opie et al., 2015), this review addresses an important gap. Establishing the extent to which the MD reduces depressive symptoms could inform the development of dietary guidance and public health nutrition policy for depression (Mozaffarian et al., 2018; Nucci et al., 2023).

1.1. Aim and Objectives

The aim of this review was to determine the effectiveness of the MD in reducing depressive symptoms among adults globally. The specific objectives were: (1) to assess the effectiveness of the MD in reducing depressive symptoms among adults, and (2) to determine whether this effectiveness varies across geographical settings.

2. Literature Review

Depression is defined by the Diagnostic and Statistical Manual of Mental Disorders (5th ed.) as the presence of five or more of nine characteristic symptoms, including persistent low mood or anhedonia, over a two-week period, and arises from a complex interplay of genetic, psychological, biochemical, behavioural and environmental determinants (Bains & Abdijadid, 2022; Marx et al., 2017; Schuch et al., 2018). As a condition shaped by social determinants of health at every level of Dahlgren and Whitehead's model, its management has long been framed around behavioural, social and ecological approaches (Liang et al., 2012).

Dietary intake is itself a product of personal, social and environmental influences (Caswell et al., 2013; Monterrosa et al., 2020), and MD interventions have typically drawn, often implicitly, on Bandura's Social Cognitive Theory (SCT). SCT proposes that behaviour change results from the interaction of behavioural, personal and environmental constructs – including self-efficacy, collective efficacy, incentive motivation, facilitation, observational learning, self-regulation and outcome expectations (Bandura, 1998; Buttriss et al., 2018). At a broader level, Story et al.'s (2008) socio-ecological model of dietary behaviour distinguishes individual factors (knowledge, attitudes, skills), social/environmental factors (workplaces, schools, food outlets) and macro-level or 'upstream' factors (food pricing, marketing, policy), all of which can facilitate or constrain adherence to a dietary pattern such as the MD.

A growing number of prospective cohort studies support an inverse association between MD adherence and depression risk (Lassale et al., 2019; Molendijk et al., 2018; Psaltopoulou et al., 2013; Yin et al., 2021), and similar associations have been reported among older adults irrespective of cognitive status (Mamalaki et al., 2023). However, other large cohort analyses have found no association (Marx et al., 2023), and associations appear weaker or absent among younger adults whose depression may be more strongly driven by genetic factors (Power et al., 2017; Rice et al., 2019). Trials of related dietary patterns have also produced mixed results: while several lifestyle-modification and nutritional-counselling trials report reductions in depressive symptoms (Aguilar-Latorre et al., 2022; Bakirhan et al., 2022), other trials found no differential effect of diet on depression prognosis once participants were already following a healthy dietary pattern (Garcia et al., 2023; Garcia-Toro et al., 2016). Conversely, vegetarian and vegan diets – which can be deficient in vitamin B12, iron and omega-3 fatty acids – have been associated with worsened mood in some studies (Hibbeln et al., 2018; Michalak et al., 2012), a pattern not expected with the nutrient-dense MD (Kris-Etherton et al., 2021).

Taken together, the existing literature establishes biological plausibility and some observational support for a protective role of the MD against depression, but is characterised by inconsistent findings, a predominance of observational designs, heterogeneous outcome measures, and an absence of RCT-focused syntheses specific to the whole-diet MD. This review was therefore designed to synthesise RCT evidence using a rigorous, PRISMA-compliant systematic review and meta-analysis methodology.

3. Methodology

A quantitative systematic review (SR) and meta-analysis of RCTs was selected as the appropriate design, as this approach sits at the top of the hierarchy of evidence for intervention effectiveness, maximises objectivity, and allows the pooled results of multiple trials to provide a more precise and trustworthy estimate of effect than any single study (Linares-Espinós et al., 2018; Siddaway et al., 2019; Tawfik et al., 2019). The review protocol was reported in line with the PRISMA-P statement (Moher et al., 2015), conducted according to the PRISMA 2020 guidelines and abstract checklist (Page et al., 2021), guided by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2022), and prospectively registered on PROSPERO.

3.1. Review Question

The review question was formulated using the Population, Intervention, Comparator, Outcome and Study design (PICOS) framework, which was preferred over PICO and SPIDER because it explicitly accounts for study design, a key consideration for this review (Methley et al., 2014; O'Driscoll, 2022). The components were: Population – adults; Intervention – use of the MD; Comparator – non-use of the MD; Outcome – reduced depressive symptoms; Study type – RCTs. The resulting review question was: “Using RCTs, is there a reduction in depressive symptoms among adults who consume the MD compared with those who do not?”

3.2. Eligibility Criteria

Eligibility criteria were defined according to relevance and acceptability (Meline, 2006; Patino & Ferreira, 2018) and are summarised in Table 1.

Table 1 Summary of eligibility criteria for studies included in this review.

Domain	Included	Excluded
Population	Adults (≥18 years) with any form of depressive disorder, diagnosed clinically, by self-report, or by a validated depressive-symptom rating scale, with or without comorbidities	Non-human studies; participants under 18 years; studies introducing a new co-treatment during the intervention period
Intervention / Comparator	Whole-diet MD interventions (group classes, individual counselling, or prescribed diet); multicomponent lifestyle interventions where non-dietary components were controlled in the comparator; inactive (usual diet/wait-list) and active (alternative diet, counselling, social-support) comparators	Interventions targeting a single MD nutrient/component (e.g., polyphenols, fish intake alone); weight-loss-focused interventions
Outcome	Change in depressive symptoms measured on any standardised depression scale	Other mental health outcomes not relating to depression
Study design	Randomised controlled trials	Non-RCTs; case series/reports; economic evaluations; studies not using a standardised depression scale
Other	English language; full text available; peer-reviewed; no geographical or time-point restriction; no publication-date limit	Non-English language; abstract/conference-only records; grey literature

3.3. Search Strategy and Study Selection

Search terms were developed using the MeSH thesaurus following a scoping search of Google Scholar, combining truncated terms for depression ("depress*", "dysthymi*") with variants of "Mediterranean diet*" (e.g., "Med-diet", "Mediterranean-style diet*"), joined using the Boolean operators AND/OR. Five databases – MEDLINE, CINAHL, APA PsycInfo, Embase and Scopus – were searched via the Swansea University "ifind" platform on 23 January 2023, applying database-specific filters for peer-reviewed, human, English-language studies. No date restriction was applied because of the scarcity of eligible RCTs. Records were imported into EndNote for de-duplication, and remaining duplicates were removed manually. Titles and abstracts were screened against the eligibility criteria, followed by full-text assessment of potentially eligible reports.

3.4. Data Extraction and Risk-of-Bias Assessment

Data extraction was performed manually using an adapted version of the Cochrane Data Collection Form for Intervention Reviews (Li et al., 2022), capturing study aims, setting, population, intervention and comparator components, outcome measures, and results. Methodological quality was independently assessed using the Cochrane Risk of Bias tool for randomised trials, version 2 (RoB 2.0; Higgins et al., 2019), which evaluates five domains – bias arising from the randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result – each rated as low risk, some concerns, or high risk. An overall judgement was derived by combining the five domain-level ratings (Table 2). Both Review Manager 5.4.1 and the Cochrane Risk-of-Bias Excel macro were used to generate, respectively, visual summaries and detailed domain-level outputs.

Table 2 Criteria for the overall risk-of-bias judgement (adapted from RoB 2.0; Higgins et al., 2019).

Overall risk-of-bias judgement	Criteria
High risk of bias	The study is judged to be at high risk of bias in at least one domain, or judged to have multiple domains raising concerns that substantially reduce confidence in the result
Some concerns	The study is judged to raise some concerns in at least one domain, but not to be at high risk of bias in any domain
Low risk of bias	The study is judged to be at low risk of bias across all domains

3.5. Data Synthesis and Statistical Analysis

Because the outcome of interest (change in depressive symptoms) was measured continuously using several different scales across studies, a standardised mean difference (SMD) approach was adopted, calculated as the between-group mean difference divided by the pooled standard deviation (Higgins et al., 2022). To ensure consistency, between-within-group mean differences (BWGMD) were calculated for each study as the within-group change in the MD arm minus the within-group change in the comparator arm, rather than relying on values as reported, which sometimes differed in calculation direction across papers. Where standard deviations were not reported, they were derived from the standard error using the t-statistic obtained via the Excel function TINV(p-value, degrees of freedom), following the approach recommended in the Cochrane Handbook (Higgins et al., 2022). Where exact p-values were not reported, conservative estimates were used (e.g., $p < 0.05$ entered as 0.05); studies reporting $p > 0.05$ without an exact value were excluded from quantitative synthesis as the missing values could not be reliably estimated.

Pooling was performed in Review Manager 5.4.1 using a random-effects model, with statistical significance set at $p \leq 0.05$. Because the outcome (reduced depressive symptoms) is desirable, forest plots were oriented such that effects favouring the MD fall to the right of the line of no effect. Heterogeneity was assessed using the Chi^2 (Cochran's Q) statistic, the I^2 statistic, and the associated p-value, with heterogeneity considered present where $p \leq 0.05$ alongside an I^2 of 41–100% (Chang et al., 2022; Sedgwick, 2015b). Where heterogeneity was identified, subgroup analyses were planned by geographical setting, measurement scale, intervention components, and methodological quality. Sensitivity analyses were planned to examine the influence of individual high-risk-of-bias or highly weighted studies on the pooled estimate.

3.6. Ethical Considerations

No ethical approval was required, as this review used only previously published, publicly available data. All procedures followed established systematic review guidance (Vergnes et al., 2010).

4. Results

4.1. Study Selection

The database search identified 1,581 records (MEDLINE = 234, CINAHL = 135, Scopus = 496, APA PsycInfo = 93, Embase = 623). After removing 1,069 duplicates (702 by automation, 367 manually), 512 records were screened by title and abstract, of which 485 were excluded (450 by title, 35 by abstract). Of the 27 reports sought for retrieval, 3 could not be obtained, leaving 24 reports assessed for eligibility at full text. Following full-text assessment, 17 were excluded (cross-sectional, n = 3; longitudinal, n = 4; cohort, n = 2; letters/replies, n = 1; health news, n = 1; insufficient duration, n = 1; other reasons, n = 5), leaving seven studies for inclusion in the review.

4.2. Risk-of-Bias Assessment

Only one study (Jacka et al., 2017) was judged to be at overall low risk of bias. Three studies (Bayes et al., 2022; Francis et al., 2019; Wade et al., 2018) raised some concerns, and three studies (Hyppa et al., 2003; Parletta et al., 2019; Wardle et al., 2000) were judged to be at high risk of bias. Across domains, attrition bias (missing outcome data) was the most frequently problematic domain, reflecting incomplete follow-up in most trials; however, this contributed substantially to an overall high-risk judgement only for Wardle et al. (2000), which had high risk of bias in two domains. Conversely, all studies were rated favourably for baseline comparability between intervention and comparator groups and for not selectively reporting from multiple analytical approaches.

4.3. Characteristics of Included Studies

The seven included studies, published between 2000 and 2022, randomised a combined 764 participants, of whom 683 (89.4%) completed their respective trials. Trial duration ranged from 3 to 24 weeks. Five studies (71.4%) were conducted in Australia (Bayes et al., 2022; Francis et al., 2019; Jacka et al., 2017; Parletta et al., 2019; Wade et al., 2018), one in Finland (Hyppa et al., 2003), and one in the United Kingdom (Wardle et al., 2000). Two studies recruited men only (Bayes et al., 2022; Hyppa et al., 2003); the remainder included both sexes. None of the seven studies reported using an explicit public health behaviour-change theory. Seven different depression scales were used across the studies, with three studies (Francis et al., 2019; Jacka et al., 2017; Wardle et al., 2000) employing more than one tool. Table 3 summarises the key characteristics of the included studies.

Table 3 Characteristics of the seven studies included in the review (n/r = not reported in extractable form).

Study	Country	Sample (n)	Sex	Duration	Depression scale(s)	Overall RoB
Bayes et al. (2022)	Australia	72	Male only	12 weeks	BDI-II	Some concerns
Francis et al. (2019)	Australia	76	Both	3 weeks	CESD-R, DASS-21, POMS	Some concerns
Hyppa et al. (2003)	Finland	n/r	Male only	12 weeks	BSI	High
Jacka et al. (2017)	Australia	56	Both	12 weeks	MADRS, HADS	Low
Parletta et al. (2019)	Australia	152	Both	24 weeks	DASS-21	High
Wade et al. (2018)	Australia	82	Both	8 weeks	POMS	Some concerns
Wardle et al. (2000)	United Kingdom	n/r	Both	12 weeks	BDI-II, POMS	High

Regarding intervention components, five of the seven studies (Bayes et al., 2022; Francis et al., 2019; Jacka et al., 2017; Parletta et al., 2019; Wardle et al., 2000) provided participants in the MD arm with three to seven sessions of dietary counselling, and five studies (Bayes et al., 2022; Francis et al., 2019; Jacka et al., 2017; Parletta et al., 2019; Wade et al., 2018) provided food hampers as an incentive. Two studies tested additional supplementation alongside the MD: Parletta et al. (2019) examined fish-oil supplementation and Wade et al. (2018) examined calcium supplementation. Comparator groups were either inactive (continuation of habitual diet; Francis et al., 2019; Hyppa et al., 2003; Wardle et al., 2000) or active, comprising either befriending/social-support sessions (Bayes et al., 2022; Jacka et al., 2017; Parletta et al., 2019) or a low-fat dietary intervention (Wade et al., 2018; Wardle et al., 2000).

4.4. Effectiveness of the Mediterranean Diet on Depressive Symptoms

Five studies (Bayes et al., 2022; Francis et al., 2019; Jacka et al., 2017; Parletta et al., 2019; Wade et al., 2018) provided sufficiently complete and comparable data for meta-analysis, comprising 221 participants in the MD group and 217 in the comparator group. Hyppa et al. (2003) and Wardle et al. (2000) were excluded from pooling because of incomplete, non-deducible data and because both trials had more than two study arms, exceeding the planned scope of the meta-analysis. Table 4 presents the standardised data used for pooling.

Table 4 Data used in the meta-analysis of standardised mean differences (SMD) in depressive symptoms, Mediterranean diet versus comparato

Study	Scale	p-value	Ne	Nc	BWGMD	SE	SD	SMD	RoB
Bayes et al. (2022)	BDI-II	0.001	36	36	-14.5	4.22	17.91	0.81	SC
Francis et al. (2019)	CESD-R	0.007	38	38	-6.47	2.77	10.17	0.64	SC
Jacka et al. (2017)	MADRS	0.001	31	25	-7.1	3.48	7.59	0.94	Low
Parletta et al. (2019)	DASS-21	0.027	75	77	-4.52	2.23	12.47	0.36	High
Wade et al. (2018)	POMS	0.03	41	41	-0.47	2.21	0.96	0.49	SC

Ne = sample size, MD group; Nc = sample size, comparator group; BWGMD = between-within-group mean difference; SE = standard error; SD = standard deviation; RoB = overall risk of bias (SC = some concerns).

The pooled random-effects analysis showed a statistically significant summary effect favouring the MD over comparator conditions (SMD = 0.50, 95% CI 0.09–0.90, p = 0.02), with no evidence of statistical heterogeneity (I^2 = 0%, Chi^2 = 0.06, df = 4, p = 1.00). Because heterogeneity was absent, subgroup analysis was not formally required; however, a post-hoc sensitivity analysis was conducted to verify that the single high-risk-of-bias study (Parletta et al., 2019) did not unduly

influence the result. After excluding this study, the pooled SMD, confidence interval, p-value and heterogeneity statistics remained essentially unchanged, indicating that the overall finding was robust to this study's exclusion.

Planned subgroup analysis by geographical setting could not be conducted, as all five pooled studies were conducted in Australia; the two excluded studies (Hyppa et al., 2003; Wardle et al., 2000) were the only ones conducted elsewhere (Finland and the United Kingdom, respectively), but could not be incorporated into the quantitative synthesis.

A post-hoc subgroup analysis compared plain MD interventions with MD interventions that included additional supplementation (fish oil or calcium). No significant difference was found between the two subgroups ($p = 0.83$); however, when considered as standalone subgroups, the supplemented-MD subgroup showed a significant effect while the plain-MD subgroup did not. Because Wade et al. (2018) contributed a disproportionately large weight to both this subgroup analysis and the overall pooled analysis, a further sensitivity analysis excluding this study was performed. With Wade et al. (2018) removed, the pooled effect became non-significant ($p = 0.58$), although the direction of effect remained in favour of the MD and heterogeneity remained at zero.

5. Discussion

5.1. Overview

This review synthesised seven RCTs reporting changes in depressive symptoms following exposure to the MD as a primary or secondary outcome. Only one study (14.3%; Jacka et al., 2017) was at overall low risk of bias, while three (42.9%; Bayes et al., 2022; Francis et al., 2019; Wade et al., 2018) raised some concerns and three (42.9%; Hyppa et al., 2003; Parletta et al., 2019; Wardle et al., 2000) were at high risk of bias. Because the reliability of a systematic review depends on both its methodology and the quality of its constituent studies (Garcia-Doval et al., 2017; Møller & Myles, 2016), this distribution raises some concern about the overall certainty of the evidence, although the pooled effect was not materially altered by the inclusion of the high-risk-of-bias study.

A key cross-cutting observation was the diversity of outcome measurement: seven different depression scales were used across the seven studies, with three studies applying more than one tool. This heterogeneity of instruments makes direct comparison of effect sizes across studies difficult (Murad et al., 2019) and was the principal reason a standardised mean difference approach was adopted for pooling. Adherence to the MD was likewise measured using six different tools, again limiting comparability, although across studies higher MD adherence was consistently associated with greater improvement in depressive symptoms.

5.2. Theoretical Considerations

Consistent with the broader literature on public health nutrition interventions, none of the seven included trials explicitly stated or applied a behaviour-change theory (Jackson & Waters, 2005; Thompson, 2018). Nevertheless, several SCT constructs were implicitly embedded in intervention design: self-efficacy and collective efficacy were reflected in informed consent and group cooking sessions; incentive motivation, facilitation, observational learning and self-regulation were operationalised through food hampers, gift cards, cooking guides and dietary self-monitoring (all studies except Hyppa et al., 2003); and outcome expectations were addressed through goal-setting in two studies (Bayes et al., 2022; Jacka et al., 2017) (Bandura, 1998; Buttriss et al., 2018).

However, the Health Belief Model suggests that adoption of a protective behaviour depends on an individual's perceived threat from the underlying condition and their belief in the effectiveness of the behaviour (Abraham & Sheeran, 2015) – factors not directly addressed by the included trials. Similarly, Story et al.'s (2008) socio-ecological model highlights that 'upstream' factors such as food pricing, availability and marketing can override individual-level intentions to change diet, yet such factors were not measured or controlled in any of the included studies. As Buttriss et al. (2018) note, the evidence base for theory-driven dietary behaviour change is itself dominated by individualistic, predominantly White populations, limiting confidence in the cross-cultural applicability of the constructs identified here.

5.3. Methodological Considerations

While RCTs represent the gold standard for evaluating intervention efficacy (Linares-Espinós et al., 2018), several methodological issues constrain the interpretation of this review's findings. First, considerable clinical heterogeneity existed across studies in comparator conditions (inactive usual-diet controls versus active social-support or low-fat-diet controls), participant sex (two male-only trials versus five mixed-sex trials), and age range (18–70 years), each of which has previously been linked to variation in depressive symptomatology and dietary adherence (Coryell et al., 2009; Ferreira-Pêgo et al., 2020; Zhao et al., 2020).

Second, trial durations were short, ranging from 3 to 24 weeks, with most trials lasting only 12 weeks; this limits inference about the durability of any benefit (Zeilstra et al., 2018). Notably, the only longer-duration trial (Parletta et al., 2019, 24 weeks) was also the only study contributing to the meta-analysis that was rated at high risk of bias, driven primarily by weaknesses in the randomisation process. Third, sample sizes were modest, ranging from 31–75 participants in the MD arm and 25–77 in the comparator arm; small trials are known to be susceptible to inflated effect sizes (Hackshaw, 2008; Turner et al., 2013), and publication bias may further favour the dissemination of positive findings (Song et al., 2010). Finally, unmeasured confounders – such as comorbidities or concurrent lifestyle changes – could not be ruled out (Hébert et al., 2016; Mirmiran et al., 2021).

5.4. Objective 1: Effectiveness of the Mediterranean Diet

The pooled analysis indicates that the MD significantly reduces depressive symptoms relative to comparator conditions (SMD = 0.50, 95% CI 0.09–0.90, p = 0.02), with no detectable heterogeneity. This is broadly consistent with findings from related trials and reviews of healthy dietary patterns and depression (Aguilar-Latorre et al., 2022; Bakirhan et al., 2022; Firth et al., 2019; Opie et al., 2015; Psaltopoulou et al., 2013; Sánchez-Villegas et al., 2013; Torres & Nowson, 2012; Ventriglio et al., 2020), and aligns with cohort evidence of a dose–response relationship between MD adherence and depression risk (Yin et al., 2021) and with findings among older adults regardless of cognitive status (Mamalaki et al., 2023).

However, the loss of statistical significance when the most heavily weighted trial (Wade et al., 2018) was excluded (p = 0.58) substantially tempers this conclusion. This mirrors the null finding reported by Marx et al. (2023) and the absence of effect reported by Garcia-Toro et al. (2016), and suggests that the overall result may be driven disproportionately by a small number of trials. Notably, participants in Wade et al. (2018) were aged 45 years and above, raising the possibility that the relationship between diet and depression differs by age – potentially reflecting a different aetiological pathway in younger adults, where genetic factors may play a larger role (Howard et al., 2020; Power et al., 2017; Rice et al., 2019), or age-related differences in the clinical presentation of depression (Bardinet et al., 2022). Conversely, findings from vegetarian-diet studies, in which nutrient-poor diets were associated with worsened mood (Hibbeln et al., 2018; Michalak et al., 2012), provide indirect support for a nutrient-mediated mechanism of the MD's effect, consistent with the absence of key micronutrient deficiencies in MD-adherent diets (Kris-Etherton et al., 2021).

5.5. Objective 2: Geographical Setting

The second objective – to examine whether the effectiveness of the MD varies by geographical setting – could not be addressed, as all five trials included in the meta-analysis were conducted in Australia. This concentration is notable given that the MD originates from, and might be expected to be most extensively studied in, Mediterranean-region countries (Berry et al., 2011; Urquiaga et al., 2017). One plausible explanation is the practical difficulty of establishing a genuine non-MD control group in regions where the MD already constitutes the habitual diet (Guasch-Ferré & Willett, 2021; Rishor-Olney & Hinson, 2022). The absence of studies from low- and middle-income countries, and the lack of attention to vulnerable groups such as pregnant or lactating women, those with a family history of depression, or those with obesity or other metabolic disorders, further limits the generalisability of these findings to the global population that this review aimed to address.

6. Conclusion

This review set out to determine the effectiveness of the MD in reducing depressive symptoms among adults globally and to examine whether this effect varies by geographical setting. Seven RCTs involving 764 randomised participants were identified, of which five (438 participants) contributed to a meta-analysis showing that the MD significantly reduces depressive symptoms compared with control conditions (SMD = 0.50, 95% CI 0.09–0.90, p = 0.02), with no evidence of heterogeneity. This result was robust to the exclusion of the single high-risk-of-bias study, but not to the exclusion of the most heavily weighted trial, indicating that the overall finding should be interpreted with caution. The second objective could not be achieved, as all trials contributing to the meta-analysis were conducted in a single country (Australia), preventing any assessment of geographical variation in effect.

Overall, this review provides cautiously encouraging evidence that the MD may be an effective, low-cost, non-pharmacological intervention for reducing depressive symptoms in adults. However, the certainty of this evidence is constrained by the small number of eligible trials, their modest sample sizes, short durations, methodological limitations, the wide variety of outcome measurement tools used, and the concentration of evidence in a single geographical and cultural setting. As the most recent systematic review and meta-analysis to evaluate RCT evidence specifically on the whole MD pattern and depression, this review makes a timely contribution to the literature while

highlighting substantial gaps that future research must address before the MD can be confidently incorporated into public health nutrition policy and practice for depression management.

Recommendations

Based on the findings, strengths and limitations of this review, the following recommendations are proposed for research, practice and policy.

- **Standardise outcome measurement.** The use of seven different depression scales and six different MD-adherence tools across only seven trials substantially limits comparability. Researchers, journal editors and relevant professional bodies should work towards adopting a small number of standardised, validated instruments for both depressive symptoms and MD adherence in future trials (Akobeng, 2005; Keszei et al., 2010).
- **Diversify the geographical and cultural base of evidence.** Future RCTs are urgently needed outside Australia, including in Mediterranean-region countries, low- and middle-income countries, and culturally diverse populations, to permit meaningful subgroup analysis by geographical setting and to assess the cross-cultural transferability of the MD as an intervention (Buttriss et al., 2018; Moore et al., 2018; Tsofliou et al., 2022).
- **Conduct larger, longer-duration trials.** Given the small sample sizes (31–75 per arm) and short durations (3–24 weeks) of the included trials, adequately powered RCTs with follow-up periods extending well beyond six months are needed to establish the durability of any benefit and to reduce the risk of inflated effect estimates (Hackshaw, 2008; Turner et al., 2013; Zeilstra et al., 2018).
- **Apply explicit behaviour-change frameworks.** Future intervention designs should explicitly draw on, and report, theoretical frameworks such as Social Cognitive Theory and socio-ecological models of dietary behaviour, including consideration of upstream/structural determinants of food choice (Story et al., 2008; Timlin et al., 2020).
- **Address cost, sustainability and accessibility.** All included trials provided incentives such as food hampers, raising concerns about the financial sustainability and scalability of MD interventions outside research settings (Alves et al., 2022; Blackford, 2021; Garnett, 2013). Future research should evaluate the cost-effectiveness of MD interventions and explore strategies to improve affordability and ease of preparation (Mills et al., 2017; Moore et al., 2018).
- **Include vulnerable populations.** Future trials should consider populations at elevated risk of depression, including pregnant and lactating women, individuals with comorbid metabolic conditions, and those with a family history of depression, who were not represented in the current evidence base.
- **Exercise caution in policy translation.** Given the current limitations in the quality, quantity and geographical spread of the evidence, the MD should not yet be promoted as a stand-alone or primary public health nutrition policy intervention for depression. Instead, it may be considered as a promising adjunct within broader public health nutrition strategies, pending stronger and more diverse evidence (Branca & Ellis, 2018).
- **Strengthen review methodology in future updates.** As this review was conducted by a single reviewer with supervisory oversight, future updates of this review should involve at least two independent reviewers at the screening, extraction and risk-of-bias stages, in line with standard systematic review guidance (Clarke, 2011).

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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