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The Effect of Vitamin D Therapy on the Level and Duration of Primary Dysmenorrhea Pain: Systematic Literature Review

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Abstract:-
Background: Dysmenorrhea is the most common problem in women of childbearing age. Treatment for dysmenorrhea includes NSID, OCP, COX-2 specific inhibitors, but due to side effects, the majority of women prefer to use complementary alternative medicine.

Objective: This study aimed to analyze the effect of vitamin D therapy on the level and duration of primary dysmenorrhea pain in women of childbearing age.

Method: Search articles through Science Direct, PubMed, and Pro-Quest databases using boolean operators (AND and OR). The study inclusion criteria were publication in English, study design Randomized Controlled Trial from 2015 to 2021, female study participants with primary dysmenorrhea, ages 18 to 49 years, intervention given was vitamin D compared with placebo, or in combination with mefenamic acid., novafen and calcium carbonate. The results of the level and duration of pain were measured by VAS (Visual Analog Scale).

Results: Statistical tests showed a significant change in pain intensity after administration of vitamin D therapy, which is where the administration of vitamin D can affect the pain of dysmenorrhea. Conclusion: Vitamin D therapy can be considered to treat primary dysmenorrhea.

Keywords:- *Dysmenorrhea, Vitamin D, Pain Level, Pain Duration, Randomized Controlled Trial.*

I. INTRODUCTION

Women's health problems are related to sexual and reproductive health, ranging from menstruation and gynecological disorders such as polycystic ovaries, risky pregnancies, abortions, sexually transmitted diseases and urinary tract infections.[1] Abnormal uterine bleeding and menstrual disorders that are commonly experienced by women include pain during menstruation (dysmenorrhea), cessation of menstruation (amenorrhea) or irregular menstruation (oligomenorrhea), as well as prolonged menstruation (menorrhagia) or excessive uterine bleeding.[2] The most common menstrual disorder experienced, however, is poorly understood and rarely considered when assessing women's health and life experiences is dysmenorrhea or referred to as menstrual pain.[3] The prevalence dysmenorrhea reaches 45-95% in women of childbearing age.[4] The results of a systematic review conducted by the World Health Organization (WHO) show that the prevalence of menstrual pain in women of childbearing age is between 17% to 81%.[2]

Women 20 years of age or younger almost always have dysmenorrhea, which refers to pain without pathological pelvic disease. This occurs after a regular ovulatory cycle.[5] dysmenorrhea is caused by pelvic abnormalities such as endometriosis, and changes in the nature of dysmenorrhea (intensity, duration) over time.[6] Pain experienced by women with dysmenorrhea causes discomfort and can affect the mood of the person. The adverse effects caused by dysmenorrhea include disruption of health and physical activity, social aspects of daily life and even economic aspects. A person who experiences dysmenorrhea generally experiences a decrease in performance in doing their work, hours or learning activities, including absenteeism from school and decreased quality of sleep.[4,7] Pain conditions that can be exacerbated by dysmenorrhea include irritable bowel syndrome, non-cyclic pelvic pain, or increase the risk of developing other chronic pain in later life.[4] The occurrence dysmenorrhea is closely related to prostaglandin F2alpha (PGF2a), oxytocin and vasopressin. Production and release of PGF2a increased significantly, causing increased uterine contractions, decreased uterine blood flow, increased peripheral nerve sensitivity, causing pain. Pharmacological therapy for the treatment of dysmenorrhea is focused on reducing pain and restoring uterine performance.[8] There are various treatment options available for people with dysmenorrhea, including Nonsteroidal Anti-inflammatory Drugs (NSAIDs), Oral Contraceptive Pills (OCP), cyclooxygenase-2 COX-2) specific inhibitors, and complementary alternative medicine.[9,10]

Conventionally dysmenorrhea is treated with NSAIDs, their efficacy has been supported by research evidence. The use of COX-2 specific inhibitors for patients with dysmenorrhea is also effective, but has been discontinued in many countries due to cardiovascular safety and cardioprotective considerations.[9,10] Simple analgesics (aspirin, paracetamol) are useful in reducing pain in the short term, but have side effects, one of which is allergic skin reactions. Oral contraceptives are also effective in the treatment of dysmenorrhea but also have side effects, including irregular uterine bleeding and induction of endometriosis.[11] The goal of dysmenorrhea is to provide adequate symptom and pain relief while minimizing the occurrence of side effects.

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A systematic review study reported that NSAIDs were more effective than placebo, but that there were various side effects such as mild neurological disturbances (headache, dizziness, drowsiness) and gastrointestinal symptoms (nausea and indigestion).[12] Adverse effects from pharmacological treatment are constantly being reported, and some women do not respond to NSAID or OCP treatment. This is one of the limitations of conventional therapy. The estimated failure rate is more than 15% for NSAIDs, about half of women taking OCPs stop taking them due to side effects. Some women choose not to take any medication to treat dysmenorrhea.[9,13] This has led many women to seek alternative therapies and prompted the importance of investigating complementary alternative medicine for dysmenorrhea.

The majority of women have a great interest in the use of medicinal plants as an alternative treatment for dysmenorrhea. A previous study described the effectiveness of using herbal medicine for dysmenorrhea primary. Some medicinal plants are reported to relieve menstrual symptoms by providing analgesic, anti-spasmodic, prostaglandin inhibitory or anti-inflammatory effects. Residents in various regions of Iran use medicinal plants such as peppermint extract, Echinophora platyloba extract, Foeniculum vulgareroot extract, Valeriana officinalis powder, Stachys Invandulifolia plant, Cinnamomum zeylanicum, Anethum graveolens extract, Zingiber officinale tea, Matricaria chamo and Matricariagraveolens, Crocus sativus and Pimpinella anisum to treat the symptoms of dysmenorrhea and its complications. It can be an alternative to conventional medicine to treat dysmenorrhea, especially in cases where conventional medicine is contraindicated or cannot be tolerated.[14,15] Alternative treatment for dysmenorrhea other than complementary therapy is taking vitamins.

In general, micronutrients including vitamins are important for maintaining body functions, and deficiency of these substances has various negative effects on human health. Absorption of vitamins plays a major role in reducing pain and the effects of dysmenorrhea.[13,16] Vitamin therapy can reduce the severity of menstrual pain, including vitamins E, B1, B6 and D.[17] Calciferol or the active form of vitamin D plays a role in regulating prostaglandin levels and calcium homeostasis which can effectively relieve dysmenorrhea.[16] The antioxidant properties of vitamin E can be used to treat dysmenorrhea. Vitamin E reduces phospholipid peroxidation and the release of arachidonic acid and its conversion to prostaglandins, thereby contributing to reducing the severity of dysmenorrhea.[18] Vitamin B1 therapy can replace the use of NSAIDs in the treatment of dysmenorrhea. Research shows effective evidence that vitamin B1 can reduce symptoms of dysmenorrhea. Vitamin B1 is a water-soluble vitamin, plays a role in muscle activity, the nervous system and affects the uterine muscles.[19,20]

Reports on the results of research on herbal and vitamin therapy on dysmenorrhea have been numerous with mixed results. One example in the study of Jafarpour et.all showed the mean level of pain in the intervention group (cinnamon) was lower than the control group (placebo) at various intervals (4.1 ± 0.5 vs. 6.1 ± 0.4 after 24intervention hours, 3.2 ± 0.6 versus 5.3 ± 0.6 at 48 hours, and 1.8 ± 0.4 versus 4.0 ± 0.3 at 72 hours) with a P value of < 0.001. The average amount of menstrual bleeding in the intervention group was significantly lower than the control group. The severity of nausea and the mean frequency of vomiting decreased significantly in the intervention group compared to the control group at various intervals ($P < 0.001$, $P < 0.05$). In conclusion cinnamon has a significant effect on reducing pain, menstrual bleeding, nausea and vomiting with dysmenorrhea without side effects. Cinnamon is considered a safe and effective treatment for dysmenorrhea in women.[21]

The above description is the background for researchers to conduct a Systematic Literature Review on "The Effect of Vitamin D Therapy on the Level and Duration Dysmenorrhea". Through this study, researchers hope that prevention and improvement efforts can be made to minimize the incidence of dysmenorrhea in adolescents.

II. METHOD

A. Design

The study design of this research is a Qualitative Systematic Literature Review using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) registration model. The protocol in this study was based on the Cochrane Risk of Bias Tool as a guide in assessing the risk of study bias and the United States Preventive Services Task Force for assessing study quality.

B. Database

This study uses secondary data obtained from the results of research that has been carried out by previous researchers. The secondary data obtained are sourced from internationally reputed journals in the form of articles with predetermined themes. The databases used to search the literature include PubMed, Science Direct, Proquest.search literature was carried out from January – May 2021.

C. Keywords

The keywords in this systematic literature review were adjusted to the Medical Subject Heading (MeSH) as follows:

Database	Search strategy using keywords
PubMed	"Herbal therapy" OR "Herb Therapy" [MeSH] AND "VITAMINS" OR "VITAMIN" [MeSH] AND "Dysmenorrhea" OR "Menstrual Pain" OR "Pains, Menstrual" OR "Pain, Menstrual" OR "Menstruation, Painful" OR "Menstruations, Painful" OR "Painful Menstruation" OR "Dysmenorrheas" OR "Painful Menstruations" OR "Menstrual Pains" [MeSH] NOT "endometriosis" OR "Endometrioses" OR "Endometriomas" OR "Endometrioma" [MeSH]
Science Direct	"Herb Therapy" OR "Herbal Therapy" [MeSH] AND "vitamin" OR "Viatmins" [MeSH] AND "Menstrual Pain" OR "Dysmenorrheas" OR "Painful Menstruations" OR "Dysmenorrhea" [MeSH]
ProQuest	"Herb Therapy" OR "Herbal Therapy" [MeSH] AND "vitamin" OR "Viatmins" [MeSH] AND "Menstrual Pain" OR "Dysmenorrheas" OR "Painful Menstruations" OR "Dysmenorrhea" [MeSH] NOT "Endometriosis"

Table 1: Medical Subject Heading (MeSH)

Inclusion and Exclusion Criteria articles

PICOS Framework	Inclusion Criteria	Exclusion Criteria
Population	Women of childbearing age (15-49 years) with primary dysmenorrhea pain	Female of childbearing age who experience secondary dysmenorrhea pain.
Intervention	The administration of peppermint, ginger and vitamins taken orally to women of childbearing age with primary	Articles using NSAID, OCP and other interventions.
Comparison	Placebo, pharmacological therapy and micronutrients	No exclusion criteria
Outcome	Measurement of the level of primary dysmenorrheal pain as measured by VAS (visual analog scale) and duration of primary dysmenorrheal pain.	Measurement of pain level using NRS (numeric analog scales) or other measurement scales.
Study Design	Randomized Controlled Trial	Review, systematic review and metaanalysis
Publication years	2015 to 2021	Prior to 2015
Language	English	Language other than English

Table 2: Inclusion and exclusion criteria in literature review

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Research Flow

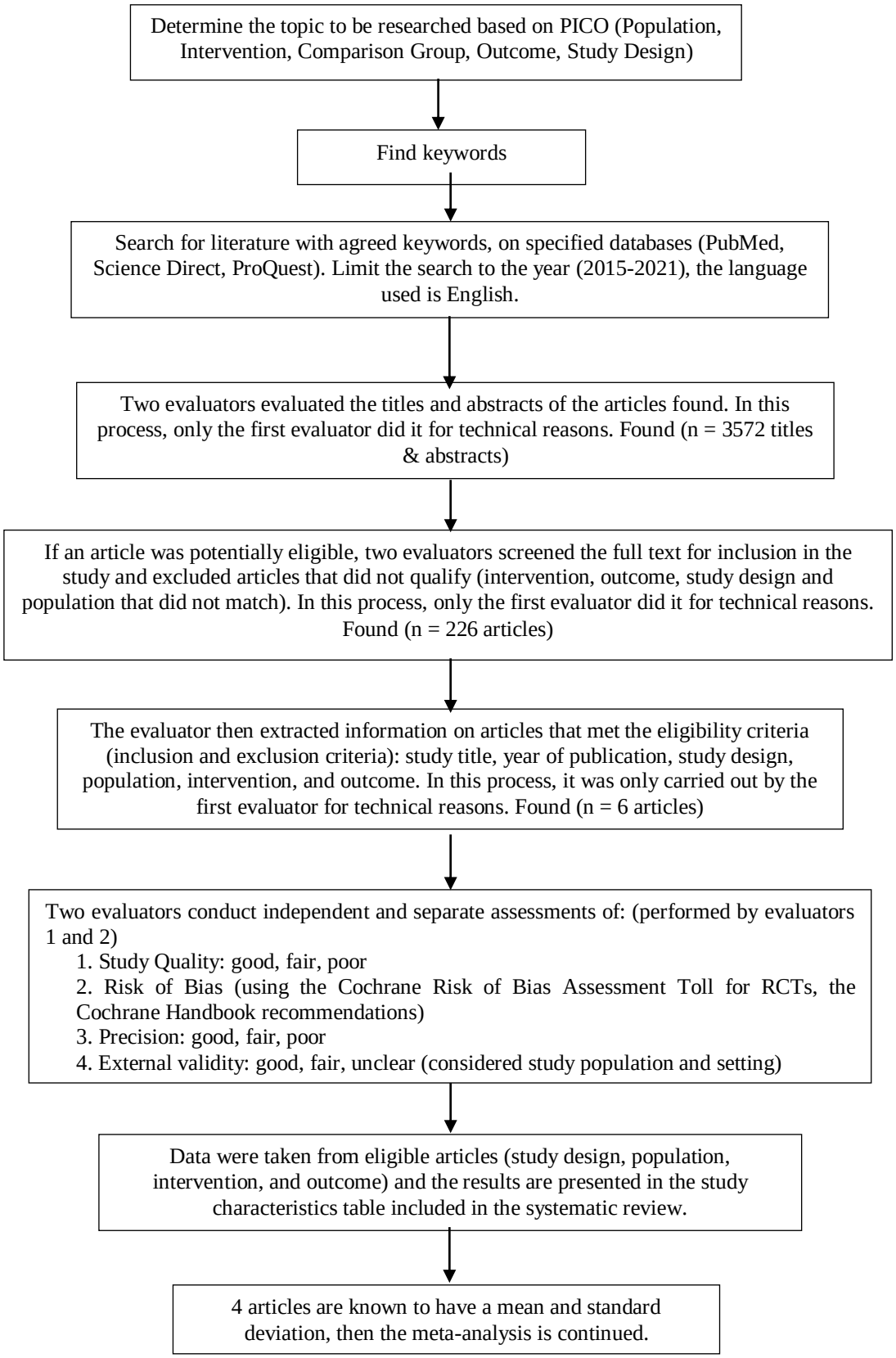

Fig. 1: Research Flowchart Research

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III. RESULTS

Results of analysis of study characteristics conducted by Zarei[22] and Moini[23] showed that there were differences in the study design, dose and combination in the intervention group, the administration of the intervention in the control group and the duration of the intervention. A randomized double-blind trial is the study design used by Zarei[22], while Moini[23] using A randomized double-blind, placebo-controlled study. Calcium was used as a combination vitamin D intervention in the Zarei[22] with a dose (1000 mg Calcium carbonate + 5000 units of Vit. D) 1 tablet/day. Moini[23] using a single vitamin D as an intervention with a dose of 50,000 IU of oral vitamin D once per week. In a study conducted by Zarei[22] used 2 comparison groups, namely Calcium (1000 mg Calcium carbonate) and placebo. The control group was only given a placebo in the Moini study.[23] The duration of the intervention in these two studies was different. Time taken Zarei[22] for intervention is 3 months and Moini[23] intervention for 8 weeks.

No.	*Study*	*Country*	*Study Design*	*Population(n)*	*Age*	*Intervention (n)*	*Control (n)*	*Time Duration*	*Main Outcome (Mean ± SD)*
1	Zarei, 2016[73]	Iran	*A randomized double-blind Trial*	Perempuan, *dysmenorrhea* primer, *moderate to severe*, teratur (n= 85)	18-32 tahun	Kalsium-Vit. D (1000 mg Kalsium karbonat + 5000 unit Vit.D) 1 tablet/hari (29)	- Kalsium (1000 mg Kalsium karbonat) (28) - Plasebo (28)	3 bulan	**VAS** *Intervention* - Kalsium- Vit. D = 4.6 ± 2.6 - *P Value* =0.236 *Control* - Kalsium =3.6 ± 2.2 - *P Value* =0.001 - Plasebo =5.7 ± 1.7 - *P Value* =0.001
2	Moini, 2016[74]	Iran	*A randomized double-blind, placebo-controlled study*	Perempuan, *dysmenorrh ea* primer (n= 60)	18-30 tahun	50.000 IU Vit.D oral 1x/minggu setelah makan(23)	Plasebo 1x/minggu setelah makan (27)	8 minggu	**VAS** - *Mild pain*= 95.7% (22) - *Moderate pain*= 4.3% (1) - *Severe pain*= 0 - *P Value* <0.001

Table 3: Characteristics of the Study and Respondents with Vitamin D Therapy

Zarei[22] mentioned in his study that after the intervention, time and group interactions there was no significant change in pain intensity. The overall effect of the intervention was reported for three cycles from before to the end of menstruation. In the calcium-vitamin D group the mean (4.6 ± 2.6) pain was lower than in the placebo group (5.7 ± 1.7), but there was no statistically significant difference (P value = 0.236), the calcium group compared to placebo (P value = 0.001). From the results mentioned there was a statistically significant difference in the calcium-containing group alone, but there was no significant difference in the calcium and calcium-vitamin D groups (P value = 0.066).

The results of the analysis of studies conducted by Moini [23] mentioned in the intervention group (vitamin D) before the intervention there were 3 (13%) patients with mild pain, 16 patients (69%) moderate pain and 4 patients (17.4%) severe pain. Changes occurred after the intervention was carried out, namely 22 (95.7%) patients experienced mild pain, 1 patient (4.3%) experienced moderate pain and none experienced severe pain. The placebo group at the end of treatment mentioned 4 patients (14.8%) mild pain, 17 (63%) moderate pain and 6 patients (22.2%) had severe pain. This indicated a significant change in pain intensity after the intervention for 8 weeks between the two groups ($p<0.001$).

IV. DISCUSSION

From assessment of risk of bias, Zarei's studies all fall into the low risk except for the other bias. This is due to baseline that were not included or measured due to the limitations of the researcher. The data is an assessment of the results of laboratory results of calcium and vitamin D status before and after the intervention, which is likely to affect the results of the study. The results of the risk bias study conducted by Moini were uncler risk in the categories of random sequence generation, allocation concealment (selection bias) and blinding of outcome assessment (detection bias). Other criteria such as blinding of participants and personnel (performance bias), incomplete outcome data (attrition bias), selective reporting and other bias are included in the low-risk category. The quality of the

studies by both of them is categorized poor because they do not include the results of the ITT in their studies. The process of randomization or group division in the Moini study is also not explained in detail.

Mechanisms of absorption of vitamins and minerals may play an important role in the treatment and severity of dysmenorrhea. Calciferol, the active form of vitamin D, plays a major role in regulating prostaglandin levels.[24] Vitamin D plays an important role in the human reproductive system. Vitamin D receptors are found in the ovaries, endometrial tissue, in the epithelial cells of the fallopian tubes, decidua and placenta.[25] Many studies have reported a close relationship between vitamin D deficit and dysmenorrhea due to the regulation of calciferol in prostaglandin levels.[16]

The reduced intensity of pain due to vitamin D contained in the endometrium is able to reduce the expression of cyclooxygenase-2 a decrease in the production of prostaglandins. Regulates 15-hydroxyprostaglandin dehydrogenase, increases prostaglandin inactivation, regulates prostaglandin receptor expression.[26,27] Bahrami et al found that high doses of vitamin D intake reduced back pain. Another study said that abnormal vitamin D levels tend to experience systemic symptoms such as nausea, vomiting, headaches and fatigue.[24,28]

Moini stated that the use of high vitamin D can reduce the severity of pain with a weekly dose of 50,000 IU carried out for 8 weeks. These results are corroborated by other studies showing that taking vitamin D supplements in any form and dose is effective in reducing the severity dysmenorrhea of primaryHigh doses of vitamin D3 (50,000 IU/week) are recommended to prevent and treat vitamin D deficiency. Other benefits of vitamin D intake can reduce the risk of PMS, affect calcium levels, fluctuations in sex steroid hormones and neurotransmitter function.[29,30]

These results are in line with Lasco who stated that there was a significant effect in reducing dysmenorrhea pain in the vitamin D group compared to the placebo group for 2 months of observation. Baseline placebo data (mean (SD): 5.60 (1.90)) versus vitamin D administration (mean (SD): 5.85 (2.00)) while the comparison results after 2 months were (mean (SD): 5.70 (1.59)) for placebo and (mean (SD): 3.50 (1.27)) vitamin D, $p < 0.001$ for all groups.[31] The results of Zarei's study stated that the administration of vitamin D-calcium could reduce the intensity of dysmenorrhea compared to placebo, but there was no significant difference between vitamin D-calcium compared to the single calcium group. Several studies have shown that calcium has been shown to be beneficial for reducing abdominal pain, general pain, and back pain. Calcium is said to be able to reduce the severity dysmenorrhea, this is related to the physiological function of calcium in uterine muscle contraction and tone.[32] Homeostatic processes are mediated by the function of calcitonin, parathyroid hormone, and 25-hydroxyvitamin D3, all of which play a role in the pathophysiology of dysmenorrhea primary. When vitamin D levels are reduced, intestinal absorption of calcium is significantly reduced.[33] In other words, vitamin D affects homeostasis calcium and effectively relieve dysmenorrhea.[18]

Low levels of vitamin D can increase the production of prostaglandins and low absorption of calcium in the intestine, so that it can increase the severity of dysmenorrhea. Intake of vitamin D can improve symptoms, while abnormal vitamin D levels can cause or worsen the systemic symptoms that arise as a result of dysmenorrhea. The conclusion of this study is that vitamin D affects the reduction of dysmenorrhea pain, and the administration of vitamin D can be used as a complementary therapy in alleviating the severity of dysmenorrhea, however the quality of studies to support evidence is still low.

V. CONCLUSION

Based on a systematic literature review that Vitamin D therapy affects the reduction of primary dysmenorrhea pain in women of childbearing age. In two studies the risk of bias was unclear (unclear risk), and the quality of the studies in both studies was weak.

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