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Medicine.**ADMINISTRATIVE INFORMATION****Support** - China Alliance for Rare Diseases; Beijing Society of Rare Disease Clinical Care and Accessibility.**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202450100**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 May 2024 and was last updated on 21 May 2024.**INTRODUCTION**

Review question / Objective To assess the effects and safety of any complementary therapies in people with neurofibromatosis type 1.

Condition being studied Neurofibromatosis type 1 (NF1) is a rare disease occurs in every 3000 newborns globally. NF1 is caused by an error on chromosome 17, which affects the development of multiple systems including skin, bone, eyes, nerves, and the cardiovascular system. Treatments for NF1 are limited.

METHODS

Search strategy We searched the following databases from inception up to 19 March 2024: the Cochrane Library, Pubmed, Embase, CNKI, Wanfang database, VIP and SinoMed.

Search strategy was written according to participants (P) and intervention (I).

Participants: "neurofibromatosis type 1", "neurofibromatosis", "complementary and alternative medicine", "Café-au-lait macules"
Interventions: "Complementary and alternative medicine", "Complementary Therapies", "Integrative Medicine", "Alternative Medicine", "Naturopathy", "Homeopathy", "Ayurveda", "Siddha Medicine", "Yoga", "Native American Medicine", "Traditional Chinese Medicine", "Persian Medicine", "Traditional Iranian Medicine", "Tibetan Medicine", "Unani Medicine", "Anthroposophic Medicine", "Acupuncture", "Meditation", "Relaxation Therapy", "Guided imagery", "Psychotherapy", "Alexander technique", "Art Therapy", "Music Therapy", "Biofeedback", "Hypnosis", "Faith Healing", "Dance therapy", "Tai Ji", "Massage", "Tuina", "moxibustion", "Musculoskeletal Manipulations", "Reflexology", "Osteopathic Medicine", "Chiropractic", "Acupressure", "Qigong", "Therapeutic Touch", "Reiki", "Aromatherapy", "Phytotherapy", "herb", "Plant Extracts", "Phytomedicine", "Diet therapy", "Dietary Supplements", "Natural supplement", "Vitamins",

“Mind-Body Therapies”, “magnet therapy”, “Cupping Therapy”, “scraping”.

Participant or population People with Neurofibromatosis type 1 without age limit. Diagnosis criteria refer to the National Institutes of Health Consensus. Development Conference Statement: neurofibromatosis and the revised diagnostic criteria for neurofibromatosis type 1 and Legius syndrome.

Intervention Interventions include different types of complementary and alternative therapies including “Complementary and alternative medicine”, “Complementary Therapies”, “Integrative Medicine”, “Alternative Medicine”, “Naturopathy”, “Homeopathy”, “Ayurveda”, “Siddha Medicine”, “Yoga”, “Native American Medicine”, “Traditional Chinese Medicine”, “Persian Medicine”, “Traditional Iranian Medicine”, “Tibetan Medicine”, “Unani Medicine”, “Anthroposophic Medicine”, “Acupuncture”, “Meditation”, “Relaxation Therapy”, “Guided imagery”, “Psychotherapy”, “Alexander technique”, “Art Therapy”, “Music Therapy”, “Biofeedback”, “Hypnosis”, “Faith Healing”, “Dance therapy”, “Tai Ji”, “Massage”, “Tuina”, “moxibustion”, “Musculoskeletal Manipulations”, “Reflexology”, “Osteopathic Medicine”, “Chiropractic”, “Acupressure”, “Qigong”, “Therapeutic Touch”, “Reiki”, “Aromatherapy”, “Phytotherapy”, “herb”, “Plant Extracts”, “Phytomedicine”, “Diet therapy”, “Dietary Supplements”, “Natural supplement”, “Vitamins”, “Mind-Body Therapies”, “magnet therapy”, “Cupping Therapy”, “scraping”.

Comparator Not applicable.

Study designs to be included Randomized control trial, non-randomized trial, cohort study, case-control study, case report, case series.

Eligibility criteria Papers published repeatedly in different journals will be compared in full text. If the content is identical, only one paper will be included.

Exclusion criteria:

1. The research subject is diagnosed with a single neurofibroma or only NF2 or schwannomatosis.
2. Missing literature on clinical outcome indicators
3. Unable to judge the efficacy of intervention for neurofibromatosis
4. Secondary analysis of original clinical studies (such as meta-analysis, secondary analysis of published outcome indicators of RCT studies, etc.)
5. Literature in language except for Chinese and English

6. The literature data is incomplete, cannot be analyzed, or the full text cannot be obtained.

Information sources We searched the following databases from inception up to 19 March 2024: the Cochrane Library, Pubmed, Embase, CNKI, Wanfang database, VIP, and SinoMed. Follow-up manual search of the reference lists of included literature and published relevant systematic reviews.

Main outcome(s) Different types of symptoms of NF1 such as number of neurofibromas, size of neurofibroma and pain, etc.

Data management During the process of initial screening, full-text review, data collection from the included studies, and methodological quality assessment of the included studies, three authors are involved in each step independently. Disagreements are resolved by discussion and, as needed, arbitration by another author.

Quality assessment / Risk of bias analysis

Quality assessment is conducted using different assessment tools according to the study types:

1. RCT: Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2.0)
2. Non-randomised Studies: Risk Of Bias In Non-randomised Studies-of Interventions (ROBINS-I)
3. Case-control studies or cohort studies: Newcastle-Ottawa Scale
4. Case report: JBI Critical Appraisal Checklist for case reports (2016)
5. Case series: JBI Critical Appraisal Checklist for Case Series (2016).

Strategy of data synthesis 1. Summary analysis of clinical research evidence: Qualitative analysis is used to summarize clinical research evidence.

2. Evaluation of the efficacy of complementary and alternative therapies in the treatment of NF1: ① When randomized controlled trials of the same type of complementary and alternative therapies include at least two studies (that is, the intervention measures and control measures are the same and can be combined), R software will be used to perform meta-analysis on the data. R software will be used to perform meta-analysis on the data. Clinical and methodological heterogeneity was assessed by P values and I² of the heterogeneity test statistic τ^2 . A two-tailed P value 50%, subgroup analysis or no meta-analysis will be performed. If the number of studies included in the meta-analysis of the primary outcome is >10, a funnel plot will be used to analyze potential publication bias.

In meta-analysis, for continuous data, the weighted mean difference (WMD) or the standardized mean difference (SMD) of the 95% confidence interval (Confidence interval, CI) is used. Continuous data with the same measurement unit are represented by WMD and 95%CI, and continuous data with different measurement units are represented by SMD and 95%CI. The two-category data used the risk ratio (relative risk, RR) with 95% CI. Even for the same complementary and alternative therapies, if the interventions differ greatly (e.g., frequency, duration, etc.), a random effects model is used to summarize the overall effect.

② For research results that cannot be subjected to Meta analysis, descriptive analysis will only be used to describe the data qualitatively. Classify according to the type of complementary and alternative therapies, and summarize and present the effect in a characteristic form.

3. Comparative analysis of traditional Chinese medicine in the treatment of NF1 and other complementary and alternative therapies in the treatment of NF1.

Subgroup analysis Subgroup analysis will be conducted if the included studies can be divided into subgroups by sex, age, and complication.

Sex: Male; female.

Age: under 18 years old; above 18 years old.

Complication: pain; bone symptoms; hypercalcemia; dizziness; vomiting; plexiform neurofibroma.

Sensitivity analysis Sensitivity analysis is conducted when necessarily. It is planned for attributes such as:

1. quality of the included studies;
2. sample size;

Sensitivity analysis aims to find out whether the conclusions of excluded studies complement or contradict the results from the meta-analysis. A sensitivity analysis will not be conducted if the included studies do not meet the condition.

Country(ies) involved All the researchers are from China.

Keywords complementary and alternative therapies; neurofibromatosis type 1; traditional Chinese medicine.

Contributions of each author

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