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Protocol

The efficacy of mud pack to eyes on cognitive functions among depressed adolescents: a study protocol for randomized controlled trial

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ABSTRACT

Background: Mud pack to eyes is a naturopathic treatment that involves applying mud pack directly over closed eyes. Mud pack will be prepared by wrapping the soaked mud in a cotton fabric strip. Mud pack to eyes are regarded to have therapeutic benefits, particularly for the treatment of stress-related symptoms and for the promotion of relaxation. Despite its extensive use in naturopathic practice, there is currently very little research investigating the precise effects of mud pack to eyes on cognitive functions, particularly in adolescents with depression.
Methods: In this study protocol, a randomized control design will be used. Eligible people will be randomly assigned to study and control groups. 40 participants in study group will get 30-minute mud pack to eyes intervention once a day for four weeks (5 days a week). Control group (n=40) will rest in supine position for 30 minutes once a day for four weeks (5 days a week). Assessments such as critical flicker fusion frequency (CFFF), auditory reaction time (ART), visual reaction time (VRT), BDI-II (Beck's depression inventory) scores and MAAS (Mindfulness attention awareness scale) scores of both study and control group participants will be assessed before and after the interventions.
Conclusions: Mud pack to eyes intervention is an easy and efficient method of enhancing mindfulness and cognitive functions as well as reduce the symptoms of depression among depressed adolescents.
Trial registration: This study was prospectively documented in clinical trial registry of India (CTRI/2023/10/059052).

Keywords: Naturopathy, Mud pack, Cognitive functions, Depression, Adolescents

INTRODUCTION

Mud is a natural material composed of a combination of inorganic and organic matter, including water. The formation of mud involves various biological and geological processes influenced by numerous physico-chemical factors.[1,2] Previous research has demonstrated the therapeutic benefits of mud therapy for several psychosomatic conditions, such as psoriatic arthritis, rheumatoid arthritis, inflammatory bowel disease-associated spondylitis, and osteoarthritis of the knee.[1,3-5]

Interestingly, mud therapy has also been observed to positively impact the state of mindfulness.[6]

Adolescence is a critical stage of development characterized by significant biological, physiological, cognitive, social, and psychological changes. This period can be particularly volatile and unstable due to factors such as the adolescent's self-perception, peer pressure, and parental influences.[7] Depression is one potential factor associated with sympathetic activation, which has been linked to a negative impact on mindfulness through increased blood pressure, cortisol levels, muscle rigidity, and mood disturbances.[8]

Prior studies have hypothesized that applying mud packs to the eyes can improve the state of mindfulness.[6] Cognitive function, which encompasses mental processes involved in learning, memory, problem-solving, and the appropriate use of stored information, can be assessed using various methods. Two commonly used tests are reaction time (RT) and CFFF.[9] CFFF measures the frequency at which a flickering light is perceived as continuous, providing insights into central nervous system (CNS) activity and attentiveness.[10,11] Existing evidence suggests a positive association between CFFF and academic performance, while a negative impact has been observed with both visual and ART.[12]

Given the potential link between depression, mindfulness, and cognitive function, this study aims to evaluate the efficacy of mud pack application to the eyes in improving cognitive function among depressed adolescents. The rationale for this investigation is based on previous findings indicating that mud therapy can enhance blood circulation, reduce muscle stiffness, blood pressure, and salivary cortisol (a marker of stress reduction), as well as improve mood, which may positively impact state of mindfulness and, consequently, cognitive function.[13,14]

METHODS

Study design and study settings

The effectiveness of mud pack to eyes on cognitive functions in adolescents with depression will be studied using a randomized, controlled trial research design. The current research investigation is being conducted at Chengalpattu's international institute of yoga and naturopathy medical sciences (IIYNMS). The current study is registered in the clinical trial registry of India with unique trial number of CTRI/2023/10/059052, and it has been authorized by the institutional ethics committee (IEC-Approval/006/2023).

Sample size

Using statistical power analysis, the sample size of 80 participants (40 in the study group and 40 in the control group) was calculated. The calculation was based on an expected medium effect size of 0.5, a desired statistical power of 80%, and an alpha level of 0.05, ensuring the study has sufficient participants to detect moderate differences between the groups while balancing statistical power and feasibility considerations.

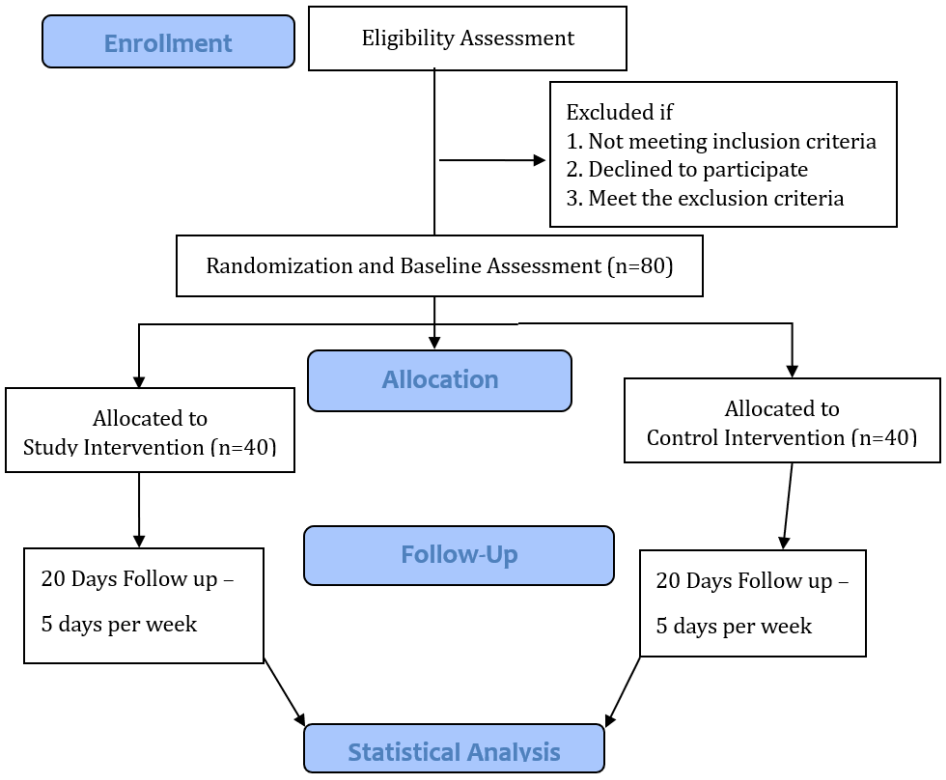

Figure 1: CONSORT 2010 flow diagram.

Recruitment

The study will recruit a total of 80 depressed adolescents after screening for eligibility criteria. Prior to participating in the study, each participant or their guardian will be asked to grant informed consent. Patients will be enrolled from OPD of IIYNMS, Chengalpattu.

Eligibility and screening

In order to ensure that the research protocol is followed as intended, participants will be investigated and screened for psychiatric illness, systemic disease, surgical history, refractive error, medication, and allergies. The integrity and validity of the research findings will be maintained since the screening approach assures that only competent and eligible participants are included in the study.

Randomization and blinding

A computer randomization will be used to assign each participant randomly to either the study or control groups. For 80 patients, a straightforward 1:1 randomization will be used to provide a sample size of (n=40) each group. The random allocation of interventions will be kept in opaque sealed envelopes until participants are assigned. Randomization will be performed by an author who is not participating in the evaluation process. Participants and Investigators will not be blinded in this study.

Preparation and procedure

Study group: The individuals who were recruited would have mud pack on their closed eyes. The mud pack will be made from mud that has been extracted around three feet below the earth's surface. The mud will be well crushed, and exposed to the sun after removal of stones and pebbles. Before 24 hours, the mud will be immersed in clean water. Before an hour of intervention, the mud will be taken and placed on a cotton fabric strip to make an eye pack (measuring 9×6×1 cm). 20-21°C water will be used to immerse the mud.[6] Each participant will be asked to lie on their back with their eyes closed. After that, a mud pack will be applied above their eyes for thirty minutes each session for four weeks.

Control group: The subjects will be asked to lie on their back for 30 minutes each session for four weeks with closed eyes (Supine Rest). There will be five intervention days during weekdays.

Outcome parameters

Primary outcome: Assessment of cognitive functions will be done using CFFF testing device with Netra software. Working range frequency is 10 Hz to 100 Hz. The PC 1000 Hz RT with audacity software (version 1.2.2) will be used to assess the visual and ART for both study and control groups.[12]

Secondary outcome: Assessment of the state of depression and mindfulness among depressed adolescents will be measured using BDI-II scale and MAAS scale respectively. BDI-II scale is a self-report questionnaire which consist of 21-item. This scale used to evaluate the degree of depression in adults as well as adolescents. Based on four response options, respondents are asked to score each item for the degree of their symptoms over the previous two weeks, ranging from no symptoms at all to severe symptoms.[15] MAAS is a 15-item self-report measures that uses both general and situation-specific statements evaluates how often people experience attentive states in their daily lives. Depending on the average of all components, MAAS scores would be change from 1 to 6. Higher mindfulness is indicated by higher scores.[16]

Data analysis

The study will employ a comprehensive statistical approach to analyze the effects of mud pack to the eyes. Descriptive statistics will summarize participant characteristics, with independent t-tests or Mann-Whitney U tests used for baseline comparisons of continuous variables, and chi-square or Fisher's exact tests for categorical variables. The primary analysis will use parametric or non-parametrcic test to evaluate changes in cognitive function, mindfulness, and depression scores over time between the study and control groups. One less than 0.05 is considered a significant the p value. Version 4.3.2 of R statistical software will be employed in the analysis.

DISCUSSION

The current study protocol aims to evaluate the efficacy of mud pack application to the eyes in improving cognitive function among depressed adolescents. The rationale for this investigation is based on the established use of CFFF and RT as measures of cognitive processes related to learning and performance.[9] The CFFF test, in particular, provides insights into changes in brain activity and cortical arousal in response to different environmental factors.[10,11] Prior research has shown a positive association between CFFF and academic achievement, while both visual and ARTs have been negatively correlated with cognitive functioning.[12]

Depressed adolescents often exhibit diminished levels of mindfulness and cognitive impairments.[8] Interestingly, mud therapy has demonstrated a range of benefits, including lowering blood pressure, reducing salivary cortisol (a marker of decreased stress), boosting mood, enhancing blood circulation, and decreasing muscle tightness.[13,14] A previous study found that applying mud packs to the eyes improved mindfulness and reduced

scores on measures of negative affect and persistent thinking.[6]

Given these observations, the current protocol aims to build upon the existing evidence and explore the potential of mud pack application to the eyes as a non-pharmacological intervention for improving cognitive function in depressed adolescents. This study addresses an important gap in the literature, as there is a need for effective, low-cost, and accessible approaches to support the mental health and cognitive well-being of this vulnerable population.

Potential challenges in implementing this protocol may include ensuring participant adherence to the intervention, managing potential dropouts, and controlling for confounding variables such as concurrent treatments or lifestyle changes. The research team will need to carefully monitor these factors throughout the complete course of the study. The results of the current study will contribute to the growing body of evidence regarding the effects of mud therapy on cognitive function and psychological health outcomes in adolescents with depression.

Limitations

Limitations of the current protocol include the single-center design and the relatively short intervention period. Future studies with larger sample sizes, multi-center designs, and longer durations may provide additional insights into the long-term effects of mud pack application on cognitive function and other relevant outcomes in this population. Overall, this study represents an important step in exploring non-pharmacological interventions to support the cognitive and mental health of depressed adolescents.

CONCLUSION

This study protocol provides a randomized controlled study to investigate the impact of mud pack to eyes on cognitive functions and psychological health wellness in depressed adolescents. These study's findings will enhance the understanding of integrative mental health therapy and may guide the future research in this field of study.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Boopalan D, Vijayakumar V, Kalidas S, Ravi P, Balakrishnan A, Shanmugam P, et al. Effect of local mud application in patients with knee osteoarthritis-A systematic review and meta-analysis. Int J Biometeorol. 2024;68(10):1923-34.
2. Akimzhanova K, Sabitova A, Mussabayeva B, Kairbekov Z, Bayakhmetova B, Proch J. Chemical composition and physicochemical properties of natural therapeutic mud of Kazakhstan salt lakes: a review. Environ. Geochem. Health. 2024;46(2):43.
3. Elkayam O, Ophir J, Brener S, Paran D, Wigler I, Efron D, et al. Immediate and delayed effects of treatment at the Dead Sea in patients with psoriatic arthritis. Rheumatol Int. 2000;19(3):77-82.
4. Codish S, Abu-Shakra M, Flusser D, Friger M, Sukenik S. Mud compress therapy for the hands of patients with rheumatoid arthritis. Rheumatol Int. 2005;25(1):49-54.
5. Cozzi F, Podswiadek M, Cardinale G, Oliviero F, Dani L, Sfriso P, et al. Mud-bath treatment in spondylitis associated with inflammatory bowel disease-a pilot randomised clinical trial. Jt. Bone Spine. 2007;74(5):436-9.
6. Jogdand R, Mooventhan A, Manjunath N. Effect of mud pack to eyes on psychological variables in healthy volunteers: a pilot randomized controlled trial. J Complement Integr Med. 2019;16(1):NA.
7. Trivedi D, Dhakappa N, Ghildiyal P, Deekonda S, Subramaniam S, Iyer JS, et al. Depression among adolescent students in South India: How serious is the issue? Indian J Psychiatry. 2016;58(3):349-50.
8. Korczak DJ, Westwell-Roper C, Sassi R. Diagnosis and management of depression in adolescents. Can Med Assoc J. 2023;195(21):E739-46.
9. Morley JE, Morris JC, Berg-Weger M, Borson S, Carpenter BD, del Campo N, et al. Brain Health: The Importance of Recognizing Cognitive Impairment: An IAGG Consensus Conference. J Am Med Dir Assoc. 2015;16(9):731-9.
10. Mankowska ND, Marcinkowska AB, Waskow M, Sharma RI, Kot J, Winklewski PJ. Critical Flicker Fusion Frequency: A Narrative Review. Medicina (B. Aires). 2021;57(10):1096.
11. Rao PS, Yuvaraj S, Kumari T, Maruti K, Sasikala P, Kumar SS, et al. Cognition, autonomic function, and intellectual outcomes of the paramedical health-care personnel in the hospital settings. J Educ Health Promot. 2020;9:26.
12. Prabu Kumar A, Omprakash A, Kuppusamy M, Maruthy KN, Sathiyasekaran BWC, Vijayaraghavan PV, et al. How does cognitive function measured by the reaction time and critical flicker fusion frequency correlate with the academic performance of students? BMC Med Educ. 2020;20(1):507.
13. Rastogi R. Therapeutic uses of Mud therapy in naturopathy. Indian J Tradit Knowl. 2012;11(3):556-9.
14. Stier-Jarmer M, Frisch D, Oberhauser C, Immich G, Kirschneck M, Schuh A. Effects of single moor baths on physiological stress response and psychological state: a pilot study. Int J Biometeorol. 22017;61(11):1957-64.
15. Erford BT, Johnson E, Bardoshi G. Meta-Analysis of the English Version of the Beck Depression Inventory–Second Edition. Meas Eval Couns Dev.

2016;49(1):3-33.
16. Black DS, Sussman S, Johnson CA, Milam J. Psychometric Assessment of the Mindful Attention Awareness Scale (MAAS) Among Chinese Adolescents. Assessment. 2012;19(1):42-52.

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