



Original Research Article

Volume 14 Issue 09

September 2025

A STUDY PROTOCOL TO KNOW THE UTILITY OF HOMOEOPATHIC REMEDIES IN REDUCING THE CALLOUS UNEMOTIONAL TRAITS IN CHILDREN AND ADOLESCENTS DIAGNOSED WITH CONDUCT DISORDER

¹Dr. M. Gnnanaprakasham* and ²Dr. Lenin KS

¹Associate Professor, BHMS, MD(Hom), PhD(Hom)

² Junior Resident, Dept of Psychiatry,

National Homoeopathy Research Institute in Mental Health, (Under CCRH, Ministry of AYUSH, Govt. of India) Affiliated to Kerala University of Health Sciences, Thrissur, Kottayam, Kerala. India

*Corresponding author's email ID: drgprakashpsy@gmail.com

ABSTRACT:

Introduction:

Conduct disorder (CD), classified under ICD-10 and ICD 11, include both Oppositional Defiant Disorder (ODD) in younger children and more severe antisocial behaviors in adolescence. A subgroup with affective insensitivity; marked by lack of guilt, empathy, concern for performance, or shallow affect, shows distinct emotional and cognitive patterns, leading to the CD specifier "With Limited Prosocial Emotions or callous unemotional traits".^[1] This protocol is designed to assess the potential role of homoeopathic interventions in reducing the callous-unemotional characteristics in children with conduct disorder.

Materials and Methods:

This intervention study follows a before-and-after design without a control group, conducted over 1.5 years (6-month enrollment and 12-month follow-up). Children and adolescents (age group 6-18) with conduct disorder, screened using DSM-5-based questions at NHRIMH OPD and peripheral clinics will undergo comprehensive homoeopathic case-taking. Baseline assessments include the Conduct Disorder Rating Scale (CDRS-Parent Version), Inventory of Callous-Unemotional Traits (ICU-P), and severity ratings. CDRS will be monitored monthly, ICU-P quarterly, and Clinical Global Impression (CGI) assessed at baseline, 6 and 12 months. Outcomes will be analyzed using the Friedman test for ICU-P changes and Wilcoxon signed-rank test for CGI scores, with $p \leq 0.05$ considered statistically significant.

Discussion:

The study results may open with exploratory ideas of using the behavioral pattern callous unemotional traits for outcome assessment. The role of Homoeopathic intervention may outstretch its utility in the management of behaviour like Callous-Unemotional Traits (CUT) in patients diagnosed with CD. The study may provide openings for further rigorous open label clinical trials with large sample size, randomized control trials in the future.

Keywords: Callous unemotional (CU), Conduct disorder (CD), Homoeopathy, Inventory callous unemotional scale (ICU-P), Study Protocol.

INTRODUCTION:

BACKGROUND AND RATIONALE

Conduct disorder (CD) is a chronic pattern of behavior in which the rights of others or age-appropriate social norms are violated. Symptoms are: (1) aggression toward people or animals, (2) property destruction, (3) deceitfulness or theft, and (4) serious rule violations. In DSM-5, CD is classified under “Disruptive, Impulse-Control, and Conduct Disorders.” Diagnosis requires at least three persistent behaviors over 12 months, with one present in the last 6 months; childhood-onset CD shows at least one symptom before age 10, while adolescent-onset CD shows none before age 10.¹

Conduct disorder with callous unemotional traits is associated with numerous long-term consequences, including poor physical health, co-occurring psychiatric conditions, early pregnancy, school dropout, and legal issues. Many of these negative outcomes persist into adulthood, leading to economic instability that can affect future generations. Given these factors, investigating the utility of homoeopathic remedies in reducing the callous unemotional traits in children and adolescents diagnosed with conduct disorder.

Frick et al focuses on the etiological significance of recognizing this subgroup of youths with severe conduct problems, its implications for diagnostic classification, and the treatment implications of this research³

SY Kim et al As transparency in research gains importance, the value of research protocols is increasingly recognized. Registering protocols is also known to help reduce biases such as publication and selective outcome reporting bias^[10]

Kumar, Priyam, and Kumar discuss Conduct Disorder in children, highlighting the challenges it presents and the role of homeopathy in addressing underlying emotional factors. They suggest that homeopathy may complement conventional treatments but emphasize the need

for further research to establish its efficacy and safety¹³ Moorthi and Radhika emphasize the importance of early diagnosis of Conduct Disorder (CD) to prevent its progression into severe adult psychiatric conditions. While conventional medicine manages acute symptoms like aggression and impulsivity, it highlights homeopathy as a personalized, long-term treatment option that may achieve complete remission without adverse effects. Remedies such as Hyoscyamus, Belladonna, Stramonium, Nux Vomica, and Tarantula are suggested for effective homeopathic management of CD.¹⁴

MATERIALS AND METHODS:

This Study will be an open-label single arm clinical trial planned to conduct at OPD and other peripheral centers of National Homoeopathy Research Institute in Mental Health, kottayam, kerala, India. The homoeopathic intervention in this study will be administered by the principal investigator, while diagnosis of each case will be confirmed by a consultant psychiatrist.

The study protocol was designed in accordance with the latest revision of the Helsinki declaration on human experimentation and Good clinical practices of India^{11,12}. All medicines used are approved formulations listed in recognized homoeopathic pharmacopoeias. The protocol has been prepared and proposed towards the Institutional Review Board and modifications have been imparted as per the directions of the board. The thoroughly reviewed protocol was presented in IEC and ethical clearance was obtained. The finalized protocol was submitted to the university for approval. The trial was approved and registered with the clinical trial registry of India with reference no- CTRI/2025/06/107949.

1. Rating Scales Used

A. Conduct Disorder Rating Scale Parent Version [CDRS-P]^[8]

- The CDRS-P is a Likert-type scale with scores ranging from 1-4 which measures CD in line with current conceptualizations as described in the DSM-V. The fifteen symptoms used in the scale are taken directly from the DSM-V definition of CD.
- The purpose of the Conduct Disorder Rating Scale- Parents (CDRS-P) is to allow for measurement of diagnostic symptoms of conduct disorder (CD). A Score of 30 or higher on the CDRS-P indicates possible diagnosis of CD.
- Internal consistency of CDRS-P = .74[Cronbach's α = 0.74] and test retest reliability r = .81^[8]

B. Inventory Callous Unemotional Traits Parent Scale [ICU-P]^[9]

The ICU is a 24-item questionnaire that assesses callous and unemotional (CU). The ICU is made up of statements with a 4-point Likert scale, ranging from 0 (Not at all true) to 3 (Definitely True), with higher scores indicating greater CU traits. Example items include statements such as: “I express my feelings openly”, “I feel bad or guilty when I do something wrong”, and “I do not care if I get in trouble”. The ICU has three subscales: Callousness (capturing a lack of empathy and remorse), Uncaring (capturing uncaring attitude about performance on tasks and others’ feelings), and Unemotional (capturing deficient emotional affect). The question number about the three subscales was

Callousness 4, 8, 9, 18, 11, 21, 7, 20, 2, 10, 12

Uncaring 15, 23, 16, 3, 17, 24, 13, 5

Unemotional 1, 19, 6, 22, 14

While there is no straight forward demarcation of mild, moderate, severe for the ICU scores, researchers suggest that higher scores on the ICU are associated with more severe Conduct problems and antisocial behaviors.

Internal consistency for ICU-P = [Cronbach’s α = 0.81 to 0.84], Test- retest reliability is .84 Test-retest reliability between parent-report ICU total at visit 1 and visit 2 was $r = .84$ (95% CIs: .80–.88)^[9].

2. Screening And Enrollment:

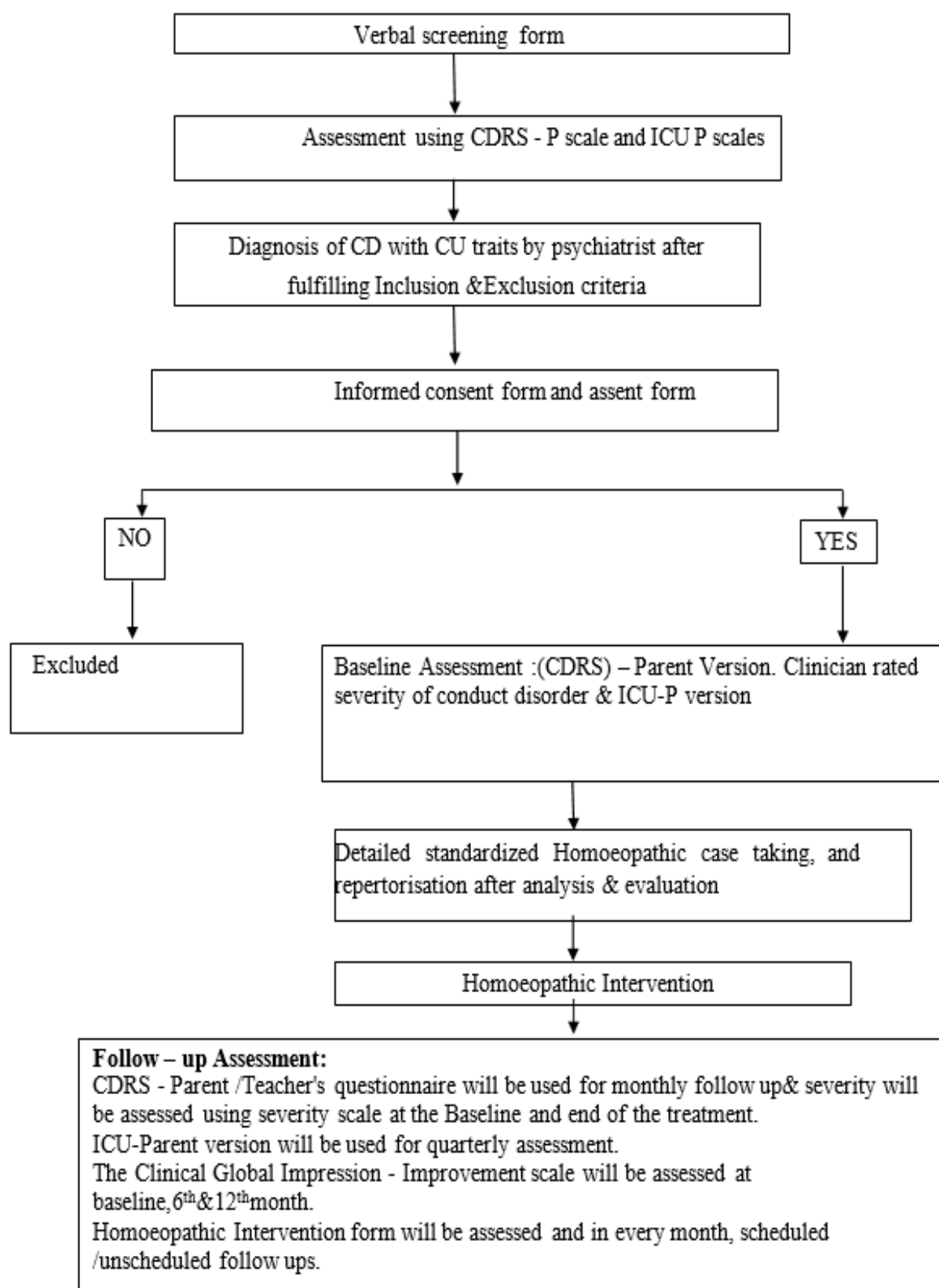
Children and adolescents presenting with behavioral changes from Out Patient Department and peripheral OPD of NHRIMH will be screened with questions developed using verbal screening form. After screening, cases of Conduct Disorder with callous unemotional traits that meet the inclusion criteria will be enrolled in the study and diagnosed by a psychiatrist. A copy of the patient Information sheet will be given to the parent /caretaker after explaining the details of the study. The Informed consent from the participant/Assent form will be obtained from parents or Legal Authoritative Representative (LAR) based on the availability. An assent form will be obtained from the patient.

3. Inclusion Criteria:

Children from 6 years to 18 years of age of both genders satisfying the symptoms of Conduct Disorder from DSM V criteria without any other major psychiatric and systemic illness will be included in the study after getting the consent.

4. The Flow Chart of Study

Figure No – 1



5. Intervention:

Homoeopathy

Investigators shall make an in-depth interview with the patient and his/her parents/caregiver. A thorough case taking will be performed and the details are recorded in standardized homoeopathic Case Recording format. With the complete case history and individualistic premorbid personality, the analysis and evaluation of the symptoms are conducted. Based on totality of symptoms repertorisation will be done with Synthesis Repertory using RADAR OPUS software. Final selection of remedy will be done in consulting with Homoeopathic Materia Medica and miasmatic evaluation. After evaluation of each case, selected medicine will be prescribed in 30C as initial intervention. On improvement, placebo will be continued. On status quo, higher potency will be prescribed. In case of no improvement or any new symptoms observed in subsequent months, the case will be retaken and a change of remedy is proposed. If any acute complaints, acute totality will be taken and the appropriate remedy will be administered. Such cases will be recorded separately for further analysis.

6. Outcome Measures:

- **Primary Outcome:** Primary outcome will be measured by the difference between the score obtained in ICU-P questionnaire in the baseline and end of the treatment.
- **Secondary outcome** will be measured by the difference between the score obtained in CDRS-P scale and Clinical global impression CGI scale in the baseline and end of the treatment.

7. Criteria for Baseline and Follow up Assessment:

Assessment of study participants of callous unemotional traits will be conducted using ICU-P at baseline and subsequently on quarterly basis. To know the improvement of conduct disorder CDRS-P scale will be assessed on baseline and monthly once. The overall improvement of callous unemotional traits in conduct disorder will be assessed on 6th and 12th month.

Results from baseline and end of the study will be compared to assess improvements in callous unemotional traits in conduct disorder with individualized homoeopathic treatment. Details of the study timeline are given in table 1.

8. Follow- Up:

The enrolled patients will be closely monitored through a follow- up chart every month. The follow- up calendar will be given for one year, with date of visit during initial enrollment. The follow up chart contains the details of follow- up dates, time and other measures scheduled for 12 months. A regular telephonic and other available communications will be done through social workers to have a good compliance.

9. Timeline of the Study:

Time	Study period						Close out
Eligibility Screening	Enrolment	Months				Every month	
		3	6	9	12		
Informed consent	+	-	-	-	-	-	-
Intervention Homeopathy	+	+	+	+	+	+	-
Assessment Verbal screening Form	+	-	-	-	-	-	-
ICU-P scale	+	+	+	+	+	-	+
CDRS-P scale	+	+	+	+	+	+	+
CGI scale	+	-	+		+	-	+

Table 1. Timeline of the study

10. Data Collection:

Standard Case recorded format and Excel spread sheet shall be used for data capturing. Data Recording shall be done through validated questionnaires /tools for outcome measures, such as Inventory Callous unemotional -Parent version(ICU-P), Conduct Disorder Rating Scale-Parent version (CDRS-P). Apart from the rating scale assessment scores, the physical, psychological, clinical and demographic Information of the patient shall also be noted. Comparison of ICU-P questionnaire score at baseline,3rd month,6th month, 9th Month, 12 month.

11. Statistical Analysis:

Baseline characteristics will be represented using Graphs and tables. Changes in Inventory callous unemotional traits scores over one year will be assessed using the Friedman test. $P < 0.05$ will be considered statistically significant. The Wilcoxon signed rank test will be used for comparing the CGI scores at baseline, 6th and 12th months.

DISCUSSION:

CU traits in adolescent boys and girls have been shown to predict adult offending and the development of Antisocial Personality Disorder⁸. Conduct disorder with callous unemotional traits is associated with numerous long-term consequences, including poor physical health, co-occurring psychiatric conditions, early pregnancy, school dropout, and legal issues. Many of these negative outcomes persist into adulthood, leading to economic instability that can affect future generations. Despite a global prevalence of approximately 5%, CD remains one of the most under-recognized and under-studied psychiatric disorders.¹¹ Given these factors, investigating the effectiveness of individualized homeopathic medicine in reducing CU trait using standard assessment tools in persons with conduct disorder may provide a novel approach to treatment.

CONCLUSION:

The present protocols are expected to assess the effect of Individualized Homoeopathic medicine in reducing the callous unemotional traits in conduct disorder in the age group between 6 to 18. The study will explore preliminary treatment outcomes, the feasibility, and the use of therapeutic approaches for reducing the callous unemotional traits in conduct disorder. The study encourages further research in this area. Absence of a comparison group and the small sample size may limit the generalizability of the results.

ACKNOWLEDGEMENT:

I thank Dr N D Mohan, Consultant Psychiatrist, and all my faculties at NHRIMH, Kottayam for guiding me through the study. I thank Dr. R. Sitharthan, Principal, NHRIMH, Dr. R. Bhuvaneswari, Officer in Charge and HOD Department of Psychiatry and faculties of Department of Psychiatry for their immense help and guidance.

COMPETING INTEREST:

The authors declare that there is no competing interest

REFERENCES:

1. American Psychiatric Association Diagnostic and statistical manual of Mental Disorders (5thed.) DSM-V.Washington, D.C, APA; 1994, pg.no:302.
2. World Health Organization the ICD Classification of Mental and Behavioural Disorders (10thed) Delhi ,A.I.T.B.S.Publishers & Distributors; 2007 pg.no:266.
3. Benjamin.J.Sadock,M.D.,Virginia.A..Sadock,M.D,Kaplan and sadock's Comprehension Textbook Of Psychiatry, Eighth Edition;Volume 2 pg.no.3209.
4. [PaulJFricket.al](#),Current Research On Conduct Disorder in Children and Adolescents, South African Journal Of Psychology,2016;pg.no 160-174 .
5. Mehrnaz Azadyekta et.al, Prevalence of conduct disorder among elementary students in Tehran city, Procedia-Social and Behavioral Sciences; 29(2011): pg.no 693-702.
6. MohanL,RayS;Conductdisorder(updated2019Dec10).Treasureisland(FL);StatPearls Publishing;2020 Jan.
7. Frick PJ, Ray JV, Thornton LC, Kahn RE. Can callous-unemotional traits enhance the understanding, diagnosis, and treatment of serious conduct problems in children and adolescents? A comprehensive review. Psychological bulletin. 2014 Jan;140(1):1.
8. Waschbusch DA, Elgar FJ. Development and validation of the conduct disorder rating scale. Assessment. 2007 Mar;14(1):65-74.
9. Kimonis ER, Frick PJ, Skeem JL, Marsee MA, Cruise K, Munoz LC, Aucoin KJ, Morris AS. Assessing callous–unemotional traits in adolescent offenders: Validation of the Inventory of Callous–Unemotional Traits. International journal of law and psychiatry. 2008 Jun 1;31(3):241-52.
10. Kim SY. Why do journals publish research protocols?. science editing. 2022 Aug 19;9(2):146-8.
11. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. JAMA2013; 310:2191-4.
12. Ethical Guidelines for Biomedical Research on Humans. Indian Council of Medical Research 2006. New Delhi. Available from: http://icmr.nic.in/ethical_guidelines.pdf. [Last cited on 2014 Oct7].
13. Kumar K, Priyam P, Kumar R. Conduct Disorder in Children and its Homoeopathic Approach. Chief editor.:65.
14. Moorthi SK, Radhika P. Homoeopathic management of conduct disorder: A case series. Homoeopathic links. 2021 Sep;34(03):241-8.