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A randomized controlled trial in the management of alcohol dependence: Homoeopathic *vs.* standard Allopathic treatment

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ABSTRACT

Background and Objective: Alcoholism (alcohol dependence) is a chronic illness marked by dependence on alcohol consumption. It interferes with health, social as well as family life and job responsibilities. Based on the experience of an observational single-arm study with positive outcomes, this protocol is being implemented to compare the effectiveness of homoeopathic intervention with standard allopathic treatment.

Materials and Methods: This will be a randomized controlled open-label comparative trial. Patients will be randomized to receive either Homoeopathy or Allopathy group of intervention using computerized randomization chart. The period of treatment cum follow up shall be for 1 year. Supportive counseling shall be given to both the groups. Primary outcome will be more than 50% reduction in 'Severity of Alcohol Dependence (SADQ)' rating scale in comparison to baseline at the exit of treatment of 1 year and secondary outcomes will comprise of changes in World Health Organisation quality of life -BREF(WHOQOL-BREF) at baseline and at end of the study, management of detoxification shall be done using Clinical Institute Withdrawal Assessment for Alcohol Scale, Revised (CIWA-Ar). Further changes in alcohol consumption pattern in terms of quantity and frequency shall be assessed.

Discussion: The study shall help in designing further rigorous randomized controlled trial (RCT)/pragmatic study with homoeopathic intervention.

Keywords: Allopathy, Alcohol dependence, Alcohol withdrawal, Comparative trial, Homoeopathy, Psychiatric illness

INTRODUCTION

Background and rationale

Alcohol is a psychoactive substance with dependence-producing properties that has been widely used in many cultures for centuries.[1] The harmful use of alcohol causes health problems as well as social and economic burden in societies. Its consumption is one of the leading causes of death and disability globally. About two billion people worldwide consume alcoholic beverages and one-third is likely to have one or more diagnosable alcohol use disorders.[2] About 16.0% of drinkers aged 15 years or older engage in heavy episodic drinking. In 2012, about 3.3 million deaths, or 5.9% of all global deaths, 139 million disability-adjusted life years (DALYs), or 5.1% of the global burden of disease and injury, were attributable to alcohol consumption.[1]

Prevalence of alcohol use in India is reported to be 21.4% and there is increasing alcohol intake among the young people. Moreover, 4.5% males and 0.6% females in age-group of 15 years and above are suffering from alcohol use disorders and 3.8% of males and 0.4% of females are suffering from alcohol dependence. Total per capita consumption in Indian adults (15 + years) is 28 litres of pure alcohol. Deaths attributed to alcohol consumption in males and females are 62.9% and 33.2%, respectively of total deaths in the country.[3] The role of alcohol in domestic violence is substantial as most of the violence takes place during intoxication.[4] The alcohol-related problems account for more than a fifth of hospital admissions; 18% of psychiatric emergencies; more than 20% of all brain injuries and 60% of all injuries reporting to India's emergency rooms.[4] Commonly used medications for alcohol abuse and dependence are Disulfiram, Naltrexone, Acamprosate and Topiramate.[5] The review of existing allopathic treatment concludes that there can be certain side effects and a major problem of non-compliance.[6,7]

A double-blind placebo-controlled trial[8] applying Homoeopathy to chemical dependency showed decreased relapse rate of recovering alcoholics and drug addicts undergoing Homoeopathic treatment. Observational studies of Homoeopathy for alcohol dependence conclude that homoeopathy can be valid and effective therapy to help patients to break the cycle of dependence as well as to improve alcohol-related problems like sleep disturbances.[9,10]

One of the studies carried out by Central Council for Research in Homoeopathy (CCRH) at its Clinical Research Unit, Varanasi, India in which out of 261 drug-dependent patients referred from a drug de-addiction, 209 patients showed improvement in withdrawal symptoms, whereas 32 patients did not improve. The outcome of the study shows that homoeopathic medicines are useful in the management of withdrawal symptoms of drug dependents and can check the menace of the chemical dependency.[11] A pilot study by Gopinadhan[12] on the effect of *Arsenic album* in alcohol dependents reflected the development of aversion to alcoholic drinks.

One barrier to developing a national alcohol policy for India is lack of data and research on this burning problem. Keeping in view the limitations of established effective intervention, i.e., allopathy, other intervention like Homoeopathy can be tested for its effectiveness.[13] Reviews of the evidence of the safety indicate that Homoeopathy medicinal products may cause mild transient side effects, but not strong or persisting side effects.[14]

Based on positive findings of previous studies, a randomized controlled trial on patients with alcohol dependence shall be conducted to assess the effects of individualized homoeopathic treatment in the management of alcohol dependence in comparison with the standard allopathy treatment.

MATERIALS AND METHODS

This study will be a randomized controlled comparative, open-label trial to be conducted at Central Research Institute, Kottayam, Kerala, India. Homoeopathy treatment will be given by trained homoeopath and allopathy treatment by the psychiatrist involved in the study. Rescue allopathy medication in severe withdrawal symptoms, if required will be prescribed by psychiatrist in both groups. Supportive assistance in maintaining follow-ups shall be provided by psychiatric social worker.

The study protocol is in accordance with the latest revision of the Helsinki declaration[15] on human experimentation and Good Clinical Practices of India.[16] Although medicines proposed to be used during the study are known homoeopathic pharmacopoeia preparations, yet necessary clearance of the Ethical Committee and Scientific Advisory Committee has been obtained before undertaking the study. Trial is registered with Clinical Trial Registry of India (CTRI/2011/12/002213).

Recruitment process and inclusion criteria

Patients shall be screened from outpatient department of the institute as per verbal screening form—Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers scale(CAGE(scale)[17]—and those satisfying the CAGE scale shall further be screened for inclusion and exclusion criteria by the investigator who is experience and trained in treating patients of alcohol dependence. Patients meeting the inclusion/eligibility criteria shall be given detailed explanation of the project requirements and shall be invited to participate in the trial. Informed consent will be obtained from all participants following which they shall be randomly divided to receive either homoeopathic/allopathic

as per the randomization chart informing the same through patient information sheet. All patients in the study shall be advised to be abstinent from alcohol, under the guidance of investigator/psychiatrist. Flow diagram of study is given in Figure 1.

Patients are eligible if they are: In age-group of 15 to 60 years, male and female; diagnosed as per International Classification of Diseases, 10th Revision (ICD-10) criteria [Table 1] for alcohol dependence; willing to quit alcohol and to take Homoeopathy/allopathy treatment; normal findings in ultrasound of upper abdomen, liver function test. Patients with any chronic systemic illness or with life-threatening disease, cirrhosis of liver, diagnosed psychological disorder associated with alcohol dependence and cases with other substance abuse/addiction shall be excluded from the study. Pregnant and lactating women, patients those are not willing to sign the consent form shall also be excluded from trial.

Randomization and group allocation

A random allocation sequence using statistical software has been generated by a statistician independent of the project prior to the commencement of recruitment. Participant allocation to group (1:1 ratio) has done immediately after baseline case recording.

Intervention

Homoeopathy

Investigator shall make an in-depth interview with the patient and his guardian, after thorough case taking in the Case Recording format (CRF), shall form totality of symptoms and repertorized the symptoms

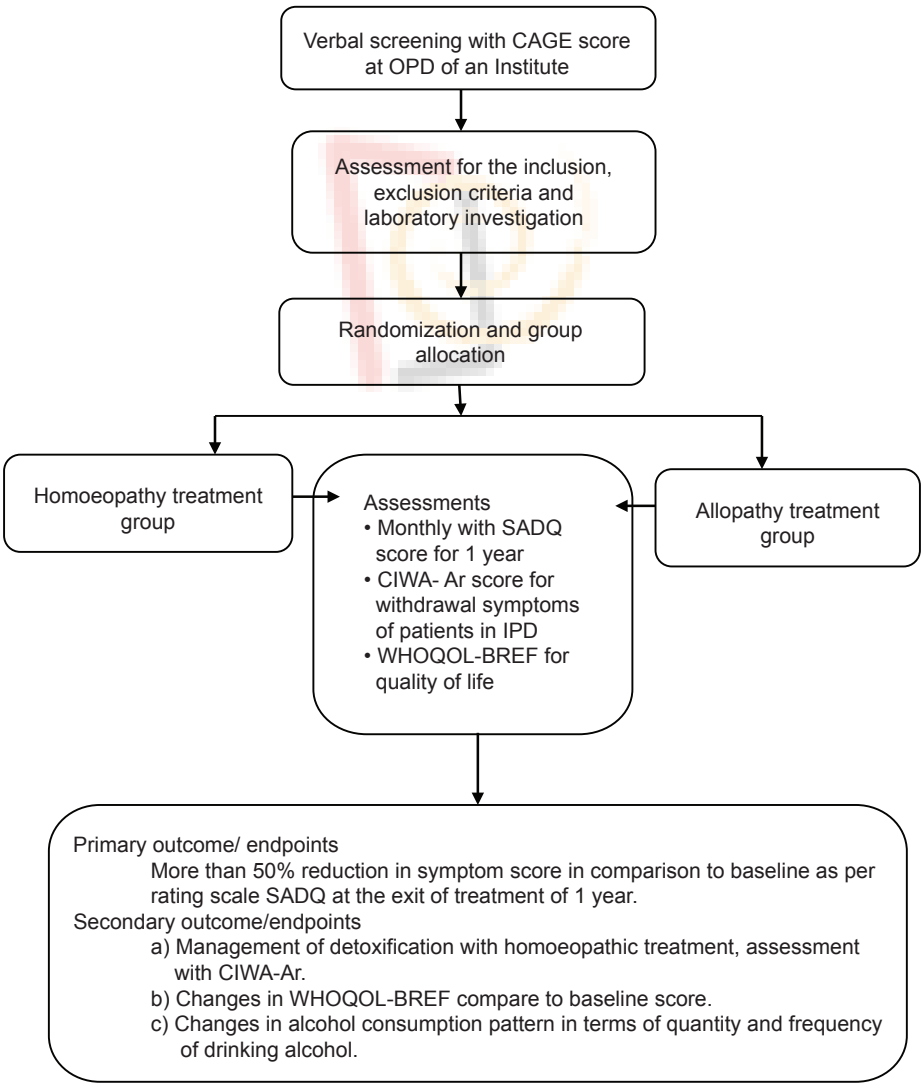

Figure 1: Flow chart of the study

Table 1: International Classification of Diseases, 10th Reviswion (ICD-10) criteria for alcohol dependence

Clustering criteria
Three or more of the following: Occurring together for at least 1 month, or if less than 1 month, occurring together repeatedly within a 12-month period
Need for significantly increased amounts of alcohol to achieve intoxication or desired effects; or markedly diminished effect with continued use of the same amount of alcohol
Physiological symptoms characteristic of the withdrawal syndrome for alcohol; or use of alcohol (or closely related substances) to relieve or avoid withdrawal symptoms
Difficulties in controlling drinking in terms of onset, termination or levels of use; drinking in larger amounts or over a longer period than intended or a persistent desire or unsuccessful efforts to reduce or control drinking
Important alternative pleasures or interests given up or reduced because of drinking
A great deal of time spent in activities necessary to obtain, to use, or to recover from the effects of drinking
Persisting with drinking despite clear evidence and knowledge of harmful physical or psychological consequences
A strong desire or sense of compulsion to drink
Duration criteria
Three or more of dependence criteria occurring for at least 1 month, or if less than 1month, occurring together repeatedly within a 12-month period

using appropriate repertory. Selection of medicine will be made out of the medicines that fetch the highest value on repertorisation. Selection of potency and repetition of medicine will be as per discretion of investigator and as per patient's condition. The CRF will include the analysis, evaluation and totality of symptoms, repertorial analysis chart.

Allopathy

Patients in this group will also have an in-depth interview with investigator. The psychiatrist involved in the study will administer the allopathic medicine. Common allopathic drugs used for alcohol dependence shall be used as per discretion of psychiatrist.

Apart from the above intervention the following procedure shall be carried out.

Withdrawal Phase (Detoxification)

Patients with withdrawal symptoms will be admitted in the Inpatient Department (IPD) of the institute till improvement noticed or for 2 weeks whichever earlier. However, the mild cases will be studied in OPD. In mild to moderate withdrawal symptoms, patients will receive assigned group of intervention but psychiatrist will manage severe withdrawal symptoms with a rescue allopathic medicines in IPD. Rescue medicines will be provided to the patients of both the groups. Data of such cases will be maintained separately. After detoxification is complete, the patient will receive his/her assigned group intervention.

Supportive counseling

Counseling shall be given to patients of both the groups by psychiatrist involved in study. Psychiatric Social Worker (PSW) will be helping the investigators in motivating patients during treatment and maintaining follow-up by home visit or personal interaction with families.

Outcome measures

Primary outcome will be more than 50% reduction in symptom score in comparison to baseline as per rating scale SADQ at the exit of treatment of 1 year.

Secondary outcome measures will comprises of changes in quality of life, management of detoxification and changes in alcohol consumption pattern in terms of quantity and frequency.

Criteria for baseline and follow up assessment

Assessment of study participants for alcohol dependence will be done using Severity of Alcohol Dependence (SADQ) every month[18]. For assessment of alcohol withdrawal symptoms, Clinical Institute Withdrawal Assessment, Revised (CIWA-Ar)[19] for alcohol scale will be used every day at the time of admission in IPD; each time when patient comes with withdrawal symptoms and admitted in IPD in 1 year period of follow up. Total episodes of detoxification for each patient will also be considered for assessment at the end of the study.

Laboratory investigations shall be conducted at 3, 6, 9 and 12 months of follow up. World Health Organisation quality of life Bref (WHOQOL-BREF) shall be filled at baseline and at end of study for assessing and comparing quality of life. Details of study timeline are given in Table 2.

Data collection

Standard CRF, pre designed spread sheet shall be used for data capturing. Data recording shall be done through validated questionnaires/tools for outcome measures, i.e. SADQ, CIWA-Ar, WHO WHOQOL-BREF. Apart from these physical, psychological, clinical and demographic information of the patient shall also be noted,

Table 2: Timeline of the study

Time point	Study period							Close-out
	Enrollment	Allocation	Post allocation in month					
	$-t_1$	0	3	6	9	12	Every month	
Enrollment								
Eligibility screening	√							
Informed consent	√							
Allocation		√						
Interventions								
Homoeopathy		√						
Allopathy		√						
Assessments								
CAGE	√							
SADQ	√		√	√	√	√	√	√
CIWA-Ar			Every time on IPD admission-daily					
WHOQOL-BREF	√					√		√
Laboratory investigations								
CBC	√		√	√	√	√		√
RBS	√		√	√	√	√		√
LFT	√		√	√	√	√		√
USG UA	√		√	√	√	√		√
Supportive Counseling			√	√	√	√	√	
Rescue medicines (Whenever required)			√	√	√	√	√	√

OPD: Outpatient department; SADQ: Severity of alcohol dependence; CIWA-Ar: Clinical institute withdrawal assessment of alcohol scale, Revised; WHOQOL-BREF: World Health Organisation-Quality of Life -BREF; CBC: Complete blood count; RBS: Complete blood count; LFT: Liver function test; USG UA: Ultrasonography, Upper abdomen; $-t_1$: Before enrollment

Sample size

Assuming the recovery of 90% with allopathic treatment and 50% with homoeopathic treatment, (on the basis of previous pilot study by using *arsenic album* which was effective in 7 out of 10 cases, at Kottayam) with $\alpha = 0.05$, power $(1-\beta) = 0.85$. The required sample sizes will be 22 sample/group for assessment. By considering the drop out of 20%, the total sample size will be 60 (30/group).

Statistical analysis

Data obtained during the study would be verified and analyzed using Statistical Package for Social Sciences (SPSS) version 20. For the primary outcome and each of the secondary outcomes, both per protocol and modified Intention To Treat (mITT) analysis will be done. Descriptive statistics shall include demographic profile. Quantitative continuous measures will be compared between the groups using t tests for normally distributed continuous variables. Chi-square tests of association or other nonparametric tests shall be used for dichotomous data or non normal data wherever appropriate. Percentage reduction of the SADQ scores shall be calculated and compared between the groups. Missing values will be filled with last observation carry forward method or as appropriate.

DISCUSSION

There is little or no evidence of the comparative effectiveness of treatments for many conditions, since most studies compare a given treatment to a placebo rather than head-to-head with competing treatments.[20] Therefore, this study protocol is designed as randomized controlled trial with allopathic treatment as a comparative arm, which will help in generating evidence to support a intervention, i.e., Homoeopathy for alcohol dependence, further leading to improvement in the delivery of patient care. Comparative effectiveness studies add to the public knowledge base about what works in health care and what does not, and may lead to cost savings. Moreover, research should provide evidence facilitating decision-making in health care.[20]

The spectrum of alcohol withdrawal symptoms ranges from minor symptoms as insomnia

and tremulousness to severe complications such as withdrawal seizure and delirium tremens.[21] Keeping in view the ethical issues and safety, rescue allopathic medication shall be available for both groups of patients to manage severe complications. Such patients will be analyzed separately as subgroup. After rescue medication patient will receive the initial assigned group of intervention.

Studies have shown better QOL with homoeopathic intervention irrespective of disease condition.[22] The alcohol dependent patients have poor quality of life and interventional studies need to consider QOL as one of the parameters for judging its effectiveness. Therefore this present protocol also aims to assess and compare quality of life of patient's on alcohol dependence.

The protocol shall generate data that can be reported as per CONSORT guidelines for reporting randomized trials with parallel groups[23] and the Reporting data on Homoeopathic Treatments (RedHot) supplement to CONSORT.[24] It is in accordance with the SPIRIT 2013.[25] Further this study involves administration of individualized homoeopathic medicine with the involvement of homoeopathic experienced doctors in treating alcohol dependents, using validated assessment scale, which will be amenable to profession at large thus covering all the domains of Model Validity of Homoeopathic Trials (MVHT).[26]

Trial status

The data analysis is in progress and the result will be published soon.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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एल्कोहल निर्भरता के प्रबंधन में एक यादृच्छिकृत नियंत्रित परीक्षण : होम्योपैथिक विरुद्ध मानक एलोपैथिक उपचार

सार

पृष्ठभूमि एवं उद्देश्यः मद्यव्यसन (एल्कोहल निर्भरता) एक चिरकालिक व्याधि है जिसका चिह्न है एल्कोहल के सेवन पर निर्भरता। यह स्वास्थ्य, सामाजिक व साथ ही पारिवारिक जीवन तथा कार्य उत्तरदायित्वों में हस्तक्षेप करती है। सकारात्मक परिणामों के साथ एक प्रेक्षणमूलक, एक–भुजीय अध्ययन के अनुभव के आधार पर, यह प्रोटोकॉल मानक ऐलोपैथिक उपचार के साथ होम्योपैथिक हस्तक्षेप की प्रभाविकता की तुलना के लिए कार्यान्वित किया जा रहा है।

सामग्रियां एवं विधियांः यह एक यादृच्छिकृत, नियंत्रित, खुला–नामपत्र, तुलनात्मक परीक्षण होगा। रोगियों को कंप्यूटरीकृत यादृच्छिकरण संचित्र का उपयोग करते हुए होम्योपैथी या ऐलोपैथी हस्तक्षेप समूह में से एक में यादृच्छिकृत कर दिया जाएगा। उपचार एवं साथ में अनुवर्तन की अवधि 1 वर्ष की होगी। दोनों समूहों को सहयोगी परामर्श दिया जाएगा। प्राथमिक परिणाम माप है 1 वर्ष के उपचार के उपरांत आधार–रेखा की तुलना में 'एल्कोहल निर्भरता की गंभीरता' (सिवेरिटी ऑफ़ एल्कोहल डिपेंडेंस, एसएडीक्यू) श्रेणी–निर्धारण पैमाने में 50: से अधिक की कमी और द्वितीयक परिणाम में शामिल है आधार–रेखा और अध्ययन की समाप्ति पर विश्व स्वास्थ्य संगठन (डब्ल्यूएचओ) जीवन गुणवत्ता संक्षिप्त प्रश्नावली में परिवर्तन। निराविषीकरण का प्रबंधन नैदानिक संस्थान एल्कोहल आहरण आकलन पैमाना, संशोधित (क्लीनिकल इंस्टीट्यूट विदड्रॉअल असेसमेंट ऑफ़ एल्कोहल स्केल, रिवाइज़्ड, सीआईडब्ल्यूए–एआर) के उपयोग द्वारा किया जाएगा। मात्रा और आवृत्ति की दृष्टि से एल्कोहल के उपभोग के प्रतिरूप में आगे के परिवर्तनों का आकलन किया जाएगा।

चर्चाः इस अध्ययन से होम्योपैथिक हस्तक्षेप युक्त आगामी कठोर यादृच्छिकृत नियंत्रित परीक्षणों (आरसीटी)/प्रयोजनात्मक अध्ययन की अभिकल्पना में सहायता मिलेगी।