

Randomized Controlledtrial on Ayurveda Interventions with Nicotexchewing Gum for De-Addiction of Tobacco Products in School Going Children of Salod and sawangi, Wardha-Study protocol

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Abstract:

Introduction: The addiction of tobacco in school going children is becoming common in rural areas of Maharashtra. It is the gate way of other substance abuse in children which is the major cause of increase in the risk of non-communicable diseases. Ayurveda has widely described *Sadvritta*(good conduct) and *Satvavajaychikitsa* (Ayurveda psychotherapy-counselling) with meditation and medicines which can be applied to detoxify as well as de-addict them. **Aim and Objectives:**to highlight a possible role of Ayurveda principles as multimodal approach at a time in comparison with Nicotex chewing gum (Standard replacement therapy-WHO) to tackle the same. **Material and Methods:** This study will be conducted in Zila Parishad Schools in and around Salod&Sawangi and Kaumarabhritya OPD of MGACHRC. In group A,Children suffering from addiction by tobacco products receiving *Madhuyashtyadi*granuels sachets with *Satvavajaychikitsa*&*Sadvritta* while in Group B: Childrenaged 6 to 16 years suffering from addiction of tobacco products receiving Nicotex chewing gum (1mg) adjuvant with*Sadvritta* (good conduct), *SatvavajayChikitsa*-counselling and meditation for equal duration of three months, at least fifty in each group. **Observations and result:** Sachets dose will be fixed as per their frequency of tobacco consumption. As per *Padanshikkrama*, tobacco sachets will be withdrawn. Data will be assessed by statistical tests. Result will be observed by reduction in rate of consumption or craving for tobacco products with reduction of urine Cotinine level during treatment and after end of interventions in follow-up period. **Conclusion:** Will be drawn on the basis of observations, result and discussion. Also, they will be educated for harmful effects on health by tobacco products and thus not to indulge in any addiction by *Satvavajaychikitsa*.

Keywords: Tobacco addiction, Sadvritta, Satvavajay, Nicotex chewing gum, De-addiction, Ayurved interventions

INTRODUCTION:

Nicotine is the most widely consumed psychotropic drug worldwide. In India, 60 % people are dependent with various substances containing tobacco which is the main gateway of other more toxic drugs^[1]. The use of tobacco products increases the risk of non-communicable diseases to many folds. Tobacco products addiction is the most common leading causes of preventable morbidity and mortality^[2]. Ayurveda has widely described *Sadvritta*(good conduct) and *Satvavajaychikitsa* (Ayurvedapsychotherapy-counselling)^[3] with meditation which can be applied in this context along with medicines which can act as detoxify the effects of tobacco and divert them from habit.

The addiction causes not only physical morbidity but also mental and social one. Underage dependence on these toxic substances is becoming a new challenge and continuously it is on rise in India. Due to environmental effect if children adopt tobacco in habit, then it becomes difficult to get rid off with more hazardous effects on developing brain^[4]. Every year the mortality rate due to consumption of nicotine is increasing in India.^[5] Ministry of social justice and empowerment has undertaken a National Household Survey (NHS), Drug Abuse Monitoring System (DAMS) and Rapid assessment Survey (RAS) to check the severity of the problem^[6,7].

The main withdrawal effects of these drugs are anxiety, irritability, sleeplessness, anger, palpitation, perspiration, headache, muscle cramps, lack of appetite etc.^[8,9]. It affects each and every organ of the body, mainly atherosclerosis, stroke, heart diseases, eye, lung-COPD, asthma, cancer, neuritis, vital organs degeneration along with psychosocial behavioral impact^[10,11].

Thus, to evaluate the efficacy of Ayurveda Polyherbal compound, Madhuyashtyadi granules will be prepared like *Gutka* in colour, taste and look in crude form with *Ela* and mint flavor to attract the children to chew it instead of *Gutka*. The probable action of the herbal compound to be used in this study will mainly to check its efficacy against deaddiction as well as *Rasayan* (rejuvenation) effect to combat the hazardous outcome of substance abuse. It contains *Triphla*, *Ashwagandha*, *Tagar*, *oat*, *Kapikachhu* and *Yashtimadhu* with *Ela* to provide not only aroma and good taste but also healing effect. The action of all these ingredients is immunomodulator, rejuvenating and healing effect.^[12] These ingredients also used for de-addiction purpose^[13]. This study is mainly based to assess the effect of herbal compound with awareness in comparison with efficacy of Nicotex chewing gum^[14] along with *Sadvritta*, *Satvavajaychikitsa* and meditation as standard control group. According to WHO^[15], replacement therapy is beneficial so Nicotex chewing gum is planned in parallel group as standard control.

***Sadvritta* (Ethical regimen):**- Ancient scholars have mentioned the various principles of code of conduct known as *Sadvritta* which helps in maintaining a healthy body and a peaceful mind.^[3] The path of ethical, social, mental, moral and physical conduct induces a positive influence on the mind and body. It helps to lead a healthy and fulfilling life. It helps

in enhancing the *Satvikguna* of mind. The following code of conduct of *Sadvritta* should be followed.

- a. Speak the truth and use pleasant words in conversation
- b. Do not lose self-control. Have a respectable and protective attitude towards elders, forefathers, teachers, women, children and colleagues.
- c. Abstain from telling lies, anger, extreme grief, jealousy and greed
- d. Avoid company of people with evil thoughts.
- e. Avoid indulgence in *Himsa*(any activity which harm others), *Asteya* (stealing habits), *Anyathakma* (unlawful sexual activity), *vyapada* (intention of harming), *viparyaya* (finding fault with scriptures, elders, etc.) Thus, the person who behaves as per the principles of *sadvritta* becomes more divine and lives a good quality of life.

Satvavjaya treatment - It is also called as *Aashwasanchikitsa* which deals with *Manonigrah*. It is used as psychological therapy^[16]. Fear of recurrence produces physical and psychological impairments result in depression, adjustment disorder, anxiety, mood disturbance, sadness, confusion and fear of future. Many of the pre-planned situations can be generated by researcher so as to raise level of confidence in the addict child and restraint his mind from unwholesome objects. For example, children have to face exam stress due to lack of study, recurrent illness or any family issue. In such a situation recitation of mantras, auspicious act, an oblation, boost child's mind to cope the situation.

Meditation: Concentration on breathing to remain thoughtless and provide calm to mind. It can be practiced to think or visualize good experiences. All the three can be practiced at a time along with trial and control group because every addiction continue to make mind cheerful and relax.

Rationale of the study and research gap analysis:

It is very difficult to de-addict from tobacco products due to strong affinity with developing brain. Its craving may compel child to do anything bad also. As early as child gets addicted it is very difficult to de-addict due to permanent changes in brain so effort has been planned to choose it as research study to de-addict as well as educate them for hazards by tobacco products on physical, mental & social life too.

The main cause is bad peer group. Parents used to send their child to purchase tobacco products for them and do eat in front of them. These environmental factors compel them to try it once and later again and again for getting temporary stimulation to brain which leads to enthusiasm in work pattern.

The aim of this study is to find out a root cause analysis of dependence problems and to highlight a possible role of Ayurveda principles as multimodal approach at a time in comparison with Nicotex chewing gum (Standard replacement therapy-WHO) to tackle the same. This study may prove as torch-bearer for prevention and management of tobacco addiction problems through Ayurvedainterventions versus replacement therapyin children.No such study has been done till date in children. The probable action of all interventions altogether to work on awareness against hazardous effects of tobacco, making desire to quit, stimulatory efficacy of trial drug on brain along with simultaneous action on treatment of

withdrawal effects. Previous studies on Satvavajaya showed a good action on mind to come out from anxiety and depression so, added in this study as best non-pharmacological intervention, necessary in childhood age as developmental period specifically.

AIM AND OBJECTIVES:

Aim- Comparative Efficacy of Ayurveda Madhuyashtyadi granules as De-addictive tool for Tobacco products use (Gutka-kharrhaetc) in comparison with Nicotex chewing gum and adjuvant as Satvavajaychikitsa, Sadvritta to both the groups in Zila Parishad school going children of Sawangi and Salod (H) Wardha

Objectives:

1. To assess the efficacy of Madhuyashtyadi granules formulation along with *Satvavajaychikitsa* (*Sadvritta*-good conduct, counselling and meditation) in reducing or complete stoppage in consumption of tobacco products.
2. To study the efficacy of Nicotex chewing gum with *Satvavajaychikitsa* (*Sadvritta*-good conduct, counselling and meditation) in reducing or complete stoppage in consumption of tobacco products.
3. To compare the efficacy of both groups.

RESEARCH QUESTION:

Whether *Madhuyashtyadi* granules are more capable or equally effective in comparison with Nicotex chewing gum or not along with *Satvavajaychikitsa*?

Previous work done: No such study has been carried out especially in children on addiction of tobacco products with Ayurvedic formulations. Some work has been carried out in adults related to addiction of smoking and alcohol consumption based on description found in *Madatyaya* chapter of classics. [18,19] Survey studies were carried out to check prevalence and health impact on addicted children of same area [7,8, 11] The main principles are to check withdrawal effects, counteract toxic effects and multi-modular educative and divertive approach towards de-addiction. The studies based on Nicotex chewing gum will be assessed.

MATERIAL & METHODS

Source of Data & Place: Zila Parishad Schools in and around Salod & Sawangi, Wardha

Duration: 2 years

Type of study- Interventional Clinical Study (RCT)

Study design- Randomized comparative study

Ethical consideration: Approval received by IEC (MGACHRC/IEC/2020/21) on 6.5.2020. Also, registration is done in CTRI, number yet to come.

Received 15 December 2020; Accepted 05 January 2021.

Setting: This study will be conducted in Zila Parishad Schools in and around Salod&Sawangi and KaumarabhrityaOPDof MGACHRC. Informed consent will be taken from informers.

Randomization:Children with tobacco product addiction will be recruited as per randomization, generated by computerized table.

Sample size based on conventional clinical studies comprising of 110 children, 50 in each group and 10% drop out rate.

Group A: Children suffering from tobacco products addiction receiving *Madhuyashtyadi* granules sachets with Satvavajaychikitsa&Sadvritta

GroupB: Children suffering from addiction oftobacco products receivingNicotex chewing gum (1mg) adjuvant with*Sadvritta* (good conduct), *SatvavajayChikitsa*-counselling and meditation.

Inclusion criteria:

- Children between age of6 to 16 years willing to get de-addicted
- Suffering from tobacco product addiction, who will be ready to participate in the study/ giving accent/consent

Exclusion criteria:

- Patients who decline to give informed consent
- Children with systemic illnesses(fever), mental problems(intellectual disability), behavioral problems-uncooperative, irritable.

Posology:

The trial drug in group A will be administered minimum three to six times a day at dose of 2.5 gm each as per their frequency of tobacco consumption.As per *Padanshikkrama*, daily 1 packet of supari or any tobacco product will be withdrawal per week then 2 packets daily for next week likely till the stoppage of tobacco product totally or maximum up to 3 months.

Follow-up: during treatment duration, children will be followed up by every week till reduction or stoppage of tobacco products.

After treatment follow up was every fortnight till 1 month.

Primary End point:

Reduction in rate of consumption or craving for tobacco products with reduction of urine Cotinine level

Secondary end point:

Reduction in rate of consumption or craving for tobacco products in follow up periodalso after stopping interventions

Laboratory Investigations: CBC to rule out the basic derangement of body functioning if neededand pre-post urine cotinine level

Drug Review-

A probable de-addictive herbal compound named ‘Madhuyashtyadi granules’ with ingredients [12] are as follows, mentioned in table no.1

Table no 1: showing details of Madhuyashtyadi granules formulation

Sr no	Name of herb	Latin name	Part used	Proportion
1	<i>Amalki</i>	<i>Embelicaofficinalis</i> Gasten	Fruit	1
2	<i>Yashtimadhu</i>	<i>Glycyrrizaglabra</i> Linn	Stem	1
3	<i>Ashwagandha</i>	<i>Withaniasomnifera</i> Linn	Root	1
4	<i>Haritaki</i>	<i>TerminaliaChebula</i> Retz	Fruit	½
5	<i>Bibhitak</i>	<i>Terminaliabelerica</i> Roxb	Fruit	½
6	<i>Oat</i>	<i>Avena Sativa</i>	Seed	1
7	Tagar	<i>ValerianoOfficinalis</i> DG	Stem or root	1
8	<i>Ela</i>	<i>Elettariacardamomum</i> Maton	Fruit seed	½
9	Food coloring agent	---	---	1/10 th
10	Kapikachhu	<i>Mucuna pruriens</i> (L.) DC	Seed	1

Preparation of Sachets: Fine powders of drugs in said proportion will be taken and mixed thoroughly. This mixture will be triturated with the decoction of first five drugs till it attains semisolid consistency. At this stage *Ela* powder will be added. Then this mass will be rubbed through sieve to get uniform granules. The effort will be taken to make it similar in look, aroma and taste as gutka. Finally, these granules will be packaged in 5 gram sachets for further use.

Assessment Criteria-

1. Serum or urine Cotinine level to test nicotine value of body
2. Frequency of chewing gutka per day-in number of sachets
3. Frequency of Craving/day- average
4. The questionnaire will be based on CIDI (WHO's composite International Diagnostic Interview version 1.1 and later version (ICD 10 & DSM -V R), after validation, it will be taken [20-21]

Methods of awareness, education and counselling:

Information will be collected from minimum 100 respondents consuming tobacco products from rural Salod and Sawangi, Wardha. Group A and B both will be given *Sadvritta*, *Satvavajay*[21] and meditation skill training along with health education about the harmful effects of tobacco use. Information will be filled up by the investigators on the preauthenticated proforma. The criteria and definition of tobacco use will be based on WHO

guidelines. Children suffering with moderate withdrawal and degenerative features will be referred to Balrog OPD for further treatment if manageable.

Evidence-based report will be prepared from various earlier important studies to aware public for the dangerous health effects of tobacco. This study will mainly highlight major facts of the use of tobacco, its adverse effects globally and role of Ayurveda in their reduction. It will also useful for system wise and general health check up to screen various issues if any.

Withdrawal Criteria: If the severe withdrawal symptoms occurred during treatment such subjects will be withdrawn from study and suitable alternative will be provided free of cost till becomes alright.

Statistical methods- The data will be analyzed by using paired t test and unpaired t test with other non- qualitative tests for subjective parameters

DISCUSSION:

There is no such direct reference found for tobacco products, effects on health and their de-addiction described in Ayurveda classics. Tobacco is pungent, astringent and irritant in nature. It causes acidity, ulcer, headache, cramps, weakness, body ache etc. It blocks personal, economic and social development. Addicted person engages in a vicious cycle of physical and mental health hazards^[11]. Due to various substances containing nicotine like tobacco, *Gutka, Kharrha, Khaini, Masala supari, Jarda, hookah, bidi*, cigarette etc. users may develop first difficulty in deglutition; lock jaw- trouble in opening mouth, change in voice etc. but pain is totally absent hence most of the times these features get neglected. Then white patch called as Leukoplakia or sub-mucous fibrosis develops. However, if not treated and nicotine products are consumed regularly then red patch appears called as Erythroplakia which later may turn into blackish one known as Melanoplakia. It is cancerous and non-healing ulcer may appear in maxilla, mandibular region or chin and oral cavity^[17]. Few of the related studies were reported by Deolia et. al.^[22] and Goyal et. al.^[23].

CONCLUSION-

will be drawn on the basis of observations and discussion.

Scope and future implications- Publications, torch bearer to other researchers for their further studies

Translational components- Awareness module can be prepared to prevent addiction by new children and to de-addict by addictive children.

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