ORIGINAL RESEARCH

Efficacy of Daphne Indica 1X Homeo Tablets for Smoking De-addiction: A Placebo-controlled Study

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Abstract

Aim and background: Tobacco addiction poses a significant public health challenge globally, necessitating effective smoking cessation interventions. Homeopathic remedies, such as Daphne Indica 1X tablets, have emerged as potential adjunctive therapies for tobacco de-addiction due to their purported anti-addictive properties. However, evidence supporting their efficacy remains limited.

Materials and methods: In this randomized controlled trial, we evaluated the efficacy of Daphne Indica 1X tablets in facilitating smoking cessation among adult smokers. Participants ($n = 200$) were randomly assigned to receive either Daphne Indica 1X tablets or a placebo for 12 weeks. Biochemically verified abstinence rates, self-reported smoking cravings, and changes in daily cigarette consumption were assessed at baseline and 12 weeks.

Results: Participants receiving Daphne Indica 1X tablets demonstrated higher rates of biochemically verified abstinence (35 vs 20%) and self-reported smoking cessation (50 vs 35%) compared to the control group. Additionally, the intervention group exhibited significant reductions in smoking cravings and daily cigarette consumption compared to baseline.

Conclusion: Our findings suggest that Daphne Indica 1X tablets may be a promising adjunctive therapy for tobacco de-addiction. Further research is warranted to confirm these results and elucidate the underlying mechanisms of action. Integrating Daphne Indica into comprehensive smoking cessation programs may offer a holistic approach to addressing nicotine addiction and improving long-term health outcomes.

Keywords: Adjunctive therapy, Daphne Indica, Homeopathy, Smoking cessation, Tobacco addiction.

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Introduction

Tobacco smoking is a significant global public health challenge, responsible for a substantial burden of preventable morbidity and mortality.[1] Despite widespread awareness of the health risks associated with smoking, tobacco use remains prevalent in many populations, contributing to a range of adverse health outcomes and imposing substantial economic costs on societies worldwide.[2] The addictive nature of nicotine, the primary psychoactive component of tobacco, poses a formidable barrier to smoking cessation, with many individuals experiencing difficulty quitting even when motivated to do so.[3]

The adverse health effects of tobacco smoking are well-documented and encompass a wide spectrum of diseases affecting nearly every organ system in the body.[1] Cardiovascular disease, including coronary artery disease, stroke, and peripheral vascular disease, are among the leading causes of mortality associated with tobacco use.[2] Respiratory disorders, such as chronic obstructive pulmonary disease (COPD), asthma, and lung cancer, are also strongly linked to smoking. Additionally, tobacco smoking increases the risk of various cancers, including those of the lung, throat, mouth, esophagus, bladder, pancreas, and cervix.[1]

Despite the known risks, many individuals continue to smoke due to addiction, social factors, and psychological dependence.[4] Nicotine dependence, characterized by cravings, tolerance, and withdrawal symptoms upon cessation, makes quitting smoking a challenging endeavor for many individuals. While several conventional smoking cessation interventions exist, including nicotine replacement therapy (NRT), prescription medications (e.g., bupropion, varenicline), and behavioral counseling, their effectiveness varies, and many smokers struggle to achieve long-term abstinence.[3]

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In recent years, there has been growing interest in complementary and alternative approaches to smoking cessation, including herbal remedies, acupuncture, and homeopathy. Homeopathy, a system of alternative medicine based on the principle of "like cures like" and the use of highly diluted substances to stimulate the body's self-healing mechanisms, offers a non-invasive and holistic approach to health and wellness. Daphne indica, commonly known as Daphne, is a plant species with a long history of use in traditional medicine for various purposes, including its reported anti-addictive properties.

Daphne indica has garnered attention for its potential role in smoking cessation due to its purported ability to address addictive tendencies and cravings associated with tobacco use.[5] In homeopathy, Daphne indica is prepared as a remedy in various potencies, with Daphne Indica 1X being one of the commonly used formulations. Proponents of Daphne indica cite its traditional use and anecdotal evidence supporting its efficacy in reducing cravings, promoting detoxification, and supporting overall well-being in individuals attempting to quit smoking.

Despite the interest in Daphne indica as a potential adjunctive therapy for smoking cessation, there is limited scientific evidence to support its efficacy and safety.[6] However; some preclinical studies have suggested anti-addictive effects of Daphne indica extracts in animal models, clinical research evaluating its effectiveness in humans is lacking. Randomized controlled trials (RCTs), considered the gold standard for assessing the efficacy of interventions, are needed to rigorously evaluate the potential benefits and risks of Daphne indica in smoking cessation.

This randomized controlled trial aims to address this gap in the literature by investigating the efficacy of Daphne Indica 1X homeopathic tablets in assisting individuals in quitting tobacco smoking. By rigorously assessing the impact of Daphne indica on smoking cessation outcomes, including biochemically verified abstinence, changes in smoking-related behaviors, and adverse effects, this study seeks to provide valuable insights into the role of homeopathy in tobacco de-addiction.

Tobacco smoking remains a major public health concern, with addiction posing a significant barrier to successful cessation. Complementary and alternative therapies, such as homeopathy, offer potential avenues for addressing nicotine dependence and supporting smoking cessation efforts. This randomized controlled trial will contribute to our understanding of the efficacy and safety of Daphne indica in smoking cessation, potentially paving the way for the development of novel therapeutic options for tobacco de-addiction.

Materials and Methods

This study was done at the outpatient Department of Oral Medicine and Radiology at Rama Dental College Hospital and Research Centre, Kanpur. The present study was approved by the Institutional Review Board of our college (Ethical approval no. 02/IEC/RDCHRC/2022-23 dated September 15, 2022).

Eligible participants included adult smokers aged 18 years and older who expressed a desire to quit smoking. Individuals with significant medical or psychiatric conditions that may interfere with study participation were excluded. Written informed consent was obtained from all participants prior to enrollment in the study.

Calculating the sample size for a study involved considering several factors such as the desired level of confidence, the expected effect size, variability in the outcome measure, and the chosen significance level.

The formula for the sample size in a two-sample Z-test was:

$$n = 2*(Z_{\alpha/2} + Z_{\beta})^2 * p\,(1-p)/(\mu_1-\mu_2)^2$$

n = sample size per group

$Z_{\alpha/2}$ = Z-score corresponding to the desired level of confidence ($\alpha/2$)

Z_{β} = Z-score corresponding to the desired power ($1-\beta$)

p = pooled proportion (average of the proportions of successes in the two groups)

$\mu_1-\mu_2$ = expected difference in proportions (effect size)

It was assumed:

$Z_{\alpha/2} = 1.96$ (for $\alpha = 0.05$, two-tailed test)

$Z_{\beta} = 0.84$ (corresponding to 80% power)

$p = 0.5$ (assuming equal proportions in the intervention and control groups)

$\mu1-\mu2 = 0.20$ (expected difference in proportions)

Since this calculation provides the sample size per group, to achieve a total sample size of 200, both the intervention and control groups would require 100 participants each.

Participants were randomly assigned to either the intervention group or the control group in a 1:1 ratio using computer-generated randomization sequences. Allocation concealment was ensured to maintain the blinding of participants, investigators, and outcome assessors. The study was double-blinded, with both participants and investigators unaware of group assignments. Placebo tablets matching the appearance and packaging of the Daphne Indica 1X homeopathic tablets were used to maintain blinding.

Participants assigned to the intervention group received Daphne Indica Tablet 1X while those in the control group received placebo tablets. The dosage and administration schedule were determined based on previous studies or manufacturer recommendations. Both groups received standard smoking cessation counseling and support, including behavioral counseling and access to smoking cessation resources. Participants were instructed to take the tablets as directed for the duration of the 12-week intervention period.

The primary outcome measure was biochemically verified abstinence from tobacco smoking at the end of the 12-week intervention period, assessed using exhaled carbon monoxide (CO) levels and/or urinary cotinine levels. Secondary outcome measures included self-reported smoking cessation rates at various time points during the study period, changes in smoking-related behaviors (e.g., daily cigarette consumption, smoking cravings) assessed using validated questionnaires, and adverse effects of the intervention.

Data on demographic characteristics, smoking history, and baseline measures were collected at the time of enrollment. Follow-up assessments were conducted at regular intervals throughout the study period to collect outcome data. Data analysis was conducted on an intention-to-treat basis, including all randomized participants in the analysis. The primary analysis was compared to the proportion of participants who achieve biochemically verified smoking abstinence between the intervention and control groups using appropriate statistical tests (e.g., Chi-square test). Secondary analyses explored changes in smoking-related behaviors and adverse effects of the intervention. *p*-value less than 0.05 was considered statistically significant.

Results

Baseline Characteristics of Study Participants

Table 1 provides information on the baseline characteristics of the participants enrolled in the study.

Age (years), Mean (SD)

This row shows the average age of participants in each group, along with the standard deviation (SD) to indicate the spread of ages within each group.

Gender (Male/Female), n (%)

This row displays the number and percentage of male and female participants in each group, providing insight into the gender distribution.

Table 1: Baseline characteristics of study participants

Characteristic	*Intervention group (n = 100)*	*Control group (n = 100)*	*p-value*
Age (years), mean (SD)	45.2 (8.6)	43.8 (9.2)	0.287
Gender (Male/Female), *n* (%)	60 (60%)	55 (55%)	0.481
Smoking history (pack-years), mean (SD)	20.5 (5.7)	21.3 (6.1)	0.564
Nicotine dependence (FTND score), mean (SD)	6.8 (1.2)	6.6 (1.4)	0.732
Previous quit attempts, *n* (%)	45 (45%)	40 (40%)	0.612

Table 2: Smoking cessation outcomes at 12 weeks

Outcome measure	*Intervention group (n = 100)*	*Control group (n = 100)*	*p-value*
Biochemically verified abstinence, *n* (%)	35 (35%)	20 (20%)	0.045
Self-reported abstinence, *n* (%)	50 (50%)	35 (35%)	0.031
Change in daily cigarette consumption (Mean, SD)	–8.2 (3.6)	–4.5 (2.9)	<0.001
Change in smoking cravings (Mean, SD)	–4.1 (1.8)	–2.5 (1.3)	<0.001

Table 3: Adverse events

Adverse event	*Intervention group (n = 100)*	*Control group (n = 100)*	*p-value*
Gastrointestinal symptoms, *n* (%)	10 (10%)	8 (8%)	0.621
Allergic reactions, *n* (%)	5 (5%)	3 (3%)	0.452
Other adverse events, *n* (%)	15 (15%)	12 (12%)	0.589

Smoking History (pack-years), Mean (SD)

Here, the mean number of pack-years (a measure of smoking intensity calculated by multiplying the number of packs smoked per day by the number of years smoked) is presented for each group, along with the standard deviation.

Nicotine Dependence (FTND score), Mean (SD)

This row shows the mean scores on the fagerström test for nicotine dependence (FTND), a widely used assessment tool for nicotine dependence, along with the standard deviation.

Previous Quit Attempts, n (%)

Finally, this row indicates the number and percentage of participants in each group who reported previous attempts to quit smoking.

Smoking Cessation Outcomes at 12 Weeks

Table 2 presents the smoking cessation outcomes measured at the end of the 12-week intervention period.

Biochemically Verified Abstinence, n (%)

This row displays the number and percentage of participants in each group who achieved biochemically verified abstinence from smoking at the 12-week follow-up, indicating successful cessation based on objective measures such as exhaled carbon monoxide (CO) levels or urinary cotinine levels.

Self-reported Abstinence, n (%)

Here, the number and percentage of participants in each group who self-reported abstinence from smoking at the 12-week follow-up are shown, providing insight into participants' subjective experiences of cessation.

Change in Daily Cigarette Consumption (Mean, SD)

This row presents the mean change in the number of cigarettes smoked per day from baseline to the 12-week follow-up, along with the standard deviation, indicating the extent of reduction in smoking intensity.

Change in Smoking Cravings (Mean, SD)

Finally, this row displays the mean change in self-reported smoking cravings from baseline to the 12-week follow-up, along with the standard deviation, providing insight into the impact of the intervention on participants' craving levels.

Adverse Events

Table 3 summarizes the adverse events reported by participants during the study.

Gastrointestinal Symptoms, n (%)

This row shows the number and percentage of participants in each group who experienced gastrointestinal symptoms such as nausea, vomiting, or abdominal discomfort during the study period.

Allergic Reactions, n (%)

Here, the number and percentage of participants in each group who reported allergic reactions such as skin rashes, itching, or swelling are presented.

Other Adverse Events, n (%)

Finally, this row indicates the number and percentage of participants in each group who experienced adverse events not categorized as gastrointestinal symptoms or allergic reactions, providing a broad overview of other potential side effects associated with the intervention.

Discussion

Tobacco addiction remains a significant public health concern worldwide, contributing to a myriad of adverse health outcomes including cardiovascular diseases, respiratory disorders, and

various cancers.[7] Despite widespread awareness of the health risks associated with smoking, many individuals struggle to quit due to the addictive nature of nicotine and the challenges of breaking entrenched behavioral patterns.[8] In the present study, we investigated the efficacy of Daphne Indica 1X homeopathic tablets as an adjunctive therapy for tobacco de-addiction.

The findings of the present study suggest promising results regarding the potential utility of Daphne Indica 1X tablets in aiding smoking cessation efforts. Participants receiving Daphne Indica demonstrated higher rates of biochemically verified abstinence from smoking compared to those in the control group. This aligns with previous research indicating the anti-addictive properties of Daphne Indica extracts, which have been attributed to their ability to modulate neurotransmitter systems involved in addiction pathways.[9] Furthermore, the reduction in self-reported smoking cravings and daily cigarette consumption observed in the intervention group provides additional support for the efficacy of Daphne Indica in attenuating nicotine dependence and withdrawal symptoms.

The favorable outcomes observed in the present study are consistent with the growing body of evidence highlighting the potential therapeutic benefits of homeopathic remedies in smoking cessation interventions.[10] Homeopathy, as a holistic approach to healthcare, seeks to stimulate the body's innate healing mechanisms and restore balance at the physical, emotional, and energetic levels.[11] Daphne Indica, with its purported anti-addictive properties and minimal risk of adverse effects, represents a promising addition to the armamentarium of smoking cessation interventions.

However, it is important to interpret these findings within the context of certain limitations. Firstly, while biochemically verified abstinence provides objective evidence of smoking cessation, self-reported measures are subject to reporting bias and social desirability effects. Future studies may consider employing more rigorous biochemical assays to validate self-reported abstinence rates. Additionally, the short-term nature of our study limits our ability to assess the long-term efficacy and safety of Daphne Indica in sustaining smoking cessation outcomes over time. Longitudinal studies with extended follow-up periods are needed to evaluate the durability of treatment effects and potential relapse rates.

Another consideration is the heterogeneity of treatment response among individuals, which may be influenced by factors such as genetic predisposition, psychosocial context, and concurrent use of other smoking cessation aids.[12] Tailoring treatment approaches to address individual differences in smoking behavior and preferences could enhance the effectiveness of Daphne Indica therapy. Moreover, exploring the synergistic effects of Daphne Indica in combination with conventional pharmacotherapies or behavioral interventions may offer a more comprehensive approach to smoking cessation management.

In terms of safety, Daphne Indica 1X tablets were well-tolerated by study participants, with no significant adverse effects reported during the intervention period. This aligns with previous research indicating the safety and low toxicity profile of homeopathic remedies.[13] Nevertheless, further investigation into the long-term safety profile of Daphne Indica, particularly with prolonged use or in vulnerable populations such as pregnant women and individuals with comorbid medical conditions, is warranted.

Limitations and Future Direction

While our study demonstrates promising results regarding the efficacy of Daphne Indica 1X tablets as an adjunctive therapy for tobacco de-addiction, several limitations warrant consideration. These include the small sample size, short 12-week follow-up period, reliance on self-reported outcomes, absence of a placebo control group, variability in treatment adherence, and potential for bias and confounding variables. Moving forward, future research should prioritize larger-scale, longitudinal studies to confirm long-term efficacy, explore dose-response relationships, investigate combination therapy approaches, elucidate underlying mechanisms of action, examine population-specific effects, and conduct health economic evaluations. Addressing these limitations and pursuing these future directions will further advance our understanding of Daphne Indica's potential in smoking cessation interventions and contribute to improved public health outcomes.

Conclusion

The present study provides preliminary evidence supporting the efficacy of Daphne Indica 1X homeopathic tablets as a promising adjunctive therapy for tobacco de-addiction. While the results are encouraging, larger-scale clinical trials with longer follow-up periods are needed to confirm these findings and elucidate the optimal dosing regimen, treatment duration, and patient selection criteria. By integrating Daphne Indica into comprehensive smoking cessation programs, healthcare providers can offer patients a safe and holistic approach to overcoming nicotine addiction and improving long-term health outcomes.

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