Nicotine Free Herbal Composition for Smoking De-Addiction - A Placebo Controlled, Double Blind, Randomized, Multi-centric Clinical Study

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Abstract

Background: Smoking is a major predisposing factor for many health problems including Cancers, Vascular disorders etc. Quitting smoking is the only solution to prevent them. Various medicinal and non-medicinal methods are used for the same.

Hypothesis/Purpose: The purpose of the present study was to evaluate the efficacy of a nicotine free herbal formulation (Smotect tablets) containing ingredients like *Mucuna pruriens, Withania somnifera, Bacopa monnieri* etc. for cessation of smoking and its effects on other health parameters related to smoking.

Study Design: The present study was a placebo controlled, double blind, randomized, multi-centric clinical study conducted at three clinical sites in India.

Methods: After ethical approval and informed consent, all participants were given nicotine free herbal composition - Smotect Tablets or Placebo tablets in a dose of 2 tablets twice daily for 90 days. A total of 103 Participants (52 in trial group and 51 in placebo group) completed the study. Evaluation of cessation of smoking was done along with other parameters like measurement of lung capacity, clinical assessment and laboratory investigations at baseline and at regular intervals till the end of the study.

Results: A significant reduction in smoking as well as in the CO and COHb levels was observed with the use of Smotect tablets as compared to placebo over a period of 90 days. Significant improvement was also observed in quality of life, energy and stamina levels, reduction of stress level. Smotect tablets were found to be safe without causing any adverse effects.

Conclusion: Smotect tablets, a nicotine free herbal composition, can be recommended as a safe and effective remedy for de-addiction of smoking along with improving health related problems arising due to smoking.

Introduction

All over the world, tobacco has been used, in chewable or smoking forms for euphoria, enjoyment, stimulation or pleasure.[1, 2] India is the second largest manufacturer and consumer of tobacco after China.[3] Tobacco smoking is among the major preventable causes of premature deaths worldwide.[4, 5] Smoking is known to be injurious to health causing several health hazards including various respiratory tract diseases, cardiovascular diseases, GI tract diseases, liver diseases, neurological diseases, stroke and cancer. [6–9] Smoking primarily impacts the respiratory tract including acute and chronic cough, emphysema, COPD, and bronchitis.[8] Nicotine present in smoke causes physical and psychological dependency and is the major factor for tobacco dependence and addiction. [6, 7]

As the avoidance of etiological factors is said to be the first line of treatment for any disease, quitting tobacco smoking is the best way to significantly reduce the risk associated with smoking.[7] However, due

to the sudden stoppage/quitting smokers can suffer from nicotine withdrawal symptoms like anxiety, irritability, increased eating, dysphoria, etc.[7] Presently behavioral treatment, Nicotine Replacement Therapy (NRT) and pharmacological treatment are used for smoking cessation.[10, 11] Nicotine patches, gums, inhalers and sprays are some of the options used currently. Some of the quitters also try e-cigarettes that are battery operated devices converting liquid nicotine to vapor. However, NRT has shown to be not a successful option by majority of the smokers. The pharmacological approaches have a beneficial role in alleviating withdrawal symptoms, but they are expensive and possess potential side effects.[12, 13] Some quitters also select to go for hypnosis, acupuncture and counselling.

Considering limitations of the treatment options, there is a need to develop an anti-smoking formulation that is free from the existing drawbacks of the anti-smoking formulations without nicotine. Need is also observed to develop formulation that not only help in de-addiction of smoking but also treats the ailments and/or side-effects caused by smoking.

Smotect Tablets is an herbal formulation comprising of standardized herbal extracts like *Mucuna pruriens, Withenia somnifera* etc. The stress relieving, mood enhancing and adaptogenic activities along with anti-inflammatory and immuno-modulatory effects of these ingredients have a potential not only in quitting smoking but also providing other therapeutic benefits. The objective of the study was to evaluate the effect of Smotect Tablets, a Nicotine free herbal formulation for cessation of smoking and its effects on other health parameters related to smoking.

Materials And Methods

- **Study design, sites –**

The present study was a placebo controlled, double blind, randomized, multi-centric clinical study conducted at three clinical sites across India, viz; Ayurved Sanshodhan Vibhag, Ayurved Seva Sangh Hospital, Ganeshwadi, Panchvati, Nashik; KVTR Ayurvedic College, Boradi, Dhule-425 428, and D.Y. Patil School of Ayurveda, Sector 7 Nerul, Navi Mumbai, Maharashtra.

- **Ethical considerations-**

Ethical approvals from Institutional ethics committees of all study centers were obtained. The study was registered on Clinical Trials Registry India (CTRI) vide registration number CTRI/2017/06/008790, dated 08/06/2017.

- **Enrolment of participants-**

Participants having a history of smoking a minimum of 5 cigarettes daily for at least 3 years and showing a high level of alveolar CO levels attending out-patient department of the study centers were considered for the study. The study was carried out and reported adhering to CONSORT statement. (Figure 1)

- **Study duration & Visits:**

The total duration of the study treatment was 3 months (90 days). Patients were asked to visit study site every 30^{th} day for 3 months.

- **Primary and secondary Outcomes:**

The primary outcome of the study was to evaluate the efficacy of Smotect Tablets in smokers by assessing cessation of smoking (reduction or complete giving up). Also, changes in Lung capacity were assessed on spirometer.

The secondary outcomes of study were to evaluate the efficacy of Smotect Tablets in smokers by assessing changes in levels of CO and COHb, Quality of life (QOL) on WHO-QOL Questionnaire, changes in the Cardiac risk markers (Apolipoprotein A1 and B), serum cortisol level, change in stress level and anxiety on HAMA scale, change in level of energy, stamina and physical strength on a 7-point scale, global assessment for overall change by the subject and investigator at the end of the study.

Safety and tolerability of study drug were assessed by any occurrence of adverse events (AEs) and adverse drug reactions and change in laboratory parameters such as LFT, RFT, lipid profile, CBC, ESR, hemoglobin and urine examinations.

- **Selection of Participants:**

Male and female participants between 18 to 70 years of age (both inclusive) having a history of smoking a minimum of 5 cigarettes daily for at least 3 years and showing a high level of alveolar CO levels and who gave written consent ready to abide to trial procedures were included in the study.

Participants suffering from any major illnesses, uncontrolled hypertension and diabetes, hepatic or renal impairment, central nervous system disorders and known hypersensitivity to any ingredient of the study drug were excluded from the study. Participants with continuing history of alcohol and/or drug abuse were excluded from the study.

- **Sample size:**

Sample size calculation was based on an assumption that a sample size of minimum 100 evaluable cases (divided into two groups of minimum 50 Participants each in placebo and study drug group) would provide an 80% power to estimate cessation of smoking and change in lung capacity at 5% level of significance at the end of the study.

- **Treatment Groups:**

After fulfilling the eligibility criteria participants were randomized to either trial group or placebo as per computer generated block randomization list. Subjects were advised to consume given medication in a dose of 2 Tablets twice daily orally after meals with a glassful of water.

- **Intervention:**

The study was double blinded study and therefore the study product and Placebo Tablets were manufactured and packed in such a way to ensure that the subject and Investigator were blinded from the same. Table 1 provides details of composition of the study product. Unblinding was done at the completion of the study. Placebo Tablets were made using inert materials IP grade – Micro Crystalline Cellulose (MCC), Hydroxy Propyl Methyl Cellulose (HPMC) and Talc.

- **Assessment Parameters:**

On baseline visit, participant's alveolar CO and COHb levels were measured. Participant's lung capacity was measured using spirometer. After an overnight fasting (10-12 hours), blood samples were collected for laboratory tests viz. CBC, ESR, BSL-Fasting, LFT, RFT, Lipid Profile, Cardiac risk markers (Apo-lipoprotein A1 and B), Total testosterone level and HIV, urine routine & microscopic examination. Subject's chest expansion was measured by measuring chest circumference (Axilla and Xiphoid process) and chest diameter (AP and ML).

Participants were asked for their average daily consumption of cigarettes at every 15 days interval. Spirometer test and CO and COHb levels were done to evaluate their lung capacity every month. On monthly basis, subject's Quality of life on WHO QOL, level of energy, level of stamina, physical strength was evaluated on a 7-point scale. Also, level of stress on VAS, level of anxiety on HAMA scale was evaluated and Subject's chest expansion was measured All the Participants were closely monitored for any adverse event, starting with the baseline visit till the end of the study visit.

Plan for statistical analysis:

All baseline and demographic data were summarized descriptively. All continuous variables were summarized using mean, standard deviation, standard error of mean and median. All categorical variables were summarized using frequency and percentages. The primary population for this study was Per-Protocol population. GraphPad InStat Version 3.6 software was used for statistical analysis of data. Comparison of variables representing categorical data was performed using Chi-square test. All other secondary outcomes were analyzed by applying appropriate statistical methods like proportion test, t-test etc. All p-values were reported based on two-sided significance test and all the statistical tests were interpreted at least up to 0.05 level of significance.

Results

Out of 119 recruited participants, 103 participants (51 in placebo group and 52 in trial group) completed the study, while 16 participants dropped out prematurely due to loss to follow-ups (see figure 1). All the participants who took even a single dose of study drug were considered for safety evaluation. The average age of participants in trial group was 40.58 ±14.64 years while the average age of the

participants in placebo group was 39.58 ±13.79 years. There was no significant difference (p> 0.05) in the age between the two groups.

Assessment of primary outcome parameters:

1) Number of cigarettes smoked per day by the participants:

At baseline visit, the average numbers of cigarettes smoked per day in trial group were 9.53 ± 6.42 which reduced significantly (p < 0.05) to 6.67 ± 5.54 at the end of 30 days. At the end of 60 days the same was 5.25 ± 4.10 and further to 4.00 ± 3.43 at the end of 90 days. In the placebo group the average number of cigarettes smoked per day reduced from 10.04 ± 6.20 to 8.73 ± 5.97 i. e. insignificant reduction (p > 0.05) at the end of 30 days. At the end of 60 days the reduction was significant and was observed to be 8.00 ± 5.55 and further to 7.09 ± 4.83 at the end of 90 days. On analysis between the groups, the reduction was significantly more (p<0.05) in trial group as compared to placebo. (The details are given in table 2)

At the end of the study complete cessation of smoking was observed in 12 (23.08%) participants in trial group and 2 (3.92 %) participants in placebo group. (p < 0.05) (The details are given in table 3)

2) Measurement of lung capacity on Spirometry:

Measurement of lung capacity on Spirometry observed that there were no significant changes in FVC, FEV_1 and FEV_1/FVC in trial group on day 30, 60 and 90 while in the placebo group a significant decrease (p < 0.05) in FVC and FEV_1 was observed on day 30, 60 and 90. No significant change was observed on FEV_1/FVC value on day 30, 60 and 90 in placebo group. The difference between both the two groups was statistically insignificant (p > 0.05) at all the follow up visits till the end of the study. The details on changes in mean FVC, FEV_1, FEV_1/FVC ratio are shown in table 4.

There was a significant increase in $FEF_{50\%}$ and $FEF_{25-75\%}$ in trial group from baseline to the end the study i. e. 90 days. However, there was no change on these parameters in placebo group from baseline to the end of the study. The difference between the groups was statistically insignificant (p > 0.05) at the end of the study.

Assessment of secondary outcome parameters:

i. Alveolar CO levels:

A significant reduction in the CO levels was observed in trial group from a baseline of 13.33 ± 7.76 ppm to 12.20 ± 9.88 ppm at the end of 30 days. There was a further reduction (p<0.05) to 10.76 ± 6.90 ppm at the end of 60 days and 10.63 ± 7.70 ppm at the end of 90 days. There was no significant (p>0.05) change in the CO levels in placebo group from baseline of 14.00 ± 7.51 ppm to 14.84 ± 8.45 at the end of 30 days. Further on day 60 and day 90 as well the change was found to be non-significant (p>0.05) as the score was 13.8 ± 7.42 and 13.53 ± 7.50 respectively. On analysis between the groups, it was observed

that the reduction in CO levels was significantly higher ($p<0.05$) in trial Group as compared to placebo. (See Graph 1)

ii. Alveolar COHb levels:

The COHb levels in trial group showed a significant reduction from 2.80 ± 1.25 % at baseline levels to 2.37 ± 1.27 % at the end of 90 days. In the placebo group the reduction was non-significant from baseline 2.87 ±1.19 to the end of the study 2.84 ±1.21. Between groups analysis showed that consumption of trial significantly reduced COHb levels as compared to placebo. (See Graph 2)

iii. Quality of life (QOL) on WHO QOL Questionnaire:

Assessment of quality of life showed that there was a significant improvement on the physical health score from 19.28 ± 2.44 at baseline visit to 20.49 ± 1.97 on day 90. In placebo group, the mean physical health score showed non-significant change ($p > 0.05$) from 20.14 ± 2.50 at baseline visit to 20.37 ± 2.29 on day 90. The improvement in trial group was found to be significantly higher as compared to placebo.

Also, in trial group, the mean psychological health domain score improved significantly ($p < 0.05$) from 19.06 ± 2.65 at baseline visit to 19.86 ± 2.37 on day 90, whereas in placebo group, the mean psychological health domain score showed non-significant change ($p > 0.05$) from 19.33 ± 2.67 at baseline visit to 19.98 ± 2.40 at day 90. The improvement in trial group was found to be significantly higher as compared to placebo.

iv. Changes in the Cardiac risk markers (Apolipoprotein A1 and B):

There was no significant change in the levels of cardiac risk markers from baseline to the end of the study in both the study groups. The levels remained in the normal physiological range at both the visits.

v. Serum cortisol and total testosterone levels:

The mean serum cortisol (µg/dl) and total testosterone (mg/dl) levels were found within normal range in all participants at baseline visit and at the end of the study in both the groups and did not show any significant change from baseline to the end of the study.

vi. Change in stress level and anxiety on HAMA scale:

The mean stress score assessed on VAS scale reduced significantly ($p<0.05$) from 40.58 ± 17.79 at baseline visit to 29.90 ± 15.12 at the end of 90 days in trial group while the score reduced from 42.16 ± 18.01 to 35.32 ± 17.43 in placebo group which was significant ($p<0.05$). Though the reduction in stress levels was better in trial as compared to placebo it was found to be non-significant ($p>0.05$). Similarly, HAMA score to assess anxiety showed significant reduction in both the groups after 90 days of treatment. However, there was no significant difference between the two groups.

vii. Chest circumference:

There were no significant changes on various parameters to measure chest circumference in both the groups.

viii. Change in level of energy, stamina and physical strength on a 7-point scale:

The levels of energy, stamina and physical strength showed a significant improvement ($p<0.05$) from baseline to monthly follow-ups in trial group while the change on these parameters was insignificant ($p>0.05$) in placebo group. The improvement on energy, stamina and physical strength was found to be significant in trial group as compared to placebo.

ix. Global assessment for overall change by the subject and investigator at the end of the study treatment:

Global assessment for overall change by the physician on CGI-I scale showed that a majority of Participants in trial group showed very much to minimal improvement as compared to placebo Also a higher percentage of Participants in placebo group either showed no change or worsening of their condition.

Assessment of safety parameters:

No significant ($p > 0.05$) changes were observed in laboratory parameters such as CBC, ESR, Hb%, LFTs, RFTs, lipid profile, blood sugar level and urine examination when compared between baseline visit and day 90 visit in both the study groups. All the laboratory values were within normal range at baseline visit and at the end of the study. No clinically significant change in vitals such as pulse rate, temperature, respiration rate and blood pressure (systolic and diastolic pressure) were observed from baseline visit to every follow up visit and at the end of the study in both the study groups.

Adverse events including abdominal discomfort, abdominal pain, fever, cough, backache and body ache were noted during the trial. In the trial group, 19 Participants reported 26 adverse events and in placebo group 24 Participants reported 31 adverse events. None of the adverse events were found to be related to the study product or procedure. No treatment or procedure or interruption was required in both the study groups to resolve these episodes. Almost all the Participants showed excellent to good tolerability to the investigational products.

Discussion

Smoking is considered as the strongest risk factor that plays role in the incidence of major diseases that cause death due to heart diseases, peripheral vascular diseases, hypertension, lung cancer, diabetes, cancer, etc. There are a wide range of treatment options that have proved effective, including behavioural and pharmacological therapies. These therapies vary widely in their efficacy, their acceptability and their cost-effectiveness. Smotect Tablets is an herbal formulation comprising of standardized herbal extracts like *Mucuna pruriens, Withania somnifera* etc. which can be supportive in cessation of smoking and reducing other effects related to smoking.

It was observed that ninety days treatment with Smotect tablets significantly reduced the mean number of cigarettes smoked per day as compared to placebo. While 23.08 % completely gave up smoking in trial group only 4.0 % did so in the placebo group. At the end of the study, only 1.92% of Participants in trial group showed increase in smoking frequency compared to 16.00 % Participants in placebo group. Also, treatment with Smotect tablets showed significant reduction in mean CO level (ppm) and COHb (%) levels. The findings suggest that Smotect tablets may help to reduce dependence on smoking and also reduce toxic residues in lungs and restore normal function of respiratory system.

Apart from reporting a significant reduction in craving for cigarette smoking, participants also reported to reduction in stress level (on VAS), anxiety level (as per HAMA scale) and other symptoms such as insomnia, irritability, nervousness, difficulty concentrating and restlessness and improved quality of life and energy, stamina and physical strength levels compared to placebo. These findings suggest that Smotect tablets were not only helpful to quit smoking but also helped in alleviating the withdrawal symptoms of tobacco smoking.

Smotect tablets is poly herbal combination of 11 standardized herbal extracts, which are helpful to smokers to quit or reduce smoking and also to reduce the ill effects and complications of smoking. *Mucuna pruriens* seed extract contains a high concentration of L-dopa a vital source of dopamine. Neuro-protective action of seeds of *Mucuna pruriens* have shown to help in restoration of the endogenous monoamine contents including dopamine in the substantia nigra of the brain indicating its dopaminergic action. [14] This Dopaminergic action helps to boost energy, elevate mood and reduce depression. This helps to overcome the urge of smoking over a period of time and thus helps in cessation of smoking. *Withania somnifera* (2% withanoloids) is used in patients with nervous exhaustion, insomnia, and debility due to stress.[15] Thus it helps in withdrawal effects of smoking cessation.

Other ingredients possess anti-anxiety, anti-inflammatory, analgesic, immunomodulator, anti-oxidant, rejuvenator, brain tonic and stimulant properties. Most of the ingredients are useful in various respiratory diseases due to their bronchodilator, anti-inflammatory, anti-allergic, anti-tussive and mucolytic actions. [16-25] The synergistic action of these ingredients could have helped in cessation of smoking and to overcome other effects related to smoking.

The adverse events reported in both the groups were unrelated to the study drug. The mean values of almost all lab parameters were within normal limits at the end of the study. No significant change in any of the vitals parameters was observed during and at the end of the study. Taken together these observations demonstrated that Smotect tablets are safe to use in smokers.

Conclusion

Three months of treatment with Smotect tablets helps in cessation of smoking. Smotect tablets helps to improve quality of life of smokers along with improvement in the levels of energy, stamina and physical strength and reduction in levels of stress. Smotect tablets, a nicotine free herbal composition, can be

recommended as a safe and effective remedy for de-addiction of smoking along with improving health related problems arising due to smoking. Further studies with larger sample size are warranted to establish the efficacy of Smotect tablets especially on various lung functions.

Declarations

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Conflicts of interest

There are no conflicts of interest.

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Tables

Table 1: Composition of Smotect Tablet (each film coated tablet contains)

Sr. No.	Ingredient	Scientific Name	Quantity
1	*Ashvagandha* extract	*Withania somnifera*	100 mg
2	*Amla* extract	*Emblica officinalis*	50 mg
3	*Gokshura* extract	*Tribulus terrestris*	50 mg
4	*Bramhi* extract	*Bacopa monnieri*	50 mg
5	*Yashtimadhu* extract	*Glycyrhizza glabra*	100 mg
6	*Shirisha* extract	*Albezzia lebbek*	25 mg
7	*Shunthi* extract	*Zingiber officinale*	25 mg
8	*Lavang* extract	*Syzygium aromaticum*	15 mg
9	*Kapikacchu* extract	*Mucuna pruriens*	250 mg
10	*Tulsi* extract	*Ocimum sanctum*	50 mg
11	*Haridra* extract	*Curcuma longa*	50 mg

Table 2: Assessment of Number of Cigarretes Smoked per Day (Cessation of Smoking)

Groups	Baseline	Day 30	Day 60	Day 90
TRIAL Group	9.53 ± 6.42	6.67 ± 5.54* #	5.25 ± 4.10* #	4.00 ± 3.43* #
Placebo Group	10.04 ± 6.20	8.73 ± 5.97	8.00 ± 5.55*#	7.09 ± 4.83*#

*p < 0.05, statistically significant – intra-group comparison with baseline values
#p < 0.05, statistically significant – inter-group comparison with placebo group

Table 3: Distribution of Participants for Cessation of Smoking

% Range for Smoking Cessation	TRIAL Group		Placebo Group	
	Number of Participants (Total 52)	% of Participants	Number of Participants (Total 51)	% of Participants
100%	12	23.08	02	03.92
81-100%	02	03.83	00	00.00
61-80%	18	34.61	06	11.76
41-60%	10	19.23	08	15.69
21-40%	06	11.53	06	11.76
0-20%	00	00.00	09	17.65
Remained Same	03	05.76	12	23.53
Increased	01	01.92	08	15.69

Table 4: Assessment of Changes in Spirometer Values (FVC, FEV_1, FEV_1/FVC ratio)

Group	Parameter	Baseline	30 Days	60 Days	90 Days
TRIAL Group	FVC (in L)	3.40 ± 0.97	3.09 ± 1.40	3.07 ± 1.40	3.15 ± 0.76
	FEV_1(in L)	2.43 ± 0.81	2.28 ± 1.19	2.34 ± 1.20	2.44 ± 0.90
	FEV_1/FVC (in %)	73.86 ± 17.31	74.55 ± 34.41	77.47 ± 33.92	76.13 ± 20.98
Placebo Group	FVC (in L)	3.27 ± 0.85	3.01 ± 0.86*	2.95 ± 1.01*	3.01 ± 0.87*
	FEV_1(in L)	2.40 ± 0.81	2.19 ± 0.84*	2.26 ± 0.89*	2.16 ± 0.91*
	FEV_1/FVC (in %)	74.11 ±16.77	73.75 ± 20.07	78.51 ±19.21	72.73 ± 21.94

*$p < 0.05$, statistically significant – intra-group comparison with baseline values
#$p < 0.05$, statistically significant – inter-group comparison with placebo group

Graphs

Graphs 1 and 2 are available in the Supplementary Files section

Figures

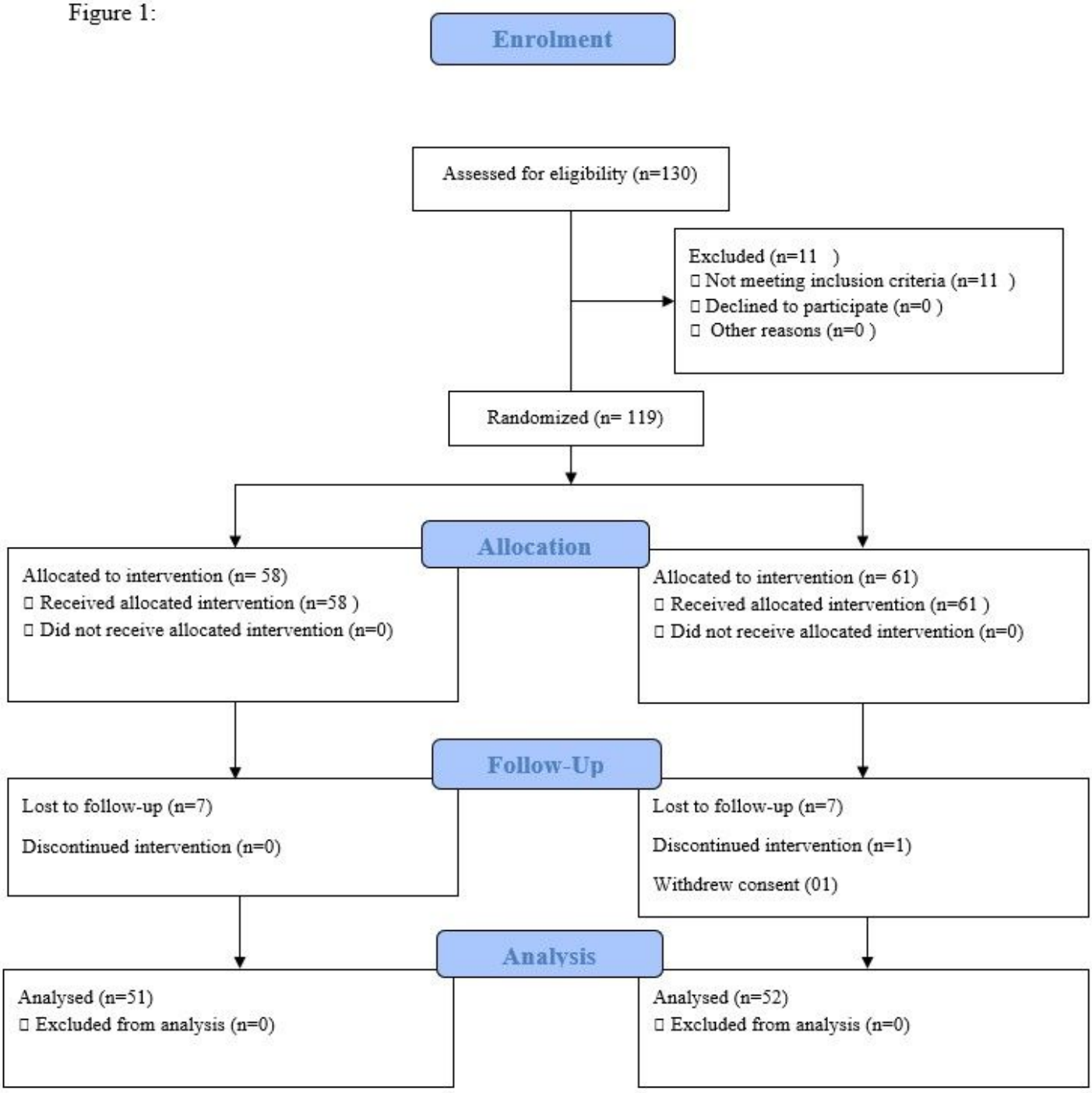

Figure 1

Legend not included with this version

Supplementary Files

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