Comparative Effectiveness of Two Behavioral Change Intervention Packages for Tobacco Cessation Initiated in the Tertiary Care Setting of North India-Protocol for a Two-Arm Randomized Controlled Trial

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Research Article

Keywords: Behavioral therapy, tobacco cessation, tertiary care setting, randomized controlled trial

Posted Date: July 23rd, 2021

DOI: https://doi.org/10.21203/rs.3.rs-511488/v1

Abstract

Background: To reduce the global burden of tobacco, clinical guidelines support behavioral and pharmacotherapy as preferred intervention for tobacco cessation. While behavioral intervention such as advice from health care provider with brief or intensive intensity has consistently shown to be impactful compared to no intervention. The current study aims to investigate efficacy of a behavioral intervention package on patients attending tertiary care setting for change in tobacco cessation behavior.

Methods/Design: A two arm randomized controlled trial shall be performed to ascertain the differential impact of various behavioral change approaches on the tobacco use status of patients in hospital settings. 574 patients fulfilling the eligibility criteria shall be included for the intervention of 3 months duration and shall be followed for a period of 12 months. To validate the self-reported tobacco abstinence urinary cotinine assessment will be performed.

Discussion: As no strong evidence exists about the effectiveness of tobacco cessation intervention in tertiary settings, thus the feasibility of its implementation by health professionals in these settings is a matter of concern. Therefore, the current study will build evidence about the feasibility of interventions in such settings.

Trial Registration: CTRI/2019/09/021406

Background:

Despite laudable actions against tobacco use for over 50 years, around 1.3 billion people still use tobacco[1], causing more than 8 million deaths each year globally.[2] In India alone, 28.6% population consumes tobacco which leads to one million deaths each year, and expected this trend is to cause 13% of all deaths by 2020.[3] Thus, to combat the problem and reduce the tobacco burden, global initiatives like WHO Tobacco Free Initiative (1990), WHO framework convention on tobacco control (2003)[4], WHO MPOWER policy (2008)[5] and United Nation's Sustainable Development Goals (SDG) (2015) established various targets.[6] Whereas the Government of India enacted Cigarettes and Other Tobacco Products Act (COTPA)[7] in 2003 to prohibit the advertisement of and regulate trade, commerce, production, supply, and distribution of cigarettes and other tobacco products. It then launched National Tobacco Control Program (NTCP) in the year 2008 to ensure effective implementation of COTPA.[8]

Besides implementing policies that transform systems of care to better address tobacco use and dependence is the promotion of evidence-based treatments for tobacco cessation. The treatments for tobacco dependence are both clinically effective and cost-effective in relation to other medical and disease prevention interventions. Evidence also suggests the supportive effectiveness of behavioral and pharmacotherapy when used alone or in combination.[9-10] Despite being a cost-effective[11] approach for reducing ill-health and preventing deaths from tobacco intake, behavioral change intervention still demands assessment in different health care settings. A review of healthcare providers' advice

demonstrated a 66% increase in quit rate than no intervention.[12] Previous studies supported motivational interviewing more effective than simply providing brief advice for tobacco cessation.[13-14]

Different behavioral change modalities like web, mobile, telephone have gained popularity for tobacco cessation since last decade. Evidence indicates a higher rate of tobacco abstinence from proactive telephone counseling than using a self-help manual.[15] While telephonic intervention, when delivered using the internet, exhibited more significant outcomes and higher tobacco abstinence.[16] Other than the use of telephone, mass media, posters, self-help material, videos, and social media applications were the other reported significant behavioral change approaches for tobacco cessation.

With the use of different modalities, an ideal time and suitable place for in-person delivery of the intervention hospitalization provides and assists patients suffering from chronic ailments to quit.[17] Being a captive audience, hospitalized patients are likely to receive consistent and regular advice from experts with minimal withdrawal symptoms. Further after discharge, these patients are likely to continue with quitting behavior because of positive reinforcement and good hospital settings experience.[17] Contrary, multiple challenges account for the treatment of tobacco dependence in hospital settings. Many clinicians do not consistently offer cessation services to patients due to lack of time, interest, low awareness about treatment, reference services[18], and lack of resources (drug, counselors, privacy, etc.).[19]

Thus, despite the evidence on success from behavioral change intervention for quitting tobacco [20-23], there is a lack of data among patients with different diagnosis in same health care setting. Furthermost most of the earlier research investigated self-reportedly change in behavior rather than biochemically verified quit rate. To our knowledge, merely two randomized controlled trials initiated in hospital settings comparing intensive with brief intervention have been documented on tobacco cessation.[24-25] While, no such study has been conducted in India. Therefore, the current study will be the first study attempting to investigate the efficacy of a behavioral change intervention package among patients attending tertiary care hospital settings.

Methods/design:

This study shall be a two-armed Randomized Controlled Trial conducted in a tertiary care setting, with the participants' randomization in an allocation ratio of 1:1 in two arms. The intervention will be implemented for three months and followed up for 12 months.

Study setting and participants

The interested participants fulfilling the eligibility criteria from four departments, i.e., (Cardiac, Pulmonary Medicine, ENT, and Neurology) of a tertiary care hospital in North India, shall be recruited simultaneously for the trial.

Inclusion criteria

Participants will be eligible provided they are

1. above 18 years of age,
2. using tobacco for the last one month and a history of using at least ten pack-year equivalent tobacco,
3. able to read and understand English, Hindi, or Punjabi,
4. have a mobile phone and active WhatsApp user for at least four days in the week,
5. willing to be part of the study and provide verbal consent for intervention and follow up of 12 months

Exclusion criteria

Participants shall not be included if they are

1. unable to understand any of the languages mentioned above,
2. severely ill or having a mental illness (major depressive or psychotic disorder),
3. already taking treatment for tobacco cessation,
4. not willing to provide consent of follow-up for 12 months.

Informed Consent

The participants complying with the eligibility criteria will be informed about the study. Consent for inclusion in the study will be taken on an informed consent form in three languages like English, Hindi, and Punjabi, according to the preference. While in case of any harm or worsening of the disease, no compensation will be provided to the participants in the study.

Randomization

Stratified block randomization for participants in four departments will randomly allocate into either of the two intervention arms. For the balanced representation in two arms, block randomization with a block size of four will be used for allocation in two arms. Participants will be blinded to the randomization sequence; however, the researcher will not be blinded to the intervention considering the study's nature. Participant's allocation will be concealed until the pre-generated random sequence for allocation is opened. The contamination bias will also be reduced as the intervention shall be provided on one to one basis.

Intervention:

Brief Intervention

Participants in the brief intervention arm shall receive a (15-20-minutes) face-to-face individualized counseling session by the researcher at baseline. Along with standard care, participants shall also receive

an information leaflet and a video for motivation. The information shall cover the harmful effects of tobacco use on health and the benefits and importance of quitting for motivation of the participants.

Intensive intervention

A brief intervention intended to enhance self-efficacy and motivation for quitting will be supported with other modalities in the intensive intervention arm. The supportive modalities include text messages and telephone counseling to increase the chances of quitting. Besides, it shall also provide information to support family and friends during quitting process; tips including coping with cravings, avoiding triggers, and distracting one's mind from tobacco use. These shall be provided through text and WhatsApp messages every week and telephone counseling for (5-10 minutes) after every 15 days for the next three months.

The researcher providing counseling shall be trained and supervised by a master-level clinical psychologist. The details of the intervention are in Figure 2.

Data collection:

The researcher will collect data from tobacco users enrolled in the study after fulfilling the inclusion criteria divided into two arms based upon the stratified block randomization technique. Baseline assessment will include tobacco use history, daily tobacco consumption, age of initiation, quit attempts, and treatment for cessation. While knowledge, attitude, and practices about tobacco use, nicotine dependence using FTND scale26 at each follow-up period, and subgroup analysis by the level of nicotine dependence shall also be collected. Further self-reporting shall be done for 7-day point prevalence and continuous tobacco abstinence at each follow-up period. While urine sample to biochemically confirm the cotinine presence shall be collected at the end of follow-up.

Measures:

Table 1: Data collection items and schedule

Measures	Baseline	1-month follow-up	3-month follow-up	6-month follow-up	12-month follow-up
Baseline measures					
Socio-demographic	×				
Tobacco: history, current use, readiness to quit, past quit attempts, use of treatment for quitting	×				
Other measures					
Nicotine dependence using FTND*	×	×	×	×	×
Knowledge, attitude and practice	×				×
Self-reported continuous abstinence		×	×	×	×
Self-reported 7DPPA** abstinence		×	×	×	×
Stage of behavior change	×	×	×	×	×
7-DPPA biochemical validated					×

**FTND: Fagerstrom Tobacco Nicotine Dependence*

***7DPPA: 7 day Point Prevalence Abstinence*

Outcome measures:

Primary outcome

• Validated 7-day point prevalence tobacco abstinence at 12 months

Secondary outcomes

Measures at follow-up period 1, 3, 6 & 12 months:

- Self-reported continuous tobacco abstinence (between quit date and at each follow-up period at 1, 3, 6 & 12 months)
- Self-reported 7-day point prevalence tobacco abstinence (abstinence for continuous seven days just before at each follow-up period)
- Self-reported tobacco use reduction at each follow-up period
- Progression in the stage of behavior change
- Scores level of Nicotine dependence by FTND instrument
- Number of quit attempts and relapses within 12 months
- Change in knowledge, attitude, and practices score after intervention

Sample Size:

Based on existing literature where tobacco abstinence rate of 14.7% and 26.7% has been reported in control and intervention arm respectively, alpha level 0.05, 20% dropout rate, and power 0.90 (90%), the total sample size 574 will be enrolled. Participants shall be assigned into two arms at a ratio of 1:1 with 287 in each arm. The trial with this sample size will have sufficient power to detect a clinically significant difference between the two arms. The planned sample size shall be recruited in approximately 6 months and followed up for 12 months.

Statistical analysis:

The data obtained shall be entered and analyzed using Statistical Package for Social Science 22.0 software (IBM, SPSS, Inc). The difference in primary and secondary outcomes between two arms, using multiple logistic regression will determine the intervention's effect. The adjusted and unadjusted p values & odds ratio will be reported along with the confidence interval. All analysis will be conducted using intention to treat principles by controlling for potential confounders and using a conventional significance level of 0.05 to reject the null hypothesis.

Dissemination Of Results:

The evidence generated on the effectiveness and feasibility of tobacco cessation intervention in India's tertiary care setting will be published in good impact journal for wider readability. This well help policymakers, implementers, and educators to use the current tobacco cessation intervention package for designing a plan, assist tobacco users in quitting tobacco use.

Discussion

To explain behavior change, the vast number of behavioral change theories, like Health belief model[27], Socio-cognitive theory[28], and Trans-theoretical framework[29], focus on different factors. The current study shall consider the Trans-theoretical framework to address the change in behavior towards tobacco cessation. This framework shall also emphasize the importance of tobacco users' motivation and self-efficacy while considering the barriers to change and cues to action. Studies worldwide using TTM to track tobacco use behavior have established its validity and reliability across various settings.[30-34] Further, this framework shall help in guiding clinicians in tracking tobacco users' movement from one stage to the next stage.[35]

The tobacco cessation intervention (TCI), brief and intensive being cost-effective, has variably shown the effectiveness and efficacy of reducing ill health and increasing QALY. A systematic review[36] concluded the cost-effectiveness of intensive over brief tobacco cessation intervention with 960 & 280 discounted cumulative number of QALYs per year gained in the two interventions. Further studies documented intensive tobacco cessation intervention in reducing ill-health, morbidity, and mortality compared to brief

intervention.[36] As no evidence could be reported on the comparative effectiveness of intensive over the brief intervention for tobacco cessation in the Indian hospital setting. The current study results will provide quality evidence to replicate in similar settings across the globe.

As strong evidence exists about the effectiveness of tobacco cessation intervention in tertiary settings, the feasibility of its implementation by health professionals in these settings is a matter of concern. Thus, the study will build evidence about the feasibility of interventions in such settings and advocate for a tailored intervention.

Besides this, the planned study has several strengths and endeavors to strengthen the theoretical framework for tobacco cessation interventions. Firstly, this will be the first comprehensive study from India conducted in tertiary care setting comparing intensive with brief intervention for tobacco cessation. Secondly, the tobacco cessation intervention will be holistically designed after obtaining all stakeholders' views, including tobacco users. Thirdly, it shall examine the effect of tobacco cessation intervention at 1, 3, 6, and 12 months follow-up, which provides an opportunity to evaluate long-term treatment effects on tobacco abstinence. At last, cotinine testing to assess tobacco use status will be done for validating self-reporting tobacco abstinence. The few limitations include the possibility of missing data throughout the follow-up period. This will thus affect the validity and internal reliability of result. However, this is a frequent phenomenon of any long-term trial involving tobacco cessation.[37]Also the results may not be generalized for the general population as the participants will be from the hospital settings in the study.

Declarations

Trial Status:

Recruitment of participants was started in December 2020 and will be completed by the end of May 2021.

Ethical Consideration and consent to participate

Permission was obtained from the Institute Ethical Committee for enrolment of participants in the study. Any modification in the protocol shall be agreed upon and ratified by the Institutional Ethics Committee and Clinical Trial Registry of India before implementation. The research purpose, procedure, and rights to the trial will be provided by researcher to all the participants before enrolment. In addition, informed consent in preference language will be signed by all the participants for voluntary participation. While to maintain confidentiality, information including reports, laboratory results, and other details of the participants shall be stored securely at the study site. At the same time, records shall be kept separately and identified by code number for identification.

Data monitoring committee

A team of experts (Doctoral committee) appointed by the Dean of Institute shall supervise the trial's progress. The designated committee members shall monitor the safety aspect and make recommendations for trial modifications if required.

Availability of data and material

The datatset analysed after the completion of study will be available from corresponding author on reasonable request

Consent for publication

All the eligible participants will be informed about the study by researcher and enrolled after taking consent.

Competing interests

The author(s) for the review declares to have no competing interests.

Funding

The study does not have any kind of funding support.

Contribution Information

The study protocol was planned and designed by PD, SG, AA, AG, DK, RV, RV & BM. All authors contributed substantially to the draft and approved it for submission.

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Figures

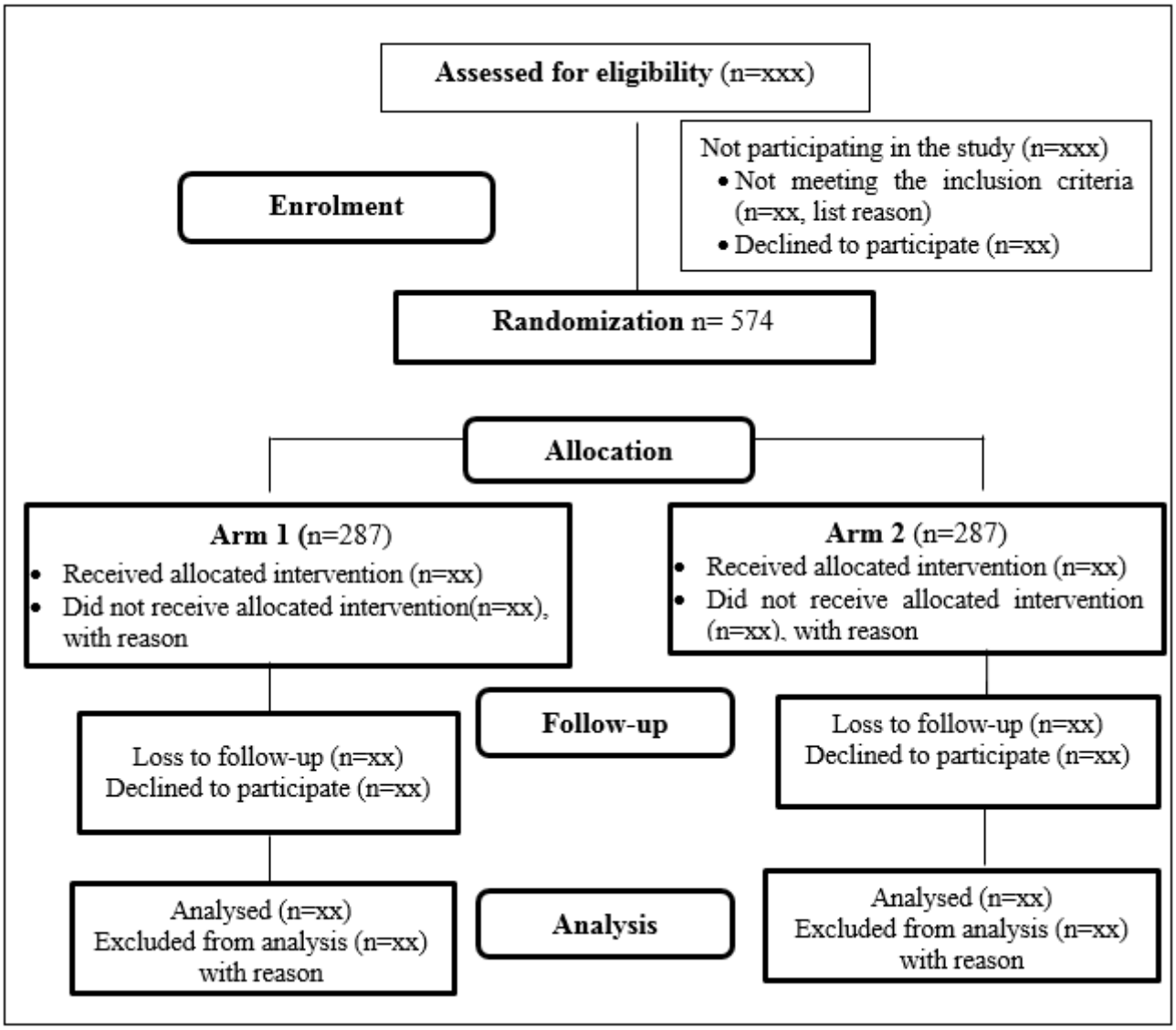

Figure 1

Consort flow chart for enrolment and follow-up plan for Randomized Controlled Trial

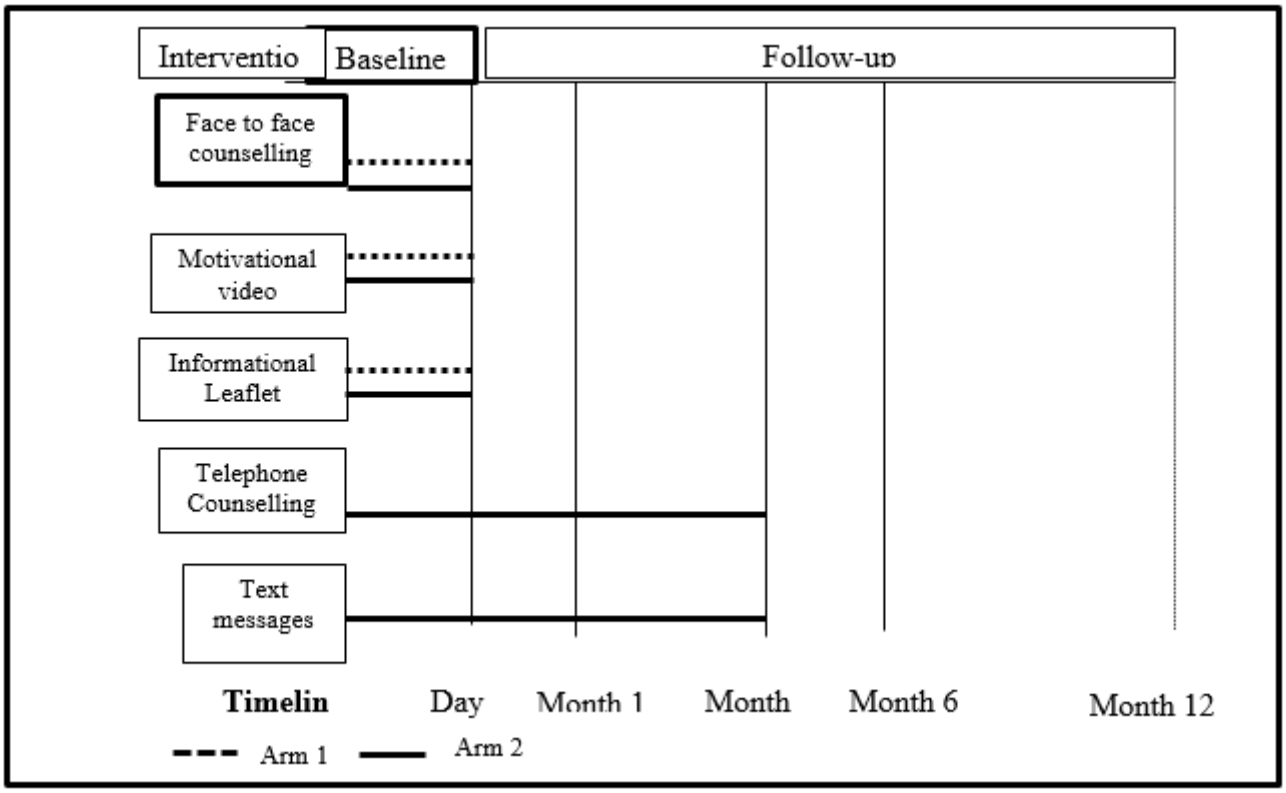

Figure 2

Trial schedule showing intervention and timeline

Supplementary Files

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