ISRCTN11353250 https://doi.org/10.1186/ISRCTN11353250

Efficacy of Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness

Submission date
06/02/2015

Recruitment status
No longer recruiting

Registration date
04/03/2015

Overall study status
Completed

Last Edited
05/03/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Overall smoking prevalence has decreased substantially in Canada over the past several decades, however, individuals with severe mental illness continue to smoke at alarming rates. Given that individuals with severe mental illness die an estimated 25 years earlier than the general population, and that tobacco accounts for 50% of all deaths for individuals with schizophrenia and mood disorders, it is imperative that effective treatments are developed to address this urgent issue. The objective of this study was to evaluate if individuals with severe mental illness who have a tobacco dependency are able to reduce or eliminate tobacco use following the administration of two specific and different smoking cessation interventions.

Who can participate?
Adults with severe mental and smoking more than 5 cigarettes a day, recruited from a community mental health agency

What does the study involve?
Participants were randomly allocated to one of two groups: smoking cessation plus (SC+) group or smoking cessation routine (SC-R) group. Both groups were offered combination Nicotine Replacement Therapy (NRT) during weekly individual meetings with a registered nurse. In addition, participants in the SC+ group were offered a weekly psychosocial support group and two individuals sessions of motivational interviewing (MI) therapy.

What are the possible benefits and risks of participating?
Benefits: Participants who are able to reduce or quit smoking experience tremendous health benefits. Additionally, given that virtually all potential clients in this study subsist on social assistance, significant financial benefits could be realized with the elimination of purchasing tobacco. Even clients who relapse and re-initiate tobacco use will have had the education and experience of the treatment that may help to improve their chances if they have an opportunity to quit at a later date. The information collected during the study could also lead to improvements in health care provisions which could eventually be of benefit to the participants as well as others entering the program. Individuals with severe mental illness experience

significant inequitable health outcomes related to their use of tobacco. It is essential that the community mental health services that support this clientele take a leadership role in addressing these inequities, including the development of interventions for smoking cessation. The research tested the effectiveness of smoking cessation interventions for individuals with severe mental illness who are homeless or vulnerably housed. Learning more about how to reduce tobacco use and ultimately the burden of disease caused by tobacco use is very beneficial to the health care system.
Risks: Clients were asked to provide a breath sample to measure the amount of carbon monoxide levels in their lungs. This procedure consists of the individual blowing into a mouthpiece that is connected to a Smokerlyzer for 10 seconds. There are no risks involved with this procedure.
Other risks involved:
1. Use of Nicotine Replacement Therapy (NRT) has been identified with physical side effects including nausea.
2. It is possible that some participants may have experienced mild discomfort associated with self-disclosure of information on their health status and experienced stressors. However, we expected this discomfort to be low level and transient in nature.
3. The amount of cigarettes smoked can alter the metabolism of psychiatric medications and reduce the blood levels of neuroleptics, some antidepressants and benzodiazepines. Smoking cessation may then increase or decrease the dosage of medication required.
Measures taken included:
1. Participants were assessed for side effects of the NRT weekly by the CMHA Nurse Practitioner. Participants only received their NRT allocation for the next week once they had been assessed by nursing staff. All treating physicians of participants were informed of the study and the NP consulted with them as necessary. Additionally, the NP consulted with CMHA's consulting psychiatrists as necessary.
2. Participant were able to refuse to answer any question. Participants could withdraw from the study at any time without any negative consequences. Confidentiality of personal information provided is guaranteed as part of the informed consent process. Interviews were conducted during business hours so that a CMHA worker was always available to talk with the participant if required.
3. Clients and their physician(s) received information regarding the impact of smoking cessation on psychiatric medications.

Where is the study run from?
University of Ottawa

When is the study starting and how long is it expected to run for?
From April 2011 to January 2015

Who is funding the study?
University of Ottawa and the Canadian Mental Health Association Ottawa Branch.

Who is the main contact?
Ms Donna Pettey
dlpettey@cmhaottawa.ca

Contact information

Type(s)
Public

Contact name
Ms Donna Pettey

Contact details
Director of Operations
1355 Bank Street
Ottawa
Canada
K1H 8K7
+1 (0)613 737 7791 ext. 121
dlpettey@cmhaottawa.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of Smoking Cessation Treatment Interventions for Individuals with Severe Mental Illness: A Pilot Randomized Controlled Clinical Trial

Study objectives
The objective of the study was to evaluate if individuals with severe mental illness who have a tobacco dependency are able to reduce or eliminate tobacco use following the administration of two specific and different smoking cessation interventions. The study was intended to answer the following research questions:
1. Do participants who receive the SC+ treatment have better smoking outcomes than participants who receive the SC-R treatment?
2. Are there differences between the two groups in other monitored and reported participant outcomes such as quality of life, use of psychiatric medication, weight and patterns of other substance use?
3. Do participants who receive the SC+ treatment and participants who receive the SC-R treatment have better smoking outcomes than individuals receiving standard care (i.e. no specific smoking cessation intervention)?
4. Is there a relationship between the amount of the nursing contact and NRT intervention received among participants in the two groups and client outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)

University of Ottawa's Office of Research Ethics and Integrity Health Sciences and Science Research Ethics Board, 01/24/2012, File number: H10-11-12

Study design
Non-blind parallel group randomised trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Tobacco addiction in individuals with severe mental illness

Interventions
Clients randomly assigned to the SC-R group were offered twenty-four weeks of no cost NRT and clients assigned to the SC+ group were offered twenty-four weeks of no cost NRT plus two initial individual counselling sessions of motivational interviewing and weekly psychosocial group support interventions for twenty-four weeks.
Types of Interventions:
Combination NRT. Clients assigned to both the SC-R and the SC+ groups were offered 24 weeks of cost-free combination NRT at upward titration doses as described in the medical directives of the “University of Ottawa Heart Institute Primary Care Smoking Cessation Program Nicotine Replacement Therapy (NRT) Protocol”. Combination NRT included 7mg, 14 mg or 21 mg patches, the inhaler, lozenges and chewing pieces. All clients were expected to meet weekly with either a registered nurse or nurse practitioner for assessment of their mental and physical health status, CO monitoring, the ongoing provision of education regarding NRT, and to receive their NRT doses for the following week.
Individual MI sessions. Clients assigned to the SC+ group were additionally offered two individual counselling sessions of MI and 24 weeks of weekly group support sessions. Each MI practitioner was assigned 16 clients from the SC+ group and offered up to 2 individual MI sessions to each client.
Weekly psychosocial support group sessions. Each of the participants in SC+ were assigned to one of three weekly 90-minute support groups. Each group was facilitated by trained mental health and addiction workers who have received additional advanced training in MI and training in addressing tobacco dependency and who have extensive experience in the facilitation of concurrent disorder treatment groups for this population. A paid peer worker who is an ex-smoker co-facilitated all of the groups.
Treatment as usual group. A previous survey, conducted at the agency in November 2010,

collected data to determine the overall smoking prevalence and level of nicotine dependency in the agency's client population. Clients in this group were eligible to receive ‘standard care’ defined as the range of integrated treatment services provided by the agency that includes intensive case management, treatment for substance use disorders, access to housing, and access to primary health care and psychiatric consultation services. A matched sample 'treatment as usual' group was randomly selected from the client data base created from the initial larger survey dataset, using sex and level of nicotine dependency as the matching variables.

Intervention Type

Primary outcome measure
Types of comparisons. Client outcomes in the SC-R treatment group were compared with the client outcomes in the SC+ treatment group. The smoking status outcome and levels of nicotine dependency of both groups were compared to the standard care group in order to provide a comparison group of individuals who did not receive the smoking cessation treatment in this program.
Types of outcomes. Treatment outcomes were monitored at three months and at six months during interviews with the research staff and during weekly monitoring contacts with the nursing staff. Baseline interviews (n=62) were conducted in February, March, and April, 2012. The primary treatment outcomes related to tobacco use were continuous abstinence of tobacco from quit day and the overall reduction of tobacco use at three months and six months (or end of the study period). These outcomes were evaluated on an intent-to-treat (ITT) basis, in that any client whose smoking status could not be verified was considered to be smoking. Client tobacco use was monitored through self-report and through regular monitoring of expired breath carbon monoxide (CO) levels taken during their weekly meetings with the nursing staff. Clients were considered non smoking through self-report of their non smoking status to the nurse and with a verified expired breath carbon monoxide level of 5 ppm or less.

Secondary outcome measures
The secondary outcomes monitored included drug and alcohol use, quality of life, hospitalization, physical health functioning, mental health functioning, and housing status. A variety of data sources and methods of data collection were utilized. Baseline interviews were conducted in February, March, and April, 2012. The interim 3 month follow-up interviews were conducted in July and August, 2012 and the final 6 month follow-up interviews were conducted between September and November, 2012. Quantitative data was collected utilizing a combination of clinician rating and self-report measures that have been commonly used in community mental health research and that have good psychometric properties: Fagerström Test for Nicotine Dependence, Multnomah Community Ability Scale. Global Assessment of Individuals Needs Substance Use Problem Scale, The Short Form-36 Health Survey (SF-36), The Colorado Symptom Index (CSI), Quality of Life Inventory-20 Item (QoLI-20)

Overall study start date
01/05/2011

Completion date
28/01/2015

Eligibility

Key inclusion criteria
Participants in the study were recruited from the client pool of a community mental health agency with an annual client census of over 1,200 individuals located in a large urban setting. Clients of the agency are adult men and women over sixteen years of age with a severe mental illness who, upon referral to the agency, are homeless or vulnerably housed. Eligibility for the study:
1. Adult men or women with severe mental illness
2. Over the age of 16
3. Smoke 5 or more cigarettes a day
4. Have identified an interest to reduce or eliminate tobacco use

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The study was designed to enrol 30 participants into each of the two treatment interventions.

Key exclusion criteria
As there is no adequate clinical research in pregnant women and smoking cessation treatments, women of childbearing age had a pregnancy test done to ensure that they were not pregnant before the study began. For women using medications to quit smoking, if they were pregnant or became pregnant during the study, these risks could affect their health or the unborn child. Therefore, women who were pregnant, breast-feeding or were planning a pregnancy within the next year would have been excluded from the study. In discussions with the study Nurse Practitioner, additional pregnancy tests were done during the study as needed.

Date of first enrolment
25/01/2012

Date of final enrolment
25/04/2012

Locations

Countries of recruitment
Canada

Study participating centre
Canadian Mental Health Association Ottawa Branch
1355 Bank Street Suite 300
Ottawa
Canada

Sponsor information

Organisation
University of Ottawa

Sponsor details
Université d'Ottawa / University of Ottawa
Vanier Hall, 5002J
Ottawa, ON
Ottawa
Canada
K1N 6N5
+1 (0)613 562 5800 x 4815
taubry@uottawa.ca

Sponsor type
University/education

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
University/education

Funder Name
University of Ottawa. This research was undertaken as partial fulfillment of the requirements for a PhD in Population Health at the University of Ottawa, and as such, was investigator initiated and funded. The site where the research occurred was the Canadian Mental Health Association, Ottawa Branch. All staff who provided clinical interventions for the the study were employees of the Branch. The Nicotine Replacement Therapy utilized in the study was supplied by the Canadian Mental Health Association and by the University of Ottawa Heart Institute.

Results and Publications

Publication and dissemination plan
Following thesis (Spring 2015), development of a publication plan with thesis supervisor (Summer 2015 and beyond).

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request