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Smoking cessation support for people with severe mental illness in South Asia

Submission date
11/12/2019

Recruitment status
No longer recruiting

Registration date
09/01/2020

Overall study status
Completed

Last Edited
15/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People living with severe mental illness (SMI), i.e. schizophrenia, schizoaffective disorder, psychosis, bipolar disorder, depression with psychotic symptoms, are twice more likely to die prematurely than the general population. On average, from birth, the number of years people living with SMI are expected to live is 10-25 years less than that of the general population. This is principally because they tend to have coexisting physical disorders, due to lifestyle choices that affect their health negatively, such as smoking, alcohol use, diet, illicit drug use, poor diet and physical inactivity. For example, people with SMI are more likely to smoke, smoke more heavily, have more severe nicotine dependence, and face worse health outcomes as a result of tobacco than the general population. Unfortunately, counselling interventions that help general population smokers to stop smoking do not seem to help people with SMI who smoke to quit. However, smoking cessation medicines alone (bupropion and varenicline), or in combination with counselling or talking therapies are safe, effective and acceptable for smoking cessation in adults with SMI. Tailored smoking-cessation interventions for people with SMI have been developed for and evaluated in high income countries, but not for low- and middle- income countries (LMICs). In this study, we aim to adapt an evidence based, combined behavioural and pharmacological support intervention (the IMPACT 4S intervention) for smoking cessation among adults with SMI attending mental health facilities in India and Pakistan, and test the feasibility and acceptability of delivering and evaluating it.

Who can participate?
Adults (≥ 18 years old) with SMI, considered to be stable by the local mental health clinical team, are smokers and are willing to cut down or quit. Living in urban or rural areas of Bangalore or Rawalpindi, are willing to attend up to 10 face-to-face counselling sessions and are not already in a treatment to quit smoking. We will enrol 172 participants in total, 86 will be from India and 86 from Pakistan.

What does the study involve?
Participants will be allocated by chance (like flipping a coin) to either receive brief advice for smoking cessation which will involve a one-off, face-to-face, one-to-one, counselling session of 5 minutes; or the IMPACT 4S intervention which involves up to 15 face-to-face/remotely delivered, one-to-one, counselling sessions which are about 15-40 minutes long, taking the prescribed

smoking cessation medicines, and having their breath carbon monoxide (CO) levels monitored at each counselling session and receiving feedback on the results.

Participants will have a face-to-face interview where they will be asked a series of questions that cover different topics such as their smoking behaviour, as well as other information related to their physical and mental health, quality of life and use of healthcare facilities. They will also have their height and weight measured. We expect completing this questionnaire to take about 30 minutes. Participants will have to come back to the health facility at one, three and six months after the first interview to have the same interview and measurements. The measurements at six months will also include breath CO levels.

We will also conduct in-depth interviews with some of the study participants at three months. However, those who will be approached to participate will receive separate information about this, and do not have to take part in the in-depth interview if they do not want to.

What are the possible benefits of participating?
We cannot guarantee any direct benefits to participants from participating in this study. However, they might find the smoking cessation counselling helpful. If they receive the smoking cessation medication they might also find it helpful as these medicines have been found to help people to stop smoking. These medicines will be provided for them in this study for free. There are potential long-term benefits for people with SMI who smoke in India, Pakistan and other countries. The findings of the research will guide the further refinement and evaluation of a smoking cessation intervention with a potential to improve the health and wellbeing of people with SMI. If the intervention developed and tested here shows promise, it will be further evaluated in a definitive study; and if effective and cost-effective it would be given to the wider population of people with SMI who smoke.

What are the potential risks of participating?
Our procedures for questionnaire completion involve interviewer-administration where participants will be asked questions that they might find uncomfortable to answer.
Bupropion is generally a safe medicine, and has very few side effects. These include nausea, stomach ache, dryness of mouth, sleeplessness, mood changes, appetite changes and headache. We will seek advice from the participant's mental health care team on whether they can take bupropion before we prescribe this for them. Nicotine gum gives participants a small amounts of nicotine through a gum. While participants will continue to get some nicotine in their system, they won't be exposed to any of the other harmful chemicals that are found in tobacco. Some of the side effects are mouth or throat, bad aftertaste, problems with existing dental work, nausea, jaw pain, racing heartbeat. Nicotine patches have the same objective as the nicotine gum. Some of the side effects of the patches are skin irritation, itching, dizziness, headache, racing heartbeat and nausea.

Where is the study run from?
1. University of York, UK (study sponsor)
2. National Institute of Mental Health and Neurosciences (NIMHANS), India
3. Institute of Psychiatry, Pakistan

When is the study starting and how long is it expected to run for?
March 2020 to March 2022

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 1.0

Study information

Scientific Title
IMPACT Smoking cessation Support for people with Severe mental illness in South Asia (IMPACT 4S): a randomised controlled pilot and feasibility trial for a combined behavioural and pharmacological support intervention

Acronym
IMPACT 4S

Study objectives
An adapted, evidence-based, combined behavioural and pharmacological support smoking cessation intervention for adults with severe mental (SMI) illness will be feasible and acceptable to deliver and evaluate among adults with SMI attending mental health facilities in India and Pakistan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/07/2019, University of York Health Sciences Research Governance Committee (University of York, Heslington, York, YO10 5GE, UK; +44 (0)1904323253; stephen.holland@york.ac.uk), ref: HSRGC/2019/346/D
2. Approved 10/12/2019, National Bioethics Committee Pakistan (Pakistan Health Research Council, Shahrah-a-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad; +92 51 9224325; nbcpakistan.org@gmail.com), ref: 4-87/NBC-434/19/1391

Study design
Open label parallel randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation in persons with severe mental illness

Interventions
Current interventions as of 15/04/2021:
Those eligible participants who consent will be randomly assigned to one of the trial arms using a computer-generated blocked stratified (by country) allocation sequence created using Stata version 15 (or later) with an allocation ratio of 1:1. A statistician not involved in the recruitment of trial participants will generate the randomisation sequence remotely at the University of York. Trial arm allocation will be using opaque sealed envelopes.

Arm 1: IMPACT 4S intervention
Combined behavioural and pharmacological support intervention (IMPACT 4S intervention): The intervention comprises of up to 15 one-to-one and/or remotely delivered smoking cessation counselling sessions, each lasting between 15-40 minutes and spread over three/four months, breath carbon monoxide monitoring and feedback, pharmacotherapy (bupropion and/or nicotine replacement therapy), and an information leaflet. Remote sessions can be delivered using a number of different options such as telephone or video platforms (e.g. What's App, messenger, Zoom etc).

The behavioural support will include the following behaviour change techniques (BCTs): goal setting, problem-solving, social support, information about health consequences and adding objects to the environment. Participants will be encouraged to: (1) reduce smoking to quit, (2) set their own quit dates and (3) make several attempts to quit if their initial attempt fails. The intervention will comprise up to 15 structured face-to-face/ remotely delivered counselling sessions delivered by trained psychology graduates in Pakistan and psychology graduates and social workers in India. Each session will be up to 15- 40 minutes in length.

Pharmacotherapies will be provided for a minimum period of three months. Participants who opt to take bupropion will be referred to their medical doctor for assessing the suitability of prescribing bupropion. Participants will be offered sustained-release bupropion, 150 mg/d for the first week and 300 mg/d thereafter.

Arm 2: Brief advice (BA)
Participants randomised this trial arm will receive verbal information on the harmful effects of tobacco and will be advised to stop smoking. BA will be delivered by trained psychology graduates in Pakistan and psychology graduates and social workers in India on the same day as enrolment and will last up to five minutes. This will be a one-time interaction: participants in this trial arm will not have any further BA sessions with the psychology graduates and social workers. Participants will be provided with an information leaflet containing the same advice in a written format to take home.

Previous interventions:
Those eligible participants who consent will be randomly assigned to one of the trial arms using a computer-generated blocked stratified (by country) allocation sequence created using Stata version 15 (or later) with an allocation ratio of 1:1. A statistician not involved in the recruitment of trial participants will generate the randomisation sequence remotely at the University of York. Trial arm allocation will be using opaque sealed envelopes.

Arm 1: IMPACT 4S intervention
Participants randomised to this trial arm will receive a behavioural support intervention, breath CO monitoring and feedback on breath CO levels at every counselling session, pharmacotherapy (bupropion and/or nicotine replacement therapy), and the same information leaflet as for the BA arm below to take home.

The behavioural support will include the following behaviour change techniques (BCTs): goal setting, problem-solving, social support, information about health consequences and adding objects to the environment. Participants will be encouraged to: (1) reduce smoking to quit, (2) set their own quit dates and (3) make several attempts to quit if their initial attempt fails. The intervention will comprise up to 10 structured face-to-face counselling sessions delivered by trained psychology graduates in Pakistan and psychology graduates and social workers in India. Each session will be up to 45 minutes in length.

Pharmacotherapies will be provided for a minimum period of three months. Participants who opt to take bupropion will be referred to their medical doctor for assessing the suitability of prescribing bupropion. Participants will be offered sustained-release bupropion, 75 mg/d for the first week and 150 mg/d thereafter.

Arm 2: Brief advice (BA)
Participants randomised this trial arm will receive verbal information on the harmful effects of tobacco and will be advised to stop smoking. BA will be delivered by trained psychology graduates in Pakistan and psychology graduates and social workers in India on the same day as enrolment and will last up to five minutes. This will be a one-time interaction: participants in this trial arm will not have any further BA sessions with the psychology graduates and social workers. Participants will be provided with an information leaflet containing the same advice in a written format to take home.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 15/04/2021:
1. Recruitment rates: Quantitative assessment of the acceptability of the research will be assessed by numbers screened, number eligible and those agreeing to participate.
2. Reasons for ineligibility/non-participation/non-consent of participants.
3. Length of time required to achieve the required sample size.
4. Retention in study: Assessed as a proportion of those enrolled in the study who are successfully followed-up at six months.
5. Retention in treatment: Evaluated by number of study intervention sessions attended as one measure of the feasibility and acceptability of the trial interventions to participants.
6. Intervention fidelity during the delivery of the behavioural support within the IMPACT 4S intervention, as well as for brief advice (BA), assessed as one measure of feasibility of intervention delivery.
7. Smoking cessation pharmacotherapy adherence: For those in the IMPACT 4S arm, adherence to smoking cessation pharmacotherapy will be assessed as one measure of the feasibility and acceptability of the smoking cessation pharmacotherapies to participants.
8. Data completeness: Data will be checked for completeness as another measure of acceptability and feasibility of data collection methods, and to identify problem areas and solutions.

Previous primary outcome measures:
Feasibility outcomes:
1. Recruitment rates: Quantitative assessment of the acceptability of the research will be assessed by numbers screened, number eligible and those agreeing to participate
2. Reasons for ineligibility/non-participation/non-consent of participants measured using patient records
3. Length of time required to achieve the required sample size
4. Retention in study: assessed as a proportion of those enrolled in the study who are successfully followed-up at six months
5. Retention in treatment: Retention in treatment will be evaluated by number of study intervention sessions attended as one measure of the feasibility and acceptability of the trial interventions to participants
6. Intervention fidelity during the delivery of the behavioural support within the IMPACT 4S intervention, as well as for BA will be assessed as one measure of feasibility of intervention delivery
7. Smoking cessation pharmacotherapy adherence: For those in the IMPACT 4S arm, adherence to smoking cessation pharmacotherapy will be assessed as one measure of the feasibility and acceptability of the smoking cessation pharmacotherapies to participants
8. Data completeness: Data will be checked for completeness as another measure of acceptability and feasibility of data collection methods, and to identify problem areas and solutions

Key secondary outcome(s))
Current secondary outcome measures as of 15/04/2021:
1. Self-reported or family/carer reported continuous smoking abstinence for at least 6 months (only five instances of smoking allowed during the total 6 months) which is biochemically verified by CO concentration (CO concentration <7 ppm) at 6 months follow-up. This will be assessed at the longest possible follow-up point for those participants where it might not be possible to have a 6 months follow-up.
2. Point abstinence, defined as a self-report or family/carer report of not smoking in the previous 7 days, assessed at 1, 3 and 6 months follow-up. This will be assessed at the longest possible follow-up point for those participants where it might not be possible to have a 6 months follow-up.
3. Cost of delivering the IMPACT 4S and the BA interventions.

Previous secondary outcome measures:
1. Self-reported or family/carer reported continuous smoking abstinence for at least 6 months (only five instances of smoking allowed during the total 6 months) which is biochemically verified by CO concentration (CO concentration <7 ppm) at 6 months follow-up.
2. Point abstinence, defined as a self-report or family/carer report of not smoking in the previous 7 days, assessed at 1, 3 and 6 months follow-up.
3. Cost of delivering the IMPACT 4S and the BA interventions.

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/04/2021:
1. Adults (≥18 years old) with SMI (i.e. schizophrenia, schizoaffective disorder, bipolar affective

disorder, psychosis, severe depression with psychosis)
2. Considered to be stable by the mental health clinical team
3. Self-reported current smoker of any form of smoked tobacco product (including cigarettes, bidis, waterpipe etc) for at least 6 months
4. Smoking on >25 days in the past month
5. Able to provide informed consent
6. Attending/remotely accessing services from included institutions during the study period
7. Willing to cut down or quit smoking
8. Willing and able to attend up to 15 face-to-face and/or remotely delivered counselling sessions
9. Living in the Rawalpindi district in Pakistan, and in Bangalore urban and rural, nearby /neighbouring districts in India.

Previous inclusion criteria:
1. Adults (≥18 years old) with SMI (i.e. schizophrenia, schizoaffective disorder, bipolar affective disorder, psychosis, severe depression with psychosis)
2. Considered to be stable by the mental health clinical team
3. Self-reported current smoker of any form of smoked tobacco product (including cigarettes, bidis, waterpipe etc) for at least 6 months
4. Smoking on > 25 days in the past month
5. Able to provide informed consent
6. Attending included institutions during the study period
7. Willing to cut down or quit smoking
8. Willing and able to attend up to 10 face-to-face counselling sessions
9. Living in the Rawalpindi district in Pakistan, and in Bangalore urban and rural districts in India

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
169

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Comorbid drug and/or alcohol problems

Date of first enrolment
15/04/2021

Date of final enrolment

07/09/2021

Locations

Countries of recruitment
United Kingdom

England

India

Pakistan

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University of York
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Study participating centre
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Study participating centre
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0000

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research [Grant reference number 17/63/130]

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/06/2023	15/06/2023	Yes	No
Protocol file	version V1.3	09/04/2021	15/04/2021	No	No