Let's talk e-cigarettes. Podcast 23, June 2023

NL - Nicola Lindson JHB - Jamie Hartmann-Boyce SP - Sarah Pratt

Transcript

Musical intro

If asking your mate down the pub about vaping is what they probably say, no one agrees if it's safer or not, so you might as well smoke anyway. Now what your mate needs is a Cochrane review. All the facts have been checked at least twice. They find there's a lot that the experts agree on and might give you different advice.

NL Hi, I'm Nicola Lindson.

JHB And I'm Jamie Hartman Boyce.

NL

We're both researchers based at the University of Oxford, where we work with the Cochrane Tobacco Addiction Group. Welcome to this edition of let's talk E cigarettes. This podcast is a companion to a research project being carried out at the University of Oxford, where every month we search the e-cigarette research literature to find new studies. We then use these studies to update our Cochrane Systematic review of E cigarettes for smoking cessation. This is called a living systematic review in each episode we start by going through the studies. We have found that month and then go into more detail about a particular study or topic related to e-cigarettes.

JHB

So this month we carried out searches on the 1st of June 2023 and we found two new ongoing studies which Dr Lindson will tell you about in a nutshell.

NL

So the first study is sponsored by the Foundation for a Smoke Free World, which has been linked to the tobacco industry. This is a 2 arm randomised controlled trial carried out in Pakistan which is planning to enroll 258 adult smokers and randomise them to either e-cigarettes or nicotine patches. The intended follow up for the study is stated to be 12 months. With a projected study start date of March 2025.

The second new ongoing study, is a kind of similar type of design. It's been carried out by New York University and is a randomised controlled trial. Also randomising people to either e-cigarettes or nicotine replacement therapy, but in this case the participants will be 60 people with serious mental illness who smoke. It's only a 12 week study. So we won't be looking at how many people quit smoking from this study in our review, but we will use it to look at health outcomes. It's currently due to complete in March 2024. And the funding source for this study is unclear.

JHB

Great. Thanks, Nichola. So this month, we also found 13 eligible abstracts from screening the abstract book for the Society for Nicotine and Tobacco Research 2023 annual meeting. All of those abstracts were linked to studies we've previously identified via other searches, and we're going to learn more about one of them. In this month's deep dive.

So this month I had the pleasure of interviewing associate Professor Sarah Pratt from Dartmouth University in the States about her study, published in Nicotine and Tobacco Research last year, and presented at the Society for Nicotine and Tobacco researchers meeting this spring. The study evaluates e-cigarette. Provision in people with serious mental illness to support them transitioning off combustible tobacco and was funded by the US National Institute on Drug Abuse. We were interested to hear more about the study itself, but also about any special considerations around vaping and people with serious mental illness as we know, smoking rates are traditionally high in this population, and we're seeing just as Nicola mentioned, in terms of the new ongoing study more ecigarette studies being conducted in people living with serious mental illness. So if you could start by just telling us a little bit about yourself and what brought you to studying e-cigarettes.

SP

So, my name is Sarah Pratt and I am an associate professor in the Department of Psychiatry at Dartmouth. I have been doing research full time, I'm a clinical psychologist by training, but I've been doing research full time for over 20 years and my story with how I got involved in e-cigarette research starts when I was a starving Graduate School student working three jobs, including one job as a counselor at a residence for people with schizophrenia and a job as a research assistant at a hospital and outpatient clinic that also served people with schizophrenia. Yeah, and serious mental illness. And it was sort of impossible not to notice how pervasive smoking was among the people that were served at these settings. And then during my last year of Graduate School, I moved to New Hampshire to complete internship at the State psychiatric hospital, and it was the same. This was a locked facility but but people had, you know, multiple opportunities to go outside on what were called fresh air breaks, quote un quote. And I went out on one of these fresh air breaks and found that it was basically a group of people walking around in a small courtyard and most of them were smoking. And it was pretty ironic to call them, quote, unquote fresh air breaks. It seemed to me that if you weren't a smoker before you came to the hospital, you were probably going to become one if you wanted to get outside the building and this is of course before all the hospitals went smoke free and you know, I had never personally tried a cigarette. I had worked as a waitress during college in smokey restaurants. This is back in the 80s when when they were smoking everywhere and I just found them incredibly noxious and I was really curious about the appeal of cigarettes. So after I graduated from my PhD and I accepted a faculty position at Dartmouth, working full time within a group that was developing and evaluating interventions designed to enhance sort of overall functioning, health and well-being in people with schizophrenia and other serious mental illnesses, I spent the first several years. Just kind of working on social skills, training and illness, selfmanagement programs. And then there were a bunch of studies and actually one seminal study came out showing that if you had a serious mental illness in this country, your life expectancy was 25 to 30 years less than the general population, and it turned out that cardiovascular disease eclipsed all other causes of premature mortality, including suicide. And then I learned that you know why is cardiovascular disease so prevalent in this group? Well, obesity rates are twice the general population. And smoking rates are two to four times as high in this population. And so I sort of simultaneously got involved in a fitness promotion program that was focused on increasing exercise and healthy eating and also smoking cessation interventions and research, I was sort of inspired that, you know, we had to do something about this life expectancy gap that this group was

experiencing that you know, really affected kind of their quality of life in general in their health. So I got involved specifically in smoking cessation research. I started to learn things like that, smoking in this population, you know, why is it so high? Well, it's multi determined, there's this biological component. People with schizophrenia, in particular their nicotinic receptor sites in their brains. They just function differently such that nicotine addiction happens more easily and quickly, and it's just much harder to extinguish. I, of course had observed first hand how mental health providers really kind of promoted smoking in this group not just the fresh air breaks. But I was visiting a large community mental Health Center that had this room with a whole wall, with cartons and cartons of cigarettes. And they told me. Ohh yeah, we hand those out as rewards for attending group or contributing to discussion that group there were, you know, scores of providers, case managers, therapists who smoked with their clients and they said like this is a way to facilitate rapport with the people that I'm serving and would suggest smoking as a coping mechanism for anxiety.

JHB

Yeah, yeah.

SP

So it was sort of ohh, you seem agitated. Why don't you go out and take a smoke break? And that you know I still hear from providers that I interact with in my research this sort of pervasive belief. Well, this is kind of their last pleasure. And you know, how can we take this away from people because they have so few pleasures in life and and you see smoking as this kind of social bonding mechanism among people with serious mental illness. So there's all these factors, but I was involved in testing interventions that included both pharmacological and behavioral support for quitting I've involved with that type of research for the past 15 years now. So to kind of make a long story longer, I got involved in e-cigarette research through my involvement in one particular smoking cessation study. It was a a large five year. Study funded by the Centers for Medicare and Medicaid it was part of a program they had to test the impact of incentives on prevention of chronic disease. And so my research team enrolled almost 700 smokers with mental illness around the state of New Hampshire into a study where we were comparing 3 different cessation interventions, while also testing the value of incentives for cessation. And this started in 2012. And within the first year, we started to notice, WOW, a lot of study participants are telling us that they're using e-cigarettes and they're asking us questions. What are these electronic cigarettes? Should I use those you know, would that maybe help me to stop using cigarettes? And we looked at the data and saw that at baseline before people enrolled, 15% of the smokers had tried an e-cigarette before they enrolled in the study. And then when we looked at their entire participation in the study, which lasted for a year, a full third of people then reported that they had tried an e-cigarette. You know, we weren't promoting them in any way at this time. This is 2012.

JHB

Like, uh, like a doubling in that figure?

SP

In fact, we really didn't know much about them. But when we looked at rates of use or experimentation to the general population, they were actually much higher than the general population, which other researchers were finding and publishing on. And nobody really knew why. I sort of personally suspected that it really illustrated how desperate people with serious than illness are to become smoke free. I mean, people with serious mental illness they know how smoking is bad for your health. They know how terrible it is. They really want to be smoke-free, they try really hard to quit and and some of them can, but quit rates even with sort of gold standard treatment are much lower and relapse rates are much higher in this group. So, my colleagues at Dartmouth, couple of my colleagues, Mary Brunette and Megan Santos and I, we decided you know if this is just

naturally occurring in the world, we better learn more about it and so Mary Brunette had some internal institutional funds and we did some sort of rapid product testing in some groups of people with serious mental illness and identified an e-cigarette to use and then cobbled together a small pre post pilot study with 19 people at a local Mental Health Center to test kind of the feasibility and appeal of e-cigarettes and people with serious mental illness. And I've been doing e-cigarettes ever since for so the past 10 years now.

JHB

Fantastic, so can you tell us a bit about your recent study that you presented at SRNT this year, your role in it, how it was designed and what it set out to look at?

SP

Sure. Yeah. So it was a randomized controlled trial based on this pilot study that we did starting in 2013 where we basically just gave 19 people who were chronic smokers but were not interested in quitting, had tried to quit but were not interested. And we just gave them free electronic cigarettes for four weeks and assess them at baseline one, two, three and four weeks. And we found that after four weeks of e-cigarettes, 20% of them switched completely to e-cigarettes. And as a group they were able to reduce their number of cigarettes per day by 65% and reduce their carbon monoxide levels by 44%, both of which were highly statistically significant and we published those data and then applied for a randomized control trial and RR1 study from the National Institute on Drug Abuse and conducted a randomized controlled trial comparing e-cigarette provision for eight weeks to just assessments only. This is with people with serious mental illness again who had tried but were not able to quit, and we're no longer interested in quitting. That was really important. We could not at all suggest back in 2014 when this first got submitted that we were using e-cigarettes in a therapeutic manner. We were simply testing the quote unquote appeal and you know would people be interested in using these because of course e-cigarettes were not FDA approved at the time. And so we couldn't say that we were providing any behavioral support or coaching either. So we were just giving people e-cigarettes and doing nothing else, so we randomized 240 people and the outcomes were very similar to our pilot study. We had a 58% reduction in the e-cigarette group in cigarettes per day and a 40% reduction in carbon monoxide levels over 4 weeks. Both were highly significant and significantly better than the comparison group, which just came in and and did assessments their cigarettes per day were only 6% reduction versus 58% and their CO was a 4% reduction versus a 40% reduction. So a huge difference. It's notable that 2/3 of the sample were smoking more than 20 cigarettes a day.

JHB

Yeah, yeah.

SP

So some of them, up to two packs a day. I mean, this is these are very heavy smokers for the most part and by 4 weeks almost 60% were smoking only five or fewer cigarettes per day versus the assessment only group. It was fewer than 3%. We're using five or fewer cigarettes per day.

JHB

Those are exciting results. Did they surprise you at all? Was there anything about the study? That surprised you?

SP

I think it surprised me that there weren't more people that were able to completely switch all of their cigarettes for e-cigarettes, but if you think about cessation studies and what people with serious mental illness really need in order to be successful, we know that they do much better if they

have pharmacotherapy, yeah plus behavioral support. So we felt like if we could only add behavioral support, I think that we would do much better. We actually designed a behavioral support intervention called switch it that and and created a coaching manual and a beautiful set of handouts that sort of begin with education about the difference between smoking and vaping and then teach people strategies for substitution their cigarettes for e-cigarettes and strategies for coping with anxiety without smoking. That's a huge factor in people with serious mental illness. They will report that a lot of their smoking is a coping mechanism for anxiety.

JHB

Yeah. Could you use that behavioral support package that you developed?

SP

Well, so we did a pilot study of the intervention in 50 smokers who were people with serious mental illness in three different states in New York, California and Rhode Island. We again gave folks electronic cigarettes free for eight weeks, but they also received eight to ten phone sessions with a switch it coach who talked to them on the phone. So it was a remote remotely delivered intervention and we compared the outcomes with that group to the outcomes of the two groups in our randomized control trial. So the e-cigarette group and the comparison group and we found that 38% of the people who received switch it achieved what we consider to be switching and we defined switching as reporting not smoking and having a CO level less than 10. We had performed an analysis with our randomized controlled trial data showing that we collected NNAL which is a nitrosamine that's a byproduct of smoke that people know about this it's a it's a highly reliable biomarker for cancer risk and not surprisingly, we found that the NNAL levels in the e-cigarette group were significantly reduced as compared to the NNAL levels in the comparison group. And we also found that when we compared groups of people who had a CO of zero. A CO between 1:00 and 5:00 and a CO between 6:00 and 9:00, their NNAL levels were the same, but each of those three groups, their NNAL levels were all significantly lower than the smokers who had a CO of 10 or more. So we use 10 as a as a cutoff for quote UN quote. Switching and found that about twice as many people who receive switch it were able to switch compared to the people who just got e-cigarettes.

JHB

OK.

SP

Alone in our randomized controlled trial, which was about 19% and 0% of the people in our randomized controlled trial were able to switch using this definition who are who had been in the control group and did not receive any e-cigarettes.

JHB

Yeah, those sound like really nice clear results and they're so aligned with what we kind of expect to have happen from the literature, right, in terms of combining behavioral support and nicotine replacement therapy, for example.

SP

Yes, yes. And we also did an interesting sort of unique analysis recently to compare the trajectories of e-cigarette initiation and cigarette reduction and Jim Sargent, who's one of my colleagues at Dartmouth who's been collaborating with my e-cigarette work, led this secondary analysis. We found that most of the substitution happens really quickly, like within the first two weeks, and then sort of levels off from 2 to 8 weeks, and the strongest correlation between e-cigarette initiation and cigarette reduction, which of course they're correlated as people use more of the e-cigarettes, they're using less of their cigarettes. They really are substituting one for the other, but it was most

significant in the heaviest smokers. So the lighter smokers didn't tend to substitute as many ecigarettes for their cigarettes, but the heavy smokers really did, which to me says, you know, this could be an extremely important and effective harm reduction tool for smokers who were really at the greatest risk of negative health outcomes from tobacco smoke. So we're preparing that analysis for publication.

JHB

So exciting, so I have a couple more follow up questions and then we'll wrap up what research other than what you've just spoken about, do you think should be done following this study? What are kind of our best next steps if you just had some funders here and they would let? You run any study you wanted to what? What you do?

SP

Well, we put in an application NIDA

NL

NIDA the acronym for the National Institute on Drug Abuse, which are a US based research funder.

SP

To conduct a larger randomized controlled trial comparing e-cigarrete provision alone, I mean that does get you something that gets a lot of people to reduce heavily. It gets some people to switch completely, but we really are interested in comparing it to switch it in a single study with a with a sample that we randomly assigned to one or the other. And the other piece that we put into that application is the idea of giving people the opportunity to sample different products because really if you've tried 1 e-cigarette, you've tried 1 e-cigarette. And yeah, we've used one type of e-cigarrete. We've used a cigalike because when we tried to use e-cigarettes where there were vials to fill or cartridges to change or, you know, E cigarettes to plug in and charge, they just didn't work for this population of people with serious mental illness who have, many of whom have some cognitive impairment and challenges and it was just easier for people to be able to use something and throw it away. But you know, some people really, really loved it, and some people didn't. And we felt like, boy, what if they were able to use a product that they really loved, would that make a difference? You know what? Yeah, among the people who aren't really taking to E cigarettes. Why is it is it just because? The product itself isn't appealing enough for them and and could there be a product out there that would be because they're all so different from each other. So we put into this application another kind of layer of allowing people after four weeks to determine, well, you know, I like this e-cigarette I think I'm going to stick with it and I'm going to learn how to buy it myself in the community. So I'm going to go on field trips with my switch it coach who's going to show me how to pick them out. It's it's hard to pick out e-cigarettes in the community. They're not sitting on a shelf like soup cans, where you can pick them up and look at the label and and check them out. They're they're trapped behind a a person who's selling them at a, you know, drugstore, convenience store, and also allowing people to try different products in case they might be more appealing than the product that we had given them.

JHB

Any other research directions you want to talk about? Happy to hear those, and if not, the final question is what advice, if anything, do you think should be given at the moment to people living with serious mental illness when it comes to vaping?

SP

Yeah, I mean I I think unfortunately they are getting advice from providers. That e-cigarettes and vaping are just as bad as cigarettes and smoking. And it's in fact the exact opposite of that. And

we're we're really challenged in the US by the pervasive myth that that that is the truth that really, people are better off continuing to smoke versus trying to at least switch to e-cigarettes while they're gearing up for their next quit attempt. I mean, people with serious mental illness that nobody in fact, can be trying to quit smoking 365 days a year, year upon year. It's just not possible. People need to take breaks and and folks with serious mental illness. We have studies where people have tried to quit. You know an average of 6 or 7 times a year. It's a lot. So they're trying, but they're not successful. And my message to folks is well, in the meantime, in between, because we we certainly want people to quit, we don't want people who don't have a nicotine addiction to initiate one. We don't want young people to be using these because those are people without a nicotine addiction, so there's no reason to initiate a nicotine addiction. But if you're already very addicted and you've tried really hard and you can't quit. Then this is a bridge to a smoke free life. This is a way to reduce your harm and then you know if you decide that you want to become completely nicotine free, we're the, you know, sort of our next chapter is probably to start working on that because there are people who who come into the idea of electronic cigarettes already saying but I want to be done with quote UN quote "all of it" and and I I think part of that feeling comes again from this misconception that these cigarettes are somehow just as bad as cigarettes.

JHB

Yeah, yeah. That it's all equally harmful.

SP

And we just know that that isn't true. We have a really hard time doing our research. We just were trying to start up a new pilot study and the mental Health Center we had lined up, ultimately said "we're not going to partner with you because we don't like e-cigarettes", so it's it's a real challenge just for us to answer some of the questions that are important to answer because we can't find partners that understand the harm reduction value and understand that harm reduction doesn't mean harm elimination. So there may still be some harm, but if you could reduce it a whole lot. Isn't that better than where you started?

JHB

Absolutely. Well, thank you so much. That's perfect. That's all I need from you. Is there anything that you would have wanted to cover that we didn't cover?

SP

The interesting thing about people with serious mental illness is I think they're willing to try new things maybe even more so than people in the general population. Again, maybe it's because they're so desperate to find something that will work, they they tend to listen to providers like primary care doctors and mental health treatment providers. And so if they could hear from those experts and professionals that, yes, we're we're not 100% sure what the long term effects of e-cigarettes and vaping is but in the short run, if you want to reduce your harm, you really ought to switch and at least not be smoking combusted combustible tobacco anymore, so that that's our goal.

JHB

Yeah, yeah.

SP

Part of our goal is to educate the providers because that will have spillover effect on our population that we care so much about

JHB

Wonderful. Well, thank you so much. This has been super interesting.

SP

Yeah. Thank you for this. Opportunity. Get the word out.

JHB

My pleasure. Well, I think that's it from us this month. Thank you guys so much for listening. Thanks so much to Professor Sarah Pratt, from Dartmouth University for the interview, and we'll be with you again next month on 'Let's talk e-cigarettes'. Please subscribe on iTunes or Spotify and stay tuned for our next episode.

Music

Vaping is safer than smoking. May help you to fit in the end. But remember to mention the findings we have can't tell us what will happen long-term. Even though we know vaping is safer than smoking, we may still find cause for concern. If you're thinking of switching to vaping, that's what the smoking so bad for you. There's much to learn about effects long term yet to be seen.

JHB

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