A Systematic Review of Alternative Nicotine Delivery System (ANDS)-Based Interventions on Smoking-Related Health Outcomes Among Marginalised Population Groups.

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Abstract

Background:

Smoking and smoking-related disease is endemic amongst many marginalised populations such as people experiencing homelessness, people who use drugs, people living with HIV, sex workers and members of the LGBTQ+, Indigenous, Traveller and migrant communities. Alternative Nicotine Delivery Systems (ANDS)-based interventions including those using Nicotine Replacement Therapy (NRT) and Electronic Nicotine Delivery Systems (ENDS) show promise in supporting people to reduce their smoking. However, little is known about ANDS-based smoking reduction interventions with marginalised populations. This systematic review provides a best evidence synthesis of ANDS-based smoking reduction interventions to address this gap.

Methods:

A systematic review protocol was registered on PROSPERO (CRD42020158832) and literature review conducted through MEDLINE/PubMed, CINAHL, EMBASE, OVID SP, ScienceDirect and Google Scholar. The primary outcomes of cigarette smoking, and biochemical validation of abstinence were reported. Secondary outcomes reported included physical health, mental health and other outcomes.

Results:

Twenty-Nine studies were included in this review. Thirteen of the included studies were randomised controlled trials (RCTs) (n= 2828) and 16 studies were quasi controlled studies (n=1172). The sample size across the studies ranged from 9 to 775 participants. The mean reported age of participants ranged from 32.4 to 56.9 years old with an overall mean age of 39.55. A minority of study participants identified as female (33.43%; with two studies not reporting gender). A range of ANDS-interventions were found to be effective in reducing smoking amongst a range of marginalised groups. However, the overall quality of both the controlled and quasi experimental studies, as evaluated using the JBI Appraisal Tool, was found to be low.

Conclusions:

Studies are often evaluated as homogenous interventions although they are frequently a group of interventions and lack power analysis of the effects of individual components of the intervention effect. Several studies suggest potential mental health benefits consequent of ANDS-based intervention, though this effect is poorly explored. There is a current lack of RCTs related to ANDS-based smoking related interventions with people experiencing homelessness. Similarly, there is a lack of properly controlled RCTs exploring the use of ENDS with marginalised populations. Future studies should aim to address these deficits.

Introduction

Although tobacco smoking has been decreasing in many higher income countries, it remains endemic amongst many marginalised populations in both lower and high income countries.^{1,2} Many of these groups are disproportionately impacted by smoking-related diseases such as Chronic Obstructive Pulmonary Disease (COPD) and lung cancer and smoking can dramatically reduce their quality of life and life expectancy.² However, there are limited reviews of evidence-based smoking reduction interventions outside specific marginalised groups such as people experiencing homelessness^{3,4} A wide range of marginalised populations have been associated with high smoking rates including people who use drugs⁵, people living with mental illness⁵ and people involved with the criminal justice system⁷. Such minority populations are often excluded from smoking reduction interventions despite their high levels of smoking and smoking-related disease.⁸ The lack of engagement with these groups may be related to a need to identify effective smoking reduction interventions with these groups.⁸

Alternative nicotine delivery systems (ANDS) including nicotine replacement therapy (for example, gums, lozenges and inhalers) and the provision of electronic nicotine delivery systems (ENDS) show some promise in helping a range of marginalised populations to quit or reduce smoking.^{2,3} The systematic review reported in this paper aimed to provide a comprehensive summary of intervention research that has examined the use of ANDS-based interventions in reducing tobacco smoking and other key outcomes in marginalised populations. Within this review marginalised populations defined were people with experience of homelessness; criminal justice involvement; drug use; severe mental illness; sex work; forced displaced or migrant people; people living with HIV and members of the Indigenous, LGBTQ+ and traveller communities.

The key outcomes of interest in this inquiry were:

- (I) Self-reported cigarette consumption;
- (II) Biochemically validated cessation
- (II) Measures of nicotine dependence
- (II) Mental outcomes
- (IV) Physical outcomes
- (VI) Other outcomes

Methodology

Our review protocol was registered with PROSPERO (CRD42020158832) and followed the PRISMA guidelines.⁹ We conducted the systematic review to summarise evidence for the use of ANDS interventions among various marginalised population groups which are linked to high smoking rates. We

defined ANDS as including all nicotine-based interventions including various forms of nicotine replacement therapy (for example, nicotine gum, patches and inhaler), ENDS devices and snus.

Studies which were included were those published in peer-review academic journals in English. This study focused broadly on a range of marginalised populations, which were defined by expert consensus. These included people with lived experience of homelessness; criminal justice involvement; drug use; severe mental illness; sex work; forced displacement or migration; people living with HIV and members of the Indigenous, LGBTQ+ and traveller communities.

Inclusion criteria

To be included in the review, studies were required to have a (i) primary ANDS intervention either controlled or uncontrolled with pre and post measures, (ii) be subject to peer review publication in an academic publication and (iii) include primarily marginalized population group (s) in the intervention - as per the search strategy described below.

Search methods and strategy

A systematic search of the literature was conducted to identify all intervention studies where ANDS-based interventions had been implemented with 10 separate marginalised population groups as shown below.

Table 1 Search Terms

<ol style="list-style-type: none"> 1. homeless OR houseless OR “precariously housed” OR unhoused; 2. prisoner OR imprisoned OR prison; 3. “person who uses drugs” OR PWUD OR “person who injects drugs” OR PWID OR “drug user” OR “substance use disorder” OR “drug dependence”; 4. Indigenous OR “Native American” OR Maori OR “First Nations”; 5. Roma OR gypsy OR Traveller; 6. “serious mental illness” OR “severe mental illness” OR “severe and persistent mental illness” OR “common mental disorder” OR “common mental illness” OR schizophrenia OR psychosis OR psychotic OR “major depression” OR depression OR dysthymia OR bipolar OR anxiety OR “post-traumatic stress disorder”; 7. “sex worker” OR prostitute OR “rent boy”; 8. “Asylum seeker” OR migrant OR refugee; 9. LGBT OR lesbian OR gay OR bisexual OR transgender OR intersex OR queer 10. “People living with HIV” OR PWLHIV OR “HIV patients”.

The primary outcomes of cigarette smoking, and biochemical validation of abstinence were reported. Secondary outcomes included physical, mental and other outcomes. Articles from inception to 2020 were included. Articles were reviewed from MEDLINE/PubMed, CINAHL, EMBASE, OVID SP, ScienceDirect and Google Scholar.

Study selection process

Three reviewers worked independently to screen articles for inclusion eligibility using Covidence. Where disagreement occurred, a discussion was held and decisions were put to a third independent author (MG, JSW) for a final decision. The data were extracted using the predetermined outcomes. These outcomes were classified under domain areas to allow for summary data extraction and analysis. The generated domain areas are shown in Table 1 below.

Table 2. Key outcomes codes for reporting

Outcomes	Examples
S1: Self-reported smoking	Number of cigarettes,
S2: Reported abstinence	7 day point abstinence
S2: Biochemical validation	CO monitoring
S3: Measures of dependence (e.g.)	Fagerstrom scores
M1: Mental health	Changes in stress, depression etc.
P1: Physical Health	Changes in blood pressure, BMI etc.
O1: Adherence	Drop out/follow up
O2: Other outcomes	Changes in substance use

Quality Appraisal

Four researchers independently assessed the quality of studies brought forward for inclusion in relation to reducing bias in design, conduct and analysis using predetermined criteria. The Joanna Briggs Institute Critical Appraisal tool for Quasi-Experimental studies and the JBI Critical Appraisal tool for Randomised Controlled Trials was adopted for use in this process.¹⁰

In analysing the results, a best evidence synthesis was conducted, whereby studies with a control group and studies without control measures were considered separately and data, as per Table 1, were extracted from each study. A meta-analysis of data was precluded given the diverse heterogeneous nature of the studies that were included in the final review.

Results

3.1. Study selection

Following the removal of duplicates, a total of 2463 articles were considered at the title and abstract level. One-hundred-and-seven full texts were reviewed, and 77 were excluded with reasons (see Fig. 1 and Appendix 1), with 29 unique studies meeting the eligibility criteria. Full details of the search results are summarized in Fig. 1. PRISMA Flowchart.

Details of included studies and participant’s characteristics

Thirteen of the included studies were randomised controlled trials (RCTs) (n= 2828) and 16 studies were quasi controlled studies (n=1172). The sample size across the studies ranged from 9³⁶ to 775 participants.²¹ The mean age of participants ranged from 32.4 years¹⁸ to 56.9³⁸ with an overall mean age of 39.55 years (three studies did not report mean age). A minority of study participants identified as female (33.43%; with two studies not reporting gender).

Several studies focussed on people with severe mental illness^{11, 13-14, 17, 21, 30-32, 38-39} and people who use alcohol and other drugs.^{12, 18, 20-21, 35, 37, 32} Other studies focussed on people experiencing homelessness^{25, 27, 28, 36} those involved with the criminal justice system^{16, 22, 34} and those living with HIV.^{16, 23-24, 26} Three studies included indigenous groups^{19, 21, 32} and LGBTQ+ populations.²⁹ One study included individuals with affective disorders; individuals with opioid use disorder and smokers with socioeconomic disadvantage²¹ whilst another study included Aboriginal people; people with serious mental illness and people who use drugs³². No studies evaluating interventions engaging with members of the Traveller community, sex worker or migrants were identified. Details regarding the included studies are summarized in Tables 1 (controlled trials) and 2 (uncontrolled trials).

Table 1 Controlled Studies

Study authors, Year	Design, region, setting	Population	Intervention	Control group	Follow up
Allen et al. (2011) ¹¹	RCT, Switzerland, psychiatric emergency service	<p>People with serious mental illness-schizophrenia (n=40);</p> <p>Gender: % female (unknown);</p> <p>Age: Mean (unknown) range (18-65 years).</p>	21mg transdermal nicotine patch	placebo patch	24 hours
Carmody et al. (2012) ¹²	RCT, hospital-based substance use program, United States	<p>People dependent on alcohol (n=162);</p> <p>3.18 % female;</p> <p>Age: median age (50), age range (unknown) .</p>	16 sessions of CBT+ NRT over 36 weeks	Usual care: Smoking cessation counselling and guideline-concordant medications	52 weeks
Chan et al., 2020 ¹³	Cluster randomised parallel study, psychiatric inpatient, Taiwan	<p>People with mental illness (n= 310)</p> <p>Gender: 10.9% female;</p> <p>Age: 36.92 ± 8.1.</p>	Inhalers, nicotine gum, and nicotine patches	N/A	8 weeks
Christiansen et al (2018) ¹⁴	RCT, outpatient care program, United States	<p>People with serious mental health issues (n=222);</p> <p>Gender (49% female);</p> <p>Age (43.8 ±9.9.</p>	Four weekly sessions; motivational component; pre-quit nicotine patch (21mg)	Attention control group	3 months
Cropsey (2008) ¹⁵	RCT, state prison, United States	Women in a state prison (treatment:	10-week group intervention with NRT (patches	No intervention	12 month follow up

		n=250; control: n= 289); Gender (100% female); Age (33.8 ±9).	according to manufacturer instructions)		
Cropsey et al., (2014) ¹⁶	Randomised pilot study, HIV clinic, United States	People living with HIV (n=40) Gender: 42.5% female; Age: 44.5±SD = 9.9.	8-weeks of combination nicotine replacement therapy (NRT) in conjunction with brief counselling (SBIRT framework)	Usual Care	8 weeks
Dennis et al., (2016) ¹⁷	RCT, outpatient hospital, United States	People with serious mental illness- Post Traumatic Stress Disorder (n=63) Gender: (55% female) Age: 42.3 ±10.7	Nicotine patch pre-loading	Placebo patch	6 month
Felicioni et al (2018) ¹⁸	RCT, outpatient clinic, United States	People who use drugs (n=25) Gender: 72% female; Age: 32.4 ±8.7.	ENDS device	Placebo liquid	4 weeks
Gould et al. (2019) ¹⁹	RCT, Aboriginal medical services, Australia	Pregnant Australian indigenous women (n=22) Gender: 100% female Age: 16+	Education resource package (including webinars; 3 hour one sessions); oral forms of NRT; CO monitoring	Stepwedge design	6 months
Hall et al. (2018) ²⁰	RCT, buprenorphine	People who use drugs (n=175)	Computerised motivational feedback;	Brochures on quitting; self-help techniques;	18 months

	clinic, United States	Gender: 22% female Age: Treatment (40.5±10.5); Control (40.6±SD 9.7)	nicotine gum lozenge; nicotine patch; optional varenicline for those who failed to achieve 24 hour abstinence	helplines; smoking cessation controls	
Higgins et al., (2020) ²¹	3 RCTs, University Setting, United States	Individuals with affective disorders; individuals with opioid use disorder and women smokers with socioeconomic disadvantage (n=775) Gender: 71.1, female; Age: 35.59 (11.05)	12 week intervention with free cigarettes provided with three concentration of nicotine 0.4, 2.4, or 15.8 mg	N/A	16 weeks
Jalali et al., (2015) ²²	RCT, prison, Iran	People involved with criminal justice system (n=43) Gender: 0% female Age: 37.59 ± 8.76	MI-based treatment, MI with NRT, and the control group, Motivation interview + 2mg gum for every cigarette smoked/ over 5 weeks	No intervention MI	90 days
Stanton et al., (2009) ²³	RCT, outpatient clinic, United States	People living with HIV (n=412) Gender: 36.89% female	8 weeks Bi weekly sessions where patch used was discussed	two study sessions, consisting largely of baseline assessments, randomization, and brief assessment of	6 months

Age:
42.04±7.53

quitting plans.
NRT for those
who wanted to
quit

Table 2 Uncontrolled studies

Study authors, Year	Design, region, setting	Population	Intervention	Follow up
Balfour et al., (2016) ²⁴	Pilot study, HIV outpatient clinic, United States	People living with HIV (n=50) ; Gender: 12% female Age: 45.10±8.68	5 session smoking cessation counselling, NRT Nicotine patch per following dosage regiment: participants smoking ≥20 cigarettes per day were prescribed 21 mg patches daily for 6 weeks, then 14 mg/day for 2 weeks, followed by 7 mg/day for 2 weeks; participants smoking 10–20 cigarettes per day were prescribed 14 mg patches daily for 6 weeks, and then 7 mg/day for 4 weeks	6 months
Buckley et al., (2017) ²⁵	Evaluation study, homeless service, United States	People experiencing homelessness (n=139) Gender: 27.3%, female; Age: 44.2± 19-74;	Student run intervention; smoking cessation education; motivational interviewing; 2 weeks supply of NRT; referral to national quitline.	26 weeks
Cioe et al., (2019) ²⁶	Pilot study, outpatient HIV clinic	People living with HIV (n=19); Gender: 30%, female; Age: 52.7±9.3.	8 week intervention; participants provided with an ENDS device; weekly allotments of nicotine liquid;	12 weeks
Collins et al., (2019) ²⁷	Emergency homeless shelter, United States	People experiencing homelessness (n=44); Gender: 34% female; Age: 48.24 ±11.46	Information/advice support; individual sessions; group sessions; NRT (gum, patches; lozenges)Choice of ENDS device; 4mg gum; 14mg and 21mg patch; 4mg lozenges	14 weeks
Dawkins (2020) ²⁸	Homeless shelter, United Kingdom	People experiencing homelessness (n=80)	ENDS device, 4 week supply of eliquid	24 weeks

		Gender: 35% female;		
		Age: 42.66±10.79.		
Dickson Spillman (2014) ²⁹	Gay health clinic, Switzerland	Men who have sex with men (n=70); Gender: 0% female; Age: 42.96 ±9.66.	Seven weekly sessions facilitated by peers. Multiple different forms of NRT	6 months
Hickling et al., (2019) ³⁰	Pre/post feasibility study, Community health team referrals, England	People with serious mental illness- psychotic disorder (n=50); Gender: 24% female; Age: 39 ±10.7	6 week intervention, ENDS	24 weeks
Johnson et al., (2020) ³¹	Feasibility study,	People with severe mental illness (n=34) Gender: 47% female; Age: 50% below 40 years old.	2 weeks of NRT (patches)	3 months
Mikhailovich and Morrison (2008) ³²	Evaluation	Aboriginal people; people with serious mental illness People who uses drugs (n=63) Gender: not reported; Age: not reported .	Tailored NRT	6 months
Pakhale ³³	A feasibility mixed methods prospective	People who use drugs (n=80)	6 month intervention; access to counselling and NRT	6 months

	cohort study, Community research office, Canada	Gender: 30% female; Age: 43.8.		
Richmond et al (2006) ³⁴	Pilot study, prison, Australia	People who are incarcerated (n=330); Gender: 0% female; Age: 35±10.	NRT (patch) 21 mg/day for six weeks, 14 mg/day for two weeks and 7 mg/day for two weeks	6 months
Saxon, McGuffin and Walker, (1997) ³⁵	Substance use treatment centre, United States	People who use alcohol and other drugs (n=49) Gender: 4.1% female; Age: 44.1 ± 7.8	NRT (patch) 21mg nicotine	6 weeks
Scheibein et al (2020) ³⁶	Feasibility study, homeless services, Ireland	People experiencing homelessness (n=9) Gender: 28.57, female; 43.89± 7.36.	ENDS device; choice of Nicotine 0,6,11,18 and 20mg liquid	3 months
Stein et al (2016) ³⁷	Methadone clinic, United States	People who use drugs-methadone (n=12); Gender: 50% female Age: 45.9±11.5	ENDS device	6 weeks
Valentine 2018 ³⁸	Veteran affairs health system	Veterans attending mental health clinics (n=43); Gender: 7% female Age: 56.9±8.0	ENDS device	4 week
White	Recovery community,	People in alcohol recovery (n=100);	prolonged	1 year

(2016) ³⁹	Iran	Gender: 11%, female Age:40.1±10.9	nicotine replacement therapy (NRT) with a broad spectrum of psychosocial supports
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3.3. Controlled trials (CTs)

3.3.1. Summary of controlled trials

The results from the included CTs are summarized in Table 3. The average length of follow up was 22.64 weeks with follow up ranging from 24 hours¹¹ and 52 weeks.¹² Studies took place in hospitals;^{11-12, 13}outpatient clinics;^{14, 17-18, 23}custodial settings;^{15,22}a HIV clinic;¹⁶a drug treatment service;²⁰ an Aboriginal health service¹⁹ and in a university setting.²¹

Results of controlled trials

Three RCTs reported on interventions with people who use drugs.^{12, 18, 20.} At 12 and 26 weeks, a 36-week intervention with alcohol dependent patients in early recovery, using 16 sessions of Cognitive Behaviour Therapy (CBT) + Nicotine Replacement Therapy (NRT) was found to have a statistically significant impact on the 7-day point prevalence quit rate (both $p = .03$).¹² However, this effect was no longer statistically significant at 38 or 52 weeks (ibid.). A study using an ENDS device¹⁸ found that the intervention was effective in reducing self-reported cigarette consumption with a biochemically verified (<8ppm CO) end of treatment smoking abstinence rate of 8.6% (intent-to-treat) and 10.7% for the per protocol group (n=28). Twenty-eight percent of those who completed the program reported a 50% reduction in cigarette consumption, however, this did not seem to have been corroborated by biochemical verification (ibid.). A NRT based intervention, which included a computerised feedback component, did not increase motivation to quit or increase long term abstinence.²⁰

Two RCTs reported mental health outcomes of interventions with people living with mental illness. One study¹¹ investigated the effect of NRT in reducing agitation in people living with schizophrenia as measured by the Mean Agitated Scale score over a 24-hour period. The mean Agitated Behaviour Scale score for the group receiving NRT was 33% lower at 4 hours and 23% lower at 24 hours than the placebo group (ibid.). Another study,¹³ also in an inpatient unit, compared the effect of patches, gum and inhalers, and found that the groups using inhalers or gum had significantly reduced psychiatric symptom severity symptoms at weeks 4 and 12 with the inhaler group showing the greatest reductions. Only the inhaler group was found to have a significant reduction in CO at weeks 4 and 12 ($P < 0.001$ and $P = 0.032$, respectively) but both the nicotine inhaler and the patch groups showed significant decrease in nicotine withdrawal symptoms from baseline at both weeks 4 and 8 (ibid.).

Two studies considered NRT pre-loading (pre supplementation with nicotine) to increase treatment efficacy for people living with mental illness.^{14, 17} One study¹⁴ which investigated the effect of NRT pre-

loading with a 21mg nicotine patch found that those receiving the intervention were more likely to be abstinent (3 months 8.5% vs. 1.0%, respectively, $p = .01$) and were more likely to accept four or more cessation sessions (50.8% vs 29.2%, respectively, $p < .001$). However, a study¹⁷ exploring NRT pre-loading with another population of people with serious mental illness found no statistically significant reduction in smoking or craving during the preloading period and no differences in terms of 6 week or 6-month abstinence when compared to the control group.

A 10 week group intervention with NRT with women in prison found that point prevalence quit rates for the intervention group, as compared to a waitlist control, were 18% at end of treatment, 17% at 3-month follow-up, 14% at 6-month follow-up, and 12% at 12-month follow-up.¹⁵ An intervention with men in prison found that Motivational Interviewing (MI) + NRT was more effective than MI only in reducing smoking as biochemically validated with CO ($p = 0.02$).²²

An intervention with pregnant Indigenous women with online sessions, NRT and CO monitoring, evaluated through a step cluster design, led to biochemically validated ($<6\text{ppm}$) 12 week 7-day point-prevalence abstinence in 13.% ($n=3$) of participants.¹⁹ A study exploring the effect of NRT contacts with people living with HIV found that the number of contacts was significantly associated with 6 month abstinence.²³ Another study with people living with HIV found that a 8 week NRT + counselling intervention found that the treatment group smoked less cigarettes per day ($\eta^2 = .07$; $p = .13$); had lower physical nicotine dependence ($\eta^2 = .18$, $p = .01$) and lower smoking urges ($\eta^2 = .16$, $p = .01$).¹⁶

A novel study²¹ compared two very low nicotine cigarettes with one higher nicotine cigarettes in an intervention with individuals with affective disorders, individuals with opioid use disorder and women smokers with socioeconomic disadvantage. The very low nicotine cigarettes led to reductions in cigarettes per day but there were no significant differences between the two very low nicotine cigarette types (ibid.).

Quality Appraisal of Controlled Trials

The overall quality of the controlled trials, as evaluated using the JBI Appraisal Tool, was found to be low with an average of 5.92/13 with a range from 3-9/13. Almost fifty percent of studies did not use or did not clearly describe true randomisation procedures (6/13 studies). All studies did not clearly describe concealing allocation to the treatment group (13/13 papers). Many of the studies (9/13 studies) reported that the treatment groups were similar at baseline. Only two of the 13 studies, clearly outlined that their participants were blind to treatment assignment whilst only one study clearly outlined that those delivering treatment were blind to treatment allocation; four studies stated assessors were blind to treatment. Most studies (11/13 studies) clearly outlined that treatment groups were treated identically other than the intervention of interest. Six of the studies completed follow up or adequately explained loss to follow up. Seven of the studies analysed participants in the groups to which they were randomised. Most studies (12/13) clearly described that outcomes were measured in the same way between treatment groups. Four of the studies delineated how their measurements were performed

reliably. Five of the studies accurately described how they had used the correct statistical techniques. Eight of the studies utilised an appropriate trial design and satisfactorily reported any deviations from the trial design.

3.3. Uncontrolled trials

3.3.1. Summary of uncontrolled trials

The results from the included uncontrolled trials are summarized in Table 3. The average length of follow up was 20 weeks, ranging from 4 weeks³⁸ and 52 weeks.³⁹ Studies took place in homeless services;^{25, 27-28, 36} drug treatment services;^{35,37,39} outpatient clinic;^{24,26} prison;³⁴ a gay health clinic;²⁹ a community health clinic³⁰ and a veteran health clinic.³⁸

Summary of Uncontrolled Trial Results

An intervention with people living with HIV consisting of 5 sessions of smoking cessation counselling with NRT led to 28% biochemically verified abstinence from smoking at 6 months.²⁴ An intervention with men who have sex with men consisting of 7 weekly sessions facilitated by peers with NRT was found to be significantly associated with point prevalence abstinence ($p=0.00$) with 38.6% reported smoking abstinence over the previous 7 days at 6 months.²⁹ A study which evaluated a decreasing regiment of NRT patches with people in prison was found to lead to biochemically validated point prevalence abstinence and continuous abstinence rates of 26% and 22% respectively.³⁴ A partially student run intervention which utilised NRT with people experiencing homelessness led to 13.7% of participants contacting the smoking cessation line.²⁵ A small scale study, using NRT patches, with people accessing mental health services found that the intervention led to a reduction in the number of daily cigarettes number of cigarettes, dependency levels and average weekly expenditure on tobacco at 3 months.³¹

Several studies evaluated interventions related to ENDS devices. An intervention with people experiencing homelessness using information advice, group sessions, NRT and providing a choice of ENDS device found an 18% increase in odds of reporting 7-day, biochemically verified, point-prevalence abstinence.²⁷ All study participants reporting abstinence used an ENDS device and those using an ENDS device were found to have a 44% reduction in smoking intensity and a 1.2-point reduction in dependence (ibid.) Another study, with people experiencing homelessness and using an ENDS device, found biochemically validated sustained abstinence 3/48 (6.25%) at 24 weeks in the treatment group compared to 0/32 (0%) for the usual care group.²⁸

A small ENDS intervention with people experiencing homelessness found a statistically significant decrease in reported cigarettes smoked and decrease in Fagerstrom scores ($p < 0.001$).³⁶ However, decreases in biochemically validated abstinence were not statistically significant (ibid.). A six week ENDS intervention with people with serious mental illness was found to lead to a ($\geq 50\%$) reduction in cigarettes consumed per day between baseline and week 6 ($p < 0.001$).³⁰ Another ENDS based intervention with

veterans with mental health issues was found to lead to significant reductions in breath CO ($p < 0.02$) and self-reported cigarettes smoked ($p < 0.001$).³⁸

A study evaluating a 21mg NRT patch intervention with people using drugs stated that seven subjects (14.3%) self-reported tobacco abstinence at 21 days, and 5 (10.2%) self-reported abstinence as outpatients at 6 weeks.³⁵ An ENDS-based intervention, with a population recruited from a methadone clinic, was found to lead to a reduction in the number of cigarettes smoked at 3 weeks ($P < 0.001$), 5 weeks $P < .001$) and 9 weeks ($P < 0.01$)³⁷. Similarly, a NRT intervention with people in a residential treatment centre reported extremely high in-treatment (85%) and posttreatment (99%) abstinence rates.³⁹

Mental health and other benefits are reported by several studies. A study with people experiencing homelessness, using an ENDS device, found that GAD-7, PHQ-9 and AUDIT scores declined from baseline.²⁸ Another study using an ENDS device with people experiencing homelessness found a decrease in “poor concentration” over the treatment period.³⁶ An intervention using NRT and weekly peer led sessions with men who have sex with men was found to increase mental health between baseline and follow up ($p = 0.00$).²⁹ However, there was no difference between depression and anxiety scores between those who had relapsed and those who did not ($p > 0.05$). A community-based study with people who use drugs found that an intervention including a NRT component led to a considerable reduction in self-reported illicit substance use (18.8%), including a reduction in the opioids heroin (6.3%), fentanyl (2.6%) and Oxycontin (3.8%).³³ Other reported benefits included improved health, return to work and greater community engagement (ibid.)

Quality Appraisal of Uncontrolled studies

The overall quality of the uncontrolled trials, using the JBI Appraisal Tool, was found to be low with an average of 2.5/9 with a range from 0-6/9. The cause and effect of the study was clearly articulated in most studies (11/16 studies). Only one study included a control group and there were differences between the treatment and control group. Four studies had completed follow up and/or used intention to treat analysis. Four studies included comparisons but only one clearly outlined that outcomes were measured in the same manner. No study clearly outlined that measurements were performed in a reliable way. Eight of the studies clearly outlined that they had used the appropriate statistical test.

Controlled studies

	Study Primary or secondary aim	Smoking outcomes	Other outcomes	Appraisal score
Allen et al (2011) ¹¹	To investigate the effect of NRT in the reduction of agitation and aggression	Not applicable	M1: Mean Agitated Behaviour Scale score for NRT group was 33% lower at 4 hours and 23% lower at 24 hours than the placebo group	8/13
Carmody (2013) ¹²	To investigate the efficacy of an intensive tobacco cessation intervention for alcohol-dependent smokers in early recovery.	At 12 and 26 weeks the 7 day point prevalence quit rates were significantly higher in the intensive care group (both $p = .03$). However, the quit rates were not statistically significant at 38 or 52 weeks	Verified 30-day alcohol abstinence were not statistically significant at any of the follow up points.	3/13
Chan et al., (2020) ¹³	To compare effectiveness and acceptability of 3 different forms of NRT	Nicotine inhaler group showed statistically significant reduction in CO level from baseline at both weeks 4 and 8 ($P < 0.001$ and $P = 0.032$, respectively). The nicotine inhaler and the patch group showed significant decrease in nicotine withdrawal symptoms from baseline at both weeks 4 and 8.	The nicotine inhaler and the gum groups showed significant decrease in psychiatric symptom severity from baseline at both weeks 4 and 8.	8/13
Christiansen et al. (2017) ¹⁴	To test a pre-cessation intervention	Smokers receiving the intervention were more likely to be abstinent at 3 months 8.5% vs. 1.0%, respectively, $p = .01$). More likely to accept 4 or more cessation sessions 50.8% vs 29.2%, respectively, $p < .001$) b		7/13
Cropsey (2008) ¹⁵	To test the efficacy of a combined pharmacologic and behavioral smoking cessation intervention	18% at end of treatment, 17% at 3-month follow-up, 14% at 6-month follow-up, and 12% at 12-month follow-up		5/13

Cropsey (2014) ¹⁶	To evaluate the acceptability, feasibility, and effects of a Screening, Brief Intervention, and Referral for Treatment (SBIRT) model i	Treatment group smoked fewer cigarettes per day($\eta^2 = .07$; $p = .13$); had lower physical nicotine dependence($\eta^2 = .18$, $p = .01$) ; lower smoking urges (lower smoking urge ($\eta^2 = .16$, $p = .01$))		8/13
Dennis et al., (2016) ¹⁷	To evaluate the efficacy of supplemental nicotine patch-preloading among smokers	: Nicotine patch-preloading failed to reduce smoking or craving during the preloading phase no differences were observed between the treatment conditions for time to lapse, 6-week abstinence, or 6-month abstinence.	No effect on smoking-associated relief from PTSD symptoms and negative affect.	9/13
Felicione et al.,(2018) ¹⁸	To examine the feasibility, acceptability, and effect of e-CIG on smoking behavior among smokers with opiate use disorder.	S1: End of treatment smoking abstinence was 8.6% (intent-to-treat; $n=35$) and 10.7% for per protocol group ($n=28$). 28% of those who completed the program were able to achieve a 50% reduction to their baseline cigarette consumption.		5/13
Gould et al., (2019) ¹⁹	To explore the feasibility and acceptability of a) a co-designed multi-component intervention for HPs at Aboriginal Medical Services (AMSs) in culturally-targeted pregnancy-specific smoking cessation care	CO validated (<6ppm) Self-reported 12-week 7-day point-prevalence abstinence was 13.6% ($n = 3$)		4/13
Higgins et al., (2020) ²⁰	To examine whether very low-nicotine-content (VLNC) cigarettes decrease smoking rates and dependence severity	At week 12, mean (SEM) CPD decreased to 17.96 (0.98) CPD in the 0.4mg/g group and to 19.53 (1.07) CPD in the 2.4mg/g group, both of which were significantly different from the 15.8 mg/g group (25.08 [1.08])		8/13

CPD at week 12) but not each other (0.4 mg/g)

Fagerstrom Dependence Test Scores were significantly different between the very low nicotine cigarettes and the higher nicotine cigarettes

Hall (2018) ²¹	To evaluate an intervention to increase cigarette abstinence rates	S1: Did not increase long term abstinence D1: Increased motivation to quit		5/13
Jalali et al., (2015) ²²	To compare the effects of MI based treatment and its combination with NRT on smoking in prison population.	S2: Lower CO with MI with NRT group (p = 0.02)		3/13
Stanton et al., (2009) ²³	To examine 6 month abstinence from Positive PATHS trial	S1: Number of NRT contacts is sig associated with abstinence at 6 month Total effect of NRT contacts suggested an increase in the regression adjusted odds of smoking abstinence by 35% per additional contact	D1: Sig direct effect of NRT contacts mediators: smoking self-efficacy and smoking decisional balance. O1: The mean number of total NRT-related contacts per patient did not differ significantly between the SC and ME groups	4/13

Uncontrolled

	Study Primary or secondary aim	Smoking outcomes	Other outcomes	Appraisal score
Balfour (2016) ²⁴	To examine the effectiveness of a specifically tailored 5-session smoking cessation counselling programme	6-month follow-up, 28% of participants demonstrated biochemically verified abstinence from smoking	Lower depression than at baseline but statistically significant (p= 0.058)	3/9
Buckley et al., (2017) ²⁵	To describe a professional and student run program;	19 (13.7%) successfully contacted the smoking cessation quitline.		1/9
Cioe et al., (2019) ²⁶	To examine the acceptability and health-related effects of ENDS	At week 8, cigarettes per day (CPD) were reduced by more than 80%, with reduction maintained at week 12 (p's < .001). Cigarette dependence scores were 40% lower at week 8 than at baseline (p < .001). Mean CO decreased significantly from BL to week 8 (p < .05) and remained significantly lower at week 12 (p < .001)		4/9
Collins et al (2019) ²⁷	To explore the feasibility, acceptability and HR QoL outcomes	S1: 18% increase in odds of reporting 7-day, biochemically verified, point-prevalence abstinence. All participants reporting abstinence used ENDS. Reductions in cigarette dependence (45%), frequency (-29%), and intensity (78%; ps < .05). Participants who used ENDS experienced an additional 44% reduction in smoking intensity and a 1.2-point reduction in dependence	Health related quality of life outcomes were not statistically significant (ps > .06).	3/9

Dawkins (2020) ²⁸	To assess the feasibility of supplying free e-cigarette starter kits to smokers accessing homeless centres and to estimate parameters to inform a possible future larger trial	CO validated sustained abstinence at 24 weeks was 3/48 (6.25%) and 0/32 (0%) respectively for the EC and UC arms	GAD-7, PHQ-9 and AUDIT scores declined from baseline	6/9
Dickson Spillman (2014) ²⁹	To examine if the impact of the intervention to facilitate smoking cessation and improve other health outcomes as well as to assess its attractiveness to the target population	S1: Point prevalence abstinence increased significantly (p=0.00) At 6 month 28.6% reported smoking abstinence over the previous 7 days	M1: Mental health increased between baseline and follow up (p=.00) There was no difference between depression and anxiety scores between those who had relapsed and those who did not (p > .05).	4/9
Hickling et al (2019) ³⁰	To investigate the utility of electronic cigarettes (e-cigarettes) as a harm reduction intervention	S1: ($\geq 50\%$) reduction in cigarettes consumed per day between baseline and week 6 (F(2.596,116.800)=25.878,p<0.001)		3/9
Johnson et al., 2020 ³¹	To test a new program for helping smokers with severe mental illness to reduce their tobacco use, together with determining the feasibility of such research in community	reduced their number of daily cigarettes, dependency levels and average weekly expenditure on tobacco		1/9

	mental health settings			
Mikhailovich and Morrison (2008) ³²	To evaluate a NRT tailored program	Low level of success		0/9
Pakhale ³³	To determine the feasibility of a Community Based Participatory Tobacco Dependence Strategy	Mean reduction of 11.2 cigarettes at 6months (P=0.0001).	considerable reduction in self-reported illicit substance use (18.8%), including a reduction in the opioids heroin (6.3%), fentanyl (2.6%) and Oxycontin (3.8%). Other reported benefits included improved health, return to work and greater community engagement	2/9
Richmond et al., (2006) ³⁴	To determine the feasibility and effectiveness of a multi-component smoking cessation	biochemically validated point prevalence and continuous abstinence rates were 26% and 22% respectively		2/9
Saxon, McGuffin and Walker, (1997) ³⁵	To undertake an open, pilot evaluation of transdermal nicotine for cigarette smokers	Seven subjects (14.3%) self-reported tobacco abstinence at 21 days, and 5 (10.2%) self-reported abstinence as outpatients at 6 weeks		2/9
Scheibein et	To explore the	Self-reported reductions in cigarette		2/9

al., (2020) ³⁶	efficacy, challenges and opportunities of using electronic nicotine delivery systems (ENDS) to support cessation of tobacco smoking	consumption were found to be statistically significant ($p < 0.001$) Reductions in carbon monoxide measurements were not statistically significant. Decreases in Fagerström Nicotine Dependence Test were statistically significant ($p = 0.001$), but decreases in MPSS “urge to smoke” and “strength of urges” composite scores were not.	
Stein et al., (2016) ³⁷	To conduct a small open pilot trial on the use of e-cigarettes as a smoking cessation	S1: Mean reductions in CPD were -12.4 (95% confidence interval [CI]: -15.0, -9.9; $P < .001$), -14.8 (95% CI: -17.4, -12.2; $P < .001$), -13.9 (95% CI: -16.6, -11.2), and -10.8 (95% CI: -13.4, -8.2; $P < .01$) at the 3-, 5-, 7-, and 9-week assessments, respectively.	3/9
Valentine 2018 ³⁸	To examine the impact of e-cigarette use on combustible tobacco use, as well as on the readiness to quit smoking and changes in nicotine dependence	Significant reductions in breath CO (9.3 ppm to 7.3 ppm, $p < 0.02$) and CPD (from 16.6 to 5.7, $p < 0.001$)	2/9
White (2016) ³⁹	To explores the introduction of a smoking cessation intervention	High in-treatment (85%) and posttreatment (99%) abstinence rates	1/9

Discussion

There is limited evidence that many NRTs (for example, gum, patches and inhalers) and ENDS based interventions have a positive effect on self-reported smoking with the marginalised groups focused upon in this review. Evidence that does exist is often not corroborated with biochemical validation. Clear standards for CO cut off points for biochemical validation seem to be lacking with studies using cut-offs as low as 4ppm CO and as high as 10ppm CO and various different devices. Additionally, the evidence for these interventions is negatively impacted by the poor design of many of the reviewed trials.

Overall, the methodological quality of the studies was very poor with an average score of 5.92/13 in the RCT group and an average score of 2.5/9 in the quasi-experimental group. Few studies were identified where outcomes were measured in a reliable manner.

It was difficult to ensure that statistical analysis was appropriate using the JBI checklist, due to a dearth of information given in the majority of studies. None of the controlled trials and only one uncontrolled trial³⁷ identified that they carried out statistical power analysis; therefore the assumption that other studies were underpowered could not be dismissed. The studies did not use power analysis to determine the effect size of different forms of NRT or ENDS or complementary psychological interventions as part of the treatment arms. Studying the reliability of ANDs intervention statistics was therefore a complex task and using more robust methods such as intention to treat in larger and statistically powered trials would improve future studies and thereby enable comparison of outcomes. The importance of the studies included in determining the feasibility and effects of ANDs in minority groups cannot be dismissed.

Preliminary evidence suggests that engagement with smoking related interventions may have a positive effect on mental health^{11,13,24,28–29,36} though this is not reported in all trials¹⁷. This may not be related to meeting smoking abstinence outcomes²⁹ although there is consistent evidence that smoking cessation is associated with mental health benefits.⁴⁰ There may also be benefits in relation to substance use, general health and employment.³³

Although there were several ENDS-based interventions found in the quasi-experimental studies^{26–28,30,36–37} only one included RCT¹⁸ evaluated this type of intervention. In the context of potential benefits for smoking reduction⁴¹ and the ongoing debates^{42–43} around the potential benefits and harms of these interventions, further study in properly powered and randomised clinical trials is warranted. Such research should evaluate the benefits and risks of such interventions in comparison to available smoking reduction options for specific groups.

This review is significantly limited due to heterogeneity regarding study type, intervention type and populations. This prevents the possibility of generalising any results. Although several quasi-experimental studies investigated interventions with people experiencing homelessness, no randomised controlled trials were identified.

Despite the fact that smoking remains extremely high in many marginalised groups,^{1,2} there is a relative absence of properly controlled trials with these groups. In this context it is important to note that this review included no studies of members of the Traveller, sex worker or migrant communities. This highlights a significant gap in the research literature that should be addressed in the future.

Conclusion

Future studies should aim to adopt best practice standards in relation to CO measurement as the large variance in cut off points reduces the possibility of comparing study outcomes. Several studies suggest potential mental health benefits arising from participation in smoking reduction-related interventions; such benefits should be explored in properly controlled trials. There is a current lack of RCTs related to smoking related interventions with people experiencing homelessness. Similarly, there is a lack of

properly controlled RCTs exploring the use of ENDS with marginalised populations. Future studies should aim to address these deficits.

Declarations

Ethics approval and consent to participate

N/A

Consent for publication

N/A

Availability of data and materials

Quality Appraisal and Statistical appraisal files are available.

Competing interests

One of the reviewed studies was co-authored by FS, JW, KM and AM. No conflict of interest from AJ

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Authors' contributions

FS, EM, JW, KM and AM developed the protocol for this study. FS completed the literature search. FS, AJ, EM and FS screened the papers. AJ, EM, FS and MG completed the quality control. All authors reviewed the final version of the paper

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Appendix

Appendix 1 is not available with this version.

Figures

Figure 1

PRISMA Flow Chart