**The Efficacy of Tobacco Cessation Interventions for Persons Living with HIV/AIDS: A Systematic Review and Meta-Analysis**

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### Abstract: While the life expectancy of People Living with HIV/AIDS (PLWHA) continues to improve due to advances in HIV treatment, including highly active antiretroviral therapy (HAART), greater attention is focusing on modifiable risk factors that may further reduce morbidity and mortality in PLWHA. One of the most important risk factors is tobacco smoking Knowing that tobacco use is highly prevalent and responsible for significant morbidity and mortality amongst PLWHA (Helleberg et al., 2013), it is of the utmost importance that evidence-based literature be available to support PLWHA, and their healthcare providers. A dedicated review of cessation interventions in PLWHA is justified as the morbidity and mortality of PLWHA somewhat differ from those of other smokers, and despite their motivation to quit, PLWHA often find it challenging to achieve unremitting abstinence from tobacco (Pool, Dogar, Lindsay, Weatherburn, & Siddiqi, 2016).

English language articles from January 2000 through February 2018 were searched. The criteria for inclusion were randomized controlled trials that described a smoking-cessation intervention in PLWHA. The search was conducted from January through March of 2018 and spanned literature published since 2000. Interventions that were not experimental or quasi-experimental (QE), or that were delivered to participants who were not PLWHA, were excluded. The studies were restricted to PLWHA smokers of any age with self-reported cigarette use. Studies were excluded if they were not randomized control trials. Included studies were those with 7-day point prevalence abstinence at weeks 12, 24, or 52; with self-reported abstinence in the past 7 days and exhaled carbon monoxide ≤10 ppm, and continuous, self-reported abstinence since baseline and exhaled carbon monoxide ≤10 ppm at all follow-up visits up to and including weeks 12, 24, or 52. There were no sample size limitations.

Using RevMan the odds ratios (OR) and the weighted pooled OR were calculated across studies. Seven of the 10 clinical trials reported favorable results on the efficacy of treatment. Three of the 10 clinical trials reviewed did not find treatment efficacy. The meta-analysis of the dichotomous 8 studies that evaluated the efficacy of the enhanced care interventions for smoking cessation resulted in a moderate statistically significant effect size for abstinence with an OR of 2.84 (95$ CI 1.93 to 4.17). For the continuous studies, only Shuter et al. was found to be effective with an OR of 4.55 (95% CI 0.11 to 9.21). Heterogeneity of the studies was assessed and found to be Chi² = 12.28, df = 6 (P = 0.06); I² = 51%, and Chi² = 3.62, df = 2 (P = 0.16); I² = 45%, respectively.

It should be noted even when intervention participants were provided nicotine replacement therapy (NRT), there was little to no difference in treatment effect. When readiness to quit, or motivation to quit was assessed either at baseline or follow-up, there was a treatment effect, leading to the conclusion that when no treatment effect was found, the participants may have either been in the pre-contemplation or contemplation stage which may have led to low cessation rates(Keith, Dong, Shuter, & Himelhoch, 2016). Based on the data presented in the included studies, targeted tobacco cessation interventions for PLWHA are effective.

**Introduction**

### Cigarette smoking is the chief cause of preventable disease and death in the United States (U.S.) and is responsible for more than 480,000 deaths every year, about 1 in 5 deaths. Since the initial Surgeon General’s report in 1964, more than 20 million premature deaths can be ascribed to smoking. (Department of Health & Services, n.d.). In 2016, more than 15.5 percent of adults aged 18 years or older in the U.S. were smokers, which translates to 37.8 million active smokers in the United States (Jamal et al., 2018). The Department of Health and Human Services estimates that 16 million Americans live with a smoking-related disease (Department of Health & Services, n.d.). Although current smoking has declined from 20.9 percent in 2005 to 15.5 percent in 2016, smoking prevalence did not change significantly during 2015-2016 (Jamal et al., 2018).

### Despite the success of public health interventions in reducing smoking prevalence, certain subgroups of the population still exhibit an unduly high prevalence of cigarette smoking. Among persons living with human immunodeficiency virus (HIV), and/or acquired immunodeficiency syndrome (AIDS) (PLWHA), the prevalence of cigarette smoking has been estimated to be between 40 to70 percent (Burkhalter, Springer, Chhabra, Ostroff, & Rapkin, 2005; Collins et al., 2001; Lifson et al., 2010). While the life expectancy of PLWHA continues to improve due to advances in HIV treatment, including highly active antiretroviral therapy (HAART), greater attention is focusing on modifiable risk factors that may further reduce morbidity and mortality in PLWHA. One of the most important of these risk factors is tobacco smoking. Causes of illness in PLWHA, including AIDS related and serious non-AIDS related illnesses. Smoking may increase the occurrence of both, as well as impact overall survival. To help current smokers quit, a variety of behavioral and pharmacological intervention strategies have been evaluated and proven to be beneficial ( Lifson & Lando,2012; Palella Jr.et al.,2006).

### Many smoking-related illnesses significantly affect PLWHA. Lung cancer and other malignancies are important causes of death among PLWHA who smoke. As well, HIV infection or use of antiretroviral drugs is attributable to increased risk of cardiovascular disease (CVD) (Aberg, 2009; Bonnet et al., n.d.; Lifson et al., n.d.). Use of effective HAART has resulted in increasing numbers of aging PLWHA, who may develop

### metabolic syndrome, obesity, and other CVD risk factors(Amorosa et al., 2005; Wand et al., 2010). PLWHA may develop a variety of pulmonary diseases, including bacterial pneumonia (Feikin, Feldman, Schuchat, & Janoff, 2004; Madeddu et al., 2008). Because PLWHA are at risk for these serious and life-threatening clinical syndromes, critical prevention questions are whether and to what extent smoking further increases the risk of developing these diseases, especially in the era of HAART.

Initiating tobacco cessation interventions for PLWHA continues to be a challenge. Because many PLWHA are in regular contact with health professionals, it provides an opportunity for tobacco cessation interventions to be initiated. However, despite recognizing the importance of tobacco cessation among PLWHA, HIV clinicians report a lack of confidence in initiating cessation therapies. (Shuter et al., 2012). Despite 80 percent of PLWHA reporting quit attempts (Shuter, Moadel, Kim, Weinberger, & Stanton, 2014), and a high proportion of PLWHA reporting that they are motivated to quit or remain motivated to quit (Bénard et al., 2010; Shuter et al., 2014), smoking prevalence remains high, which reflects an unmet need for effective tobacco cessation interventions. There is need for transparency in how to provide tobacco cessation interventions to PLWHA, whether it is brief advice, motivational interviewing ,pharmacological, behavioral, or a combination of methods. Behavioral interventions may include group or individual counselling, advice and encouragement. Pharmacological interventions may include use of nicotine replacement therapy (NRT), bupropion or varenicline. Previous studies have reported that individual pharmacotherapies coupled with behavioral interventions can be effective for tobacco cessation (Stead, Koilpillai, Fanshawe, & Lancaster, 2016).

Knowing that tobacco use is highly prevalent and responsible for significant morbidity and mortality among PLWHA (Helleberg et al., 2013), it is of the utmost importance that evidence-based literature be available to support PLWHA, and their healthcare providers. A dedicated review of cessation interventions in PLWHA is justified as the morbidity and mortality of PLWHA somewhat differ from those of other smokers, and despite their motivation to quit, PLWHA often find it challenging to achieve unremitting abstinence from tobacco (Pool, Dogar, Lindsay, Weatherburn, & Siddiqi,2016).

### Methods

**Eligibility Criteria**

English language articles from January 2000 through February 2018 were searched. The criteria for inclusion were randomized controlled trials that described a smoking-cessation intervention in PLWHA. The study search was conducted from January through March of 2018 and spanned literature published since 2000. Interventions that were not experimental or quasi-experimental (QE) or that were delivered to participants who were not PLWHA, were excluded. The studies were restricted to PLWHA smokers of any age with self-reported cigarette use. Studies were excluded if they were not randomized control trials. Included studies were those with 7-day point prevalence abstinence at weeks 12, 24, or 52; with self-reported abstinence in the past 7 days and exhaled carbon monoxide ≤10 ppm, and continuous, self-reported abstinence since baseline and exhaled carbon monoxide ≤10 ppm at all follow-up visits up to and including weeks 12, 24, or 52. There were no sample size limitations.

Information Sources

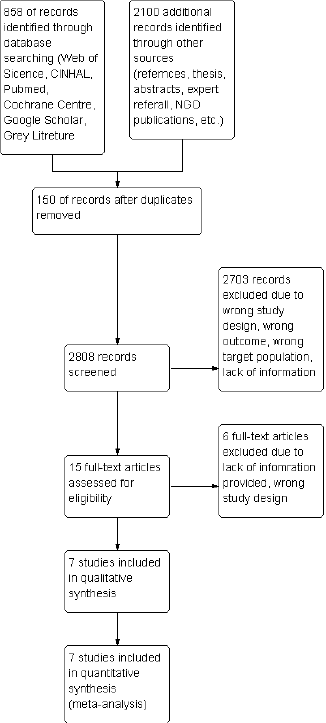
Web of Science (2000 to 03/2018), CINHAL (2000 to 02/2016), PubMed (2000 to 03/2018), Cochrane (2000 to 03/2018), Google Scholar (2000 to 03/2016), and a literature review through bibliographies of related articles were searched.

**Search**

The electronic search strategy was conducted on Web of Science, CINHAL, PubMed, Cochrane, and Google Scholar using the following search terms: smoking cessation, tobacco use cessation, acquired immunodeficiency syndrome, HIV, immune compromised, smokers, behavioral intervention, therapy, nicotine replacement therapy, individual therapy, group therapy, counseling, online, internet, cell phone, and telephone. Search filters were used to restrict studies to randomized controlled trials, published in English. Google Scholar search included the key phrases such as HIV, randomized controlled trials, and smoking cessation. The bibliographies of included articles were searched for any additional studies.

**Study Selection**

Search results were reviewed for any duplicate studies. Two authors (O.B. and S.H.) independently reviewed all study titles and abstracts for eligibility criteria. If studies met the eligibility criteria through title and abstract, the full article was reviewed. Seventeen full articles were reviewed, and 7 were selected (see Figure 1.). The reviewers independently reviewed the titles and abstracts of articles retrieved. Differences in inclusion articles were resolved through discussion. Both reviewers independently extracted data from included articles using a standardized extraction form developed by the reviewers. The primary outcomes of interest were self-reported 7-day point prevalence abstinence at follow-up, biochemically verified abstinence, and continuous abstinence ranging from 1-month through 12-month follow-up.

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**Figure 1 Study Identification**

**Risk of Bias in Individual Studies**

All included studies were independently reviewed by two reviewers and the validity and reliability were determined according to the ‘Cochrane Risk of Bias Tool’, including allocation concealment, blinding, completeness of outcome data reporting, selective outcome reporting, and presence of other sources of bias (see Figures 2 and 3). All included studies were reasoned to be of high quality and free of selective outcome reporting or incomplete outcome reporting.

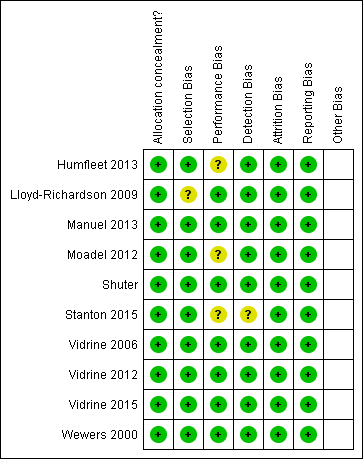
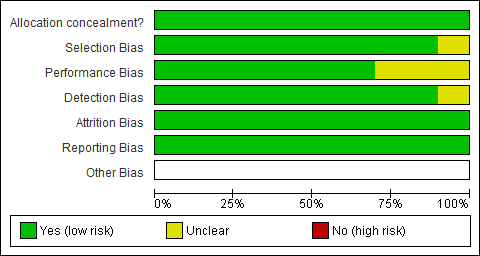


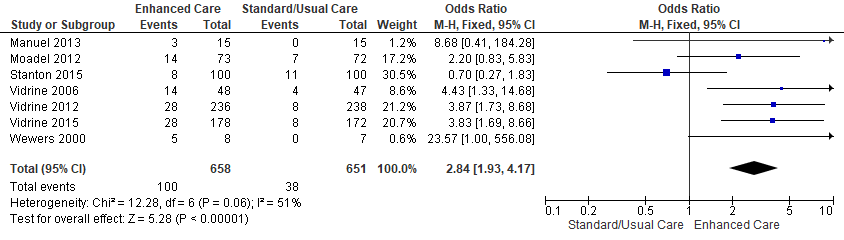
Figure 2 Risk of Bias Summary: Review Authors' Judgements of Bias for Each Included Study



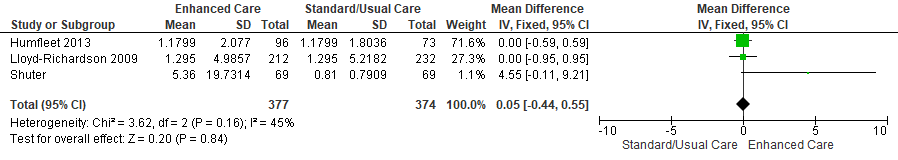
**Figure 3 Risk of Bias Graph: Review Authors' Judgements about Each Included Study**

Using RevMan the odds ratios (OR) and the weighted pooled OR were calculated across studies. The Mantel–Haenszel method (fixed effects) model was used to provide weight estimates for the five studies with dichotomous outcomes, and the Inverse Variance method for the two continuous studies, using the mean-difference. The Q statistic and I2 statistic were used to evaluate heterogeneity. The Q statistic quantifies the magnitude of heterogeneity, whereas the I2 statistic quantifies the total variation due to between-study variance (see Figures 4 and 5). Publication bias was not formally tested, as tests for publication bias (e.g., funnel plot) may be too low to distinguish chance from real asymmetry when using meta-analytic techniques with 10 studies or less (Ioannidis & Trikalinos, 2007).

Figure 3 Forest plot of comparison: Enhanced Care vs Standard Usual Care-Dichotomous.



**Figure 5 Forest plot of comparison: Enhanced Care vs Standard Usual Care-Continuous.**



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### Results

Seven of the 10 clinical trials reported favorable results on the efficacy of treatment. Manuel et al. detected no significant differences between intervention (n=15) and control groups (n=15) in self-reported 7-day point prevalence abstinence at the one-month follow-up, with only one participant in the intervention group reporting abstinence. Urinalysis testing for nicotine and cotinine was performed on two of the urine samples, with. Of the two urine samples analyzed, only one confirmed nicotine and tobacco abstinence (Manuel, Lum, Hengl, & Sorensen, 2013). Moadel et al. reported found, in the intention to treat analysis, Intervention participants (n=73) had nearly double the quit rate of participants receiving standard/usual care (n= 72), at 19.2% vs 9.7% respectively (Moadel et al., 2012).

Vidrine et al found a statistically significant increase in abstinence at 3 months among the intervention group (n = 48) with a rate of 36.8%, compared to standard/usual care control group (n =

47) with rates at 10.3% (Vidrine, Arduino, Lazev, & Gritz, 2006). A larger study conducted by Vidrine et al found a statistically significant increase in abstinence at 3 months for those randomized to the telephone group (n = 236), with a rate of 11.9%, compared to the control group (n = 238), with a rate of 3.4% (Vidrine, Marks, Arduino, & Gritz, 2012). In an ancillary study to test for mediating factors, from the 444 participants, Vidrine et al., chose 350 participants for the analytical sample. The abstinence rate for the standard/usual care control group (n=172) was 4.7%, while the abstinence rates for the intervention group (n=178) were at 15.7% (Vidrine et al., 2015).

Wewers et al. found a significant increase in abstinence at 8 weeks for those randomized into the intervention group(n=8), compared to those in the standard/usual care control group(n=7) at 67.5% vs. 0%, verified by expired air carbon monoxide (ECO) < 8. Shuter et al. found no difference in abstinence at 3 months among those in the intervention group (n = 69), with abstinence at 10.3%, compared to standard/usual care control group (n = 69) with abstinence at 4.3% (Shuter, Morales, Considine-Dunn, An, & Stanton, n.d.-a)

Three of the 10 clinical trials reviewed did not find treatment efficacy. Humfleet et al. found no difference in abstinence at 52 weeks among those randomized to either a counseling intervention (n = 69), with abstinence at 20.4%, or computer-based intervention (n = 58), with abstinence at 25.6%, compared to standard/usual care control (n = 82) with abstinence at 19.8% (Humfleet, Hall, Delucchi, & Dilley, 2013). Lloyd-Richardson et al. found no difference in abstinence at 6 months among those among the intervention group (n=232), with abstinence at 9 %, compared to those in standard/usual care control group (n= 212), with abstinence rates at 10% (Lloyd-Richardson et al., 2009). Stanton et al. found no significant differences in the intervention group (n = 131), with abstinence rates at 8.5%, compared to enhanced standard/usual care (n = 131), with abstinence rates of 9.1% (Stanton et al., 2015) (see Table 1).

Table 1 Intervention Outcomes for Tobacco Cessation for PLWHA

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Author/Year | Intervention | Follow-Up | Total #  Of  Participants | Intervention Abstinence Rate | Standard/Usual Care Abstinence Rate | Abstinence Definition |
| Manuel 2013 | Enhanced care (Brief Motivational Interview) vs. brief counseling (Prescribed Advice) | 1 mo | 30 | 20.0% | 0.0% | Urinalysis testing for nicotine and cotinine |
| Moadel 2012 | 8 group therapy  sessions + NRT  vs. brief counseling + NRT | 3 mo | 145 | 19.2% | 9.7% | ≥10 ppm ECO-  verified PPA |
| Stanton 2015 | 4 intervention sessions  + NRT vs. 2 brief advice (enhanced standard care) + NRT | 6 mo  12 mo | 302 | 6 mo: 8%  12 mo:6% | 6 mo: 11%  12 mo: 7% | ≥10 ppm ECO-  verified PPA |
| Vidrine 2006 | 8 one-on-one telephone  counseling sessions + NRT vs. brief  counseling + NRT | 3 mo | 95 | 16.7% | 6.4% | ≥7 ppm ECO-  verified PPA |
| Vidrine 2012 | 11 one-on-one telephone  counseling sessions + NRT vs. brief  counseling + NRT | 3 mo | 474 | 11.9% | 3.4% | ≥7 ppm ECO-  verified PPA |
| Vidrine 2015 | Data for this ancillary study derived from Vidrine 2012 | 3 mo | 350 | 15.7% | 4.7% | ≥7 ppm ECO-  verified PPA |
| Wewers 2000 | 8 telephone counseling  sessions + offer of NRT vs. self-help | 2 mo | 15 | 62.5% | 0.0% | 8 ppm ECO-  verified PPA |
| Humfleet 2013 | 6 in-person  counseling sessions + NRT vs. 5 web sessions  vs. brief counseling | 12 mo | 209 | IC: 20.4%;  CBI: 25.6% | SH: 19.7% | ≥10 ppm ECO-  verified PPA |
| Lloyd-Richardson 2009 | 4 motivational  interviewing sessions +  NRT vs. 2 counseling sessions + NR | 2 mo  4 mo  6 mo | 444 | 9% | 10% | ≥10 ppm ECO-  verified PPA |
| Shuter 2014 | 8 sessions of web-based  intervention + NRT vs. briefcounseling + NRT | 3 mo | 138 | 10.1% | 4.3% | ≥10 ppm ECO-  verified PPA |
| NRT = Nicotine Replacement Therapy  ECO = Expelled Carbon Monoxide | | | | | | |

Meta-Analysis Results

The meta-analysis of the dichotomous 8 studies that evaluated the efficacy of the enhanced care interventions for smoking cessation resulted in a moderate statistically significant effect size for abstinence with an OR of 2.84 (95$ CI 1.93 to 4.17). For the continuous studies, only Shuter et al. was found to be effective with an OR of 4.55 (95% CI 0.11 to 9.21). Heterogeneity of the studies was

assessed and found to be Chi² = 12.28, df = 6 (P = 0.06); I² = 51%, and Chi² = 3.62, df = 2 (P = 0.16); I² = 45%, respectively.

### Discussion

This systematic review and meta-analysis of the 10 randomized controlled trials of tobacco cessation interventions for PLWHA demonstrated a meaningful effect in terms of increasing the odds at long-term tobacco cessation for PLWHA. Studies that integrated longer counseling and support sessions had a significant effect on long-term smoking cessation, while studies with shorter therapies did not yield significant results. These results suggest that providing longer, or even a greater number of sessions, is a contributing factor to long term cessation.

The delivery of the interventions differed between trials. Three studies used cell phone-based interventions, that provided support via text messaging counseling (Vidrine et al., 2015, 2006, 2012). One used group therapy (Lloyd-Richardson et al., 2009). Two used computer-based interventions (Humfleet et al., 2009; Shuter, Morales, Considine-Dunn, An, & Stanton, n.d.-b) and 3 used individual therapy (Humfleet et al., 2009; Lloyd-Richardson et al., 2009; Stanton et al., 2015). The 2 web-based interventions had no significant results but did however, have the advantages of ease in scheduling, ease of access, and low cost. Both interventions employed software that was at the sixth-grade reading level. Shuter et al excluded participants with low literacy scores, while Humfleet et al did not, which may be of note because Shuter et al reports higher educational levels were associated with more website visits and was also associated with higher cessation rates. This suggests that literacy or experience using the web-based may be important mediators and predictors of the success of a web-based intervention.

Wewers et al. used lay facilitators, or peer health educators, and yielded statistically significant results, demonstrating the advantage of peer-based interventions is that they may bridge potential barriers, suggesting that this method of intervention may be one of the best ways to deliver tobacco cessation interventions. It should be noted even when intervention participants were provided NRT, there was little to no difference in treatment effect. When readiness to quit, or motivation to quit was assessed either at baseline or follow-up, there was a treatment effect, leading to the conclusion that when no treatment effect was found, the participants may have either been in the pre-contemplation or contemplation stage which may have led to low cessation rates (Keith, Dong, Shuter, & Himelhoch, 2016). Based on the data presented in the included studies, targeted tobacco cessation interventions for PLWHA are effective. The future should assess readiness to quit and may need to assess literacy as these were the two modifying factors leading to greater efficacy of the intervention.

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Consent for publication: All authors consent for publication

Availability of data and material: NA

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Authors' contributions: OB was responsible for conceptualizing the idea, searching databases, screening papers, data extraction and data analysis. SH was responsible as a second screener and data extractor. SJ was the supervising mentor for the student (OB), analyzed the data, critically appraised the manuscript. JBF edited the manuscript and critically appraised the article and JNI critically appraised the study.

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