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RESEARCH ARTICLE



Serial mediation between self-efficacy and motivation as a mechanism of change in tobacco cessation: analysis of the Guided Self-Change therapy effectiveness

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ABSTRACT

Background: Behavioral interventions are effective for smoking cessation; however, little is known about the underlying mechanisms of treatment outcomes. Self-efficacy and motivation to quit are two central mediators of therapy success, however, their interaction during tobacco cessation remains unclear. The aims of this study were to analyze the effectiveness of Guided Self-Change (GSC) therapy for smoking cessation and to examine parallel and serial mediation between self-efficacy and motivation during therapy.

Method: We conducted a one-group pretest-posttest design with the participation of 145 treatment-seeking smokers (age $= 55.8 \pm 10.3$ years; 59.3% women) from the General University Hospital of Alicante. We assessed participants' daily tobacco use, self-efficacy, and motivation to quit at baseline and at the end of treatment. Descriptive, bivariate, and mediation analyses were performed.

Results: A total of 49% ($n\!=\!71$) of participants completed GSC therapy (3–5 sessions), of which 52.1% ($n\!=\!37$) stopped using tobacco after treatment (McNemar's $p\!<\!0.001$; $\theta\!=\!5.85$). Mediation analyses showed GSC therapy significantly increased ($p\!<\!0.01$) both self-efficacy ($a_1\!=\!1.19$; 95%CI = 0.47, 1.91) and motivation ($a_2\!=\!1.95$; 95%CI = 1.34, 2.56). However, only the serial path from self-efficacy to motivation to quit showed significant indirect effects in tobacco reduction ($a_1a_3b_2\!=\!-0.29$; 95%CI=-1.1, 0.03; Z=-4.36; $p\!<\!0.001$).

Conclusions: GSC therapy demonstrated effectiveness in quitting smoking by partially increasing self-efficacy, which in turn enhanced motivation to quit leading to a reduction of use. These findings expand empirical knowledge about theorized mechanisms of change in addictive behaviors that could contribute to improving psychological interventions.

ARTICLE HISTORY

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KEYWORDS

Motivation; self-efficacy; tobacco; smoking; mediation; behavior change

1. Introduction

Tobacco use causes over 7 million deaths worldwide every year, nonetheless, more than one billion people are current smokers, placing tobacco cessation as a priority in public health (Global Burden of Disease, 2021). The costs associated with smoking are noticeable in healthcare expenses for treating smoking-related illnesses, such as cancer, cardiovascular disease, or lung diseases among others (Larsson and Burgess 2022). Additional costs are attributed to reduced workforce productivity due to morbidity and premature mortality caused by tobacco (Rey-Brandariz et al. 2023), amounting to nearly 6% of global health expenditures (Goodchild et al. 2018; Nargis et al. 2022).

The implementation of behavioral interventions has proven to be efficacy in smoking cessation (Wray et al. 2018), and can improve quitting rates when combined with pharmacotherapies, which can contribute to reducing healthcare expenses and prevent smoking-related diseases (Hartmann-

Boyce et al. 2019; Duncan et al. 2019). However, successful attempts to quit still remain low (García-Rodríguez et al. 2013; Robinson et al. 2019) and treatment mechanisms for tobacco cessation need further study.

Regarding this, recent literature suggests that self-efficacy and motivation to quit act as two key mechanisms of change in smoking cessation (Klemperer et al. 2017; Hopkins et al. 2022). Self-efficacy refers to the person's perception of her or his capacity to successfully achieve a goal (Bandura 1977). In tobacco addiction, self-efficacy refers to smokers' belief about their ability to quit, or their confidence to change their smoking behavior (Elshatarat et al. 2016). Hence, self-efficacy is often considered both a coping resource and an indicator of treatment success (Boudreaux et al. 2012; Porcaro et al. 2021). Smokers with low confidence in their ability to quit are more likely to fail on their quit attempts compared to those with a positive perception (Hopkins et al. 2022). In this sense, self-efficacy acts as a central mediator

in treatments for smoking treatments (Vidrine et al. 2015; Li et al. 2015; Klemperer et al. 2017; Lepore et al. 2019).

Similarly, motivation to quit has surfaced as another underlying mechanism of treatment success (Klemperer et al. 2020; Hopkins et al. 2022). Motivation refers to the state of readiness to change that gives purpose to achieving a particular behavior (Miller & Rollnick, 1991). Smokers with higher levels of motivation to quit have more chances of successfully quitting smoking (OR = 1.36-4.88) than unmotivated smokers (Piñeiro et al. 2016; Klemperer et al. 2020). Behavioral interventions aimed at enhancing motivation have demonstrated that motivation represents a psychological moderator and mediator of tobacco cessation (Klemperer et al. 2017; Catley et al. 2021)

Although self-efficacy and motivation stand as two recognized mechanisms of behavior change, few studies have analyzed their joint effect or their interaction during tobacco cessation. Based on Social Cognitive Theory (SCT; Bandura 1977), motivation seems to contribute to the willingness to undertake a goal, while achieving that goal may increase one's perception of self-efficacy (Bandura 1977; Bandura 1989). On the other hand, the perception of self-confidence in achieving a goal may increase motivation to achieve and maintain that goal (Bandura 1977; Bandura 1989). Theoretically, both constructs act as precursors of each other, contributing to behavior change. However, the empirical evidence about how they interact is limited and suggests that they fluctuate in a dynamic process of change (Hopkins et al. 2022).

In this regard, several interventions have been designed to improve these two mechanisms of change, with the Guided Self-Change (GSC) therapy (Sobell and Sobell 1998) being endorsed by the American Psychological Association (APA) Division 12 as a recommended approach for treating substance use (APA 2017). The GSC emerged as a brief therapy and cost-effective intervention to reduce substance use following a motivational cognitive-behavioral approach (Sobell and Sobell 1998; Sobell and Sobell 2005). In contrast to other behavioral interventions, GSC therapy takes a nonconfrontational approach aimed at minimizing ambivalence and increasing motivation to stop using drugs. Furthermore, GSC therapy incorporates the development of action plans to effectively manage potential relapse situations and it focuses on reinforcing positive changes in behavior, thereby enhancing smokers' confidence in their ability to change behaviors (Sobell and Sobell 2011). This therapy has demonstrated to be effective in individual and group interventions for alcohol use and other drugs (Sobell et al. 2009). However, few studies have analyzed GSC effectiveness for smoking cessation (Zarghami et al. 2019) and the GSC underlying mechanisms of treatment success.

Based on this, and the importance of understanding quitting-related factors to improve interventions, the aims of this study were: (1) to analyze the effectiveness of GSC therapy among smokers willing to quit; and (2) to analyze how self-efficacy and motivation interact as mediators of treatment outcomes. Our hypotheses held that GSC would decrease tobacco use in smokers through the enhancement

of self-efficacy and motivation to quit; and that improvement of these psychological variables would contribute to an enhancement of each.

2. Materials and methods

2.1. Participants

We performed a power analysis to estimate the required minimal sample for assessing the pre-post differences for within-participants. With a significance level of 0.05, statistical power of 0.8, and a desired medium effect size of 0.5 (Sharifpour et al. 2020), a minimum sample size of n = 41 participants was estimated for this study. Given the high percentage of dropouts during smoking treatment (37%) (Garey et al. 2020), we increased the minimal sample size of 56 participants.

Eligibility criteria included being over the age of majority (\geq 18 years), meeting diagnostic criteria for nicotine addiction according to the Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-5; American Psychiatric Association 2013), and being eligible for varenicline treatment. A total of 148 participants from the Tobacco Unit met inclusion criteria, of which n=3 were discarded because they stopped smoking before the baseline assessment.

As shown in Table 1, the mean age of eligible participants (n = 145) was 55.8 years (SD = 10.3; range = 21–78), the majority were women (59.3%; n = 86), with secondary level education (60%; n = 87) and were married or in a stable relationship (66.9%; n = 97).

2.2. Variables and measures

The sociodemographic variables of sex, age, marital status, and educational level were assessed with an *ad hoc* semi-structured interview.

Table 1. Sample characteristics at baseline (N = 145).

	% (n)
Women	59.3 (86)
Marital status	
Married/stable relationship	66.9 (97)
Single or divorced	27.6 (40)
Widowed	5.5 (8)
Education level	
Elementary education	20 (29)
Secondary education	60 (87)
Postsecondary education	20 (29)
	mean (SD)
Age	55.8 (10.3)
Tobacco use	
Daily cigarettes	17 (8.6)
FTND	5.5 (2.1)
Years smoking	34.5 (12)
Number of quit attempts	2.4 (2.3)
Psychological variables	
Motivation	6.9 (2)
Self-efficacy	7.3 (2.3)
Attended GSC sessions	2.3 (2.1)
n: number of participants; SD: Standard Devia	ition: FTND: Fagerström Test for

n: number of participants; SD: Standard Deviation; FTND: Fagerström Test fo Nicotine Dependence.

We used the TimeLine Follow-Back (TLFB; Sobell and Sobell, 1992) to assess daily tobacco use. The TLFB uses a calendar to retrospectively register the number of daily cigarettes. This measure has demonstrated adequate validity in estimating daily tobacco use up to 12 months prior to the interview (Robinson et al. 2014). In this study, we asked participants for the last 7 days prior to the assessments.

Nicotine addiction was evaluated with the 6-item Fagerström Test for Nicotine Dependence (FTND; Heatherton et al. 1991). Total scores range from 0-10, where values ≤ 4 indicate low, < 6 medium, and ≥ 6 high levels of addiction. The FTND is a reliable ($\alpha = 0.7$) and valid measure to evaluate the degree of nicotine addiction in the Spanish population (Becoña and Vázquez 1998).

Motivation to quit and self-efficacy were assessed with the Readiness Ruler and the Confidence Ruler, respectively (Miller and Rollnick 1991). Each ruler uses a single-item scale of 10 points to evaluate motivation as a state of readiness to change, and self-efficacy as the confidence perceived to achieve abstinence. Scores for motivation range from 1, Definitely not ready to change, and 10, Definitely ready to change. Scores for self-efficacy range from 1, Not confident at all to achieved abstinence, to 10, Most confident to achieved abstinence. Both tools have been widely used demonstrating predictive validity for behavior change in smoking cessation (Boudreaux et al. 2012).

2.3. Smoking treatment

Guided Self-Change Therapy (Sobell and Sobell, 2011) for smoking cessation consisted of 5 group-sessions (4-8 people) of 90 min. Sessions were delivered once a week over 5 consecutive weeks by a health psychologist with GSC and motivational interview training. Following a cognitive-behavioral approach, sessions of GSC therapy focus on psychoeducation of tobacco cessation, reduction of inconsistencies between smoking behaviors and participants' goals, increasing the motivation to quit, identification of high-risk situations, and establishment of action plans to prevent relapse (Sobell and Sobell 2005). In addition to GSC therapy, the medical head of the Tobacco Unit prescribed varenicline for 12 weeks to all participants.

2.4. Procedure

The design of this study corresponds to a one-group pretestposttest design and involved treatment-seeking smokers from the Tobacco Unit of the General University Hospital of Alicante (GUHA). Through convenience sampling, we recruited smokers who were referred to varenicline treatment combined with GSC therapy. Before initiating treatment, we informed patients about the characteristics of the study and the anonymity of the data provided. Eligible participants who expressed interest in participating provided written informed consent and underwent the baseline assessment interview.

All participants were scheduled for two monthly appointments over a period of 3 months to receive supervision for varenicline use and for one weekly GSC group session of 90 min for 5 consecutive weeks. Tobacco use was assessed at the Tobacco Unit at baseline and during the 5 GSC sessions. In addition, participants' motivation to quit and self-efficacy were assessed at baseline and at GSC session 5.

Participants did not receive any compensation for their collaboration in this study. Ethical approval for this study was granted by the Clinical Research Ethics Committee of the GUHA (Reference: PI2019/096).

2.5. Data analyses

We performed descriptive analyses for sample characteristics (means, standard deviations, and frequencies), pretest-posttest comparisons, and mediation analyses using the statistical software SPSS version 26. We performed a repeated measures Analysis Of Variance (ANOVA) for within-participants comparisons in continuous variables including participants who completed GSC therapy (≥ 3 sessions; n = 71; Garey et al. 2020). We used a seven-day point prevalence abstinence measurement as the success criteria. To control the effects of varenicline use during GSC therapy, we also performed an ANCOVA to analyze interaction effects. Here, we included the time using varenicline (in weeks) as a covariate. We also tested the effects of sociodemographic variables (age, sex, marital status, and education level). We estimated omega squared (ω^2) effect size, where values > 0.01 indicate a small effect, > 0.06 moderate, and > 0.14 large (Keren and Lewis 1979).

For binominal variables, we used McNemar test for repeated observations. We calculated McNemar's effect size with an odds ratio (θ) where values >0.05 represent weak effect size, >0.1 moderate, >0.15 strong, and >0.25 very strong (Cramér 1946).

We used the macro MEMORE to estimate mediation in two-occasion within-participants (Montoya and Hayes 2017) using a path-analytical framework with ordinary least squares regressions. We estimated the total, direct, and indirect effects of X (two repeated measurements) on Y (tobacco use changes) through change scores of mediators (motivation and self-efficacy) between the pretest and posttest. Mediation was examined using a bias-corrected bootstrap of 95% confidence interval with 5000 replications including those participants who completed the post-test assessment. We first tested parallel mediation in which the effects of motivation and self-efficacy were analyzed simultaneously accounting for shared variances. Next, we examined serial mediation. Since motivation and self-efficacy could theoretically enhance each other (Bandura 1977), we tested motivation as the predecessor of self-efficacy, as well as self-efficacy as the predecessor of motivation. Results were interpreted based on a 95% level of significance.

3. Results

3.1. Participants' smoking and treatment characteristics

Participants were daily smokers for an average of 34.5 years (SD = 12) and had made 2.4 previous attempts at quitting (SD = 2.3). At baseline, the average daily to bacco use was 17 cigarettes (SD = 8.6) with moderate nicotine addiction (FTND = 5.5; SD = 2.1) (Heatherton et al. 1991). As seen in Table 1, participants showed medium to high scores in motivation to quit (M=6.9; SD = 2) and self-efficacy (M=7.3; SD = 2.3) at baseline.

As shown in Figure 1, 61.4% (n = 89) started GSC therapy, of which 79.8% (n = 71) completed the intervention (≥ 3 sessions; Garey et al. 2020). On the other hand, the percentage of participants who initiated varenicline treatment was 53.8% (n = 78), but only 15.2% (n = 22) complied with the prescription (>9 weeks; Vrijens et al. 2012).

3.2. Effectiveness of GSC therapy for tobacco cessation

As illustrated in Figure 2, to bacco use decreased during GSC therapy. Before initiating the rapy, 15.5% of participants (n=11) quit to bacco and the number of daily cigarettes significantly decreased from 17.2 (SD = 9.4) at baseline to 9.8 (SD = 7.9) at session 1 (F=37.9; n=67; $\omega^2=0.35$; p<0.001).

During the five sessions of GSC therapy, the percentage of quitters significantly increased up to 52.1% (n=37; $\theta=5.85$; McNemar's p<0.001), and the daily smoking was significantly reduced between session 1 (10.4 cigarettes; SD = 8.2) and session 5 (2.9 cigarettes; SD = 5.1) yielding a large effect size (F=64.2; n=57; $\omega^2=0.52$; p<0.001). Based on ANCOVA, the tobacco reduction was significant regardless of the number of weeks taking varenicline (F=0.5; $\omega^2=0.01$; p=0.491). Therefore, the effectiveness of GSC therapy in reducing tobacco use was consistent despite

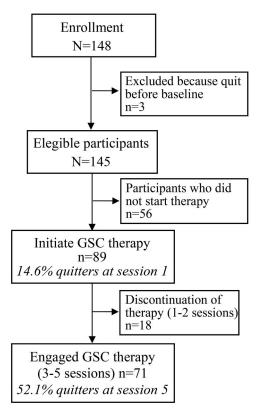


Figure 1. Flowchart of participants through the study.

the effect of using varenicline. Likewise, none of the sociode-mographic variables showed a significant effect on treatment outcomes (p > 0.7).

3.3. Motivation and self-efficacy mediation analyses

Self-efficacy scores at baseline significantly increased from 7.5 points (SD = 2.5) to 8.6 (SD = 1.6) at session 5 (F=11.1; p=0.002), with a large effect size (ω^2 =0.15). Motivation also increased from 7.1 points at baseline to 8.9 (SD = 1.5) at session 5 (F=42.7; p<0.001) with a large effect size (ω^2 =0.38). Since both mechanisms of behavior change significantly increased after GSC therapy, mediation analyses were performed to explore how changes in self-efficacy and motivation impacted daily tobacco use reduction.

3.3.1. Parallel mediation

As shown in Figure 3, parallel mediation showed significant total effects of GSC therapy in reducing tobacco of c=13.24 (95%CI=-15.56, -10.92; p < 0.001). Significant paths were also found in self-efficacy (a_1 =1.19; 95%CI = 0.47, 1.91; p = 0.002) and in motivation to quit (a_2 =1.95; 95%CI = 1.34, 2.56; p < 0.001), which suggests GSC therapy contributed to improving both psychological dimensions. However, the changes in self-efficacy (a_1b_1 =0.14; 95%CI=-0.94, 1.618; p = 0.846) and motivation to quit (a_2b_2 =-1.72; 95%CI=-3.465, 0.999; p = 0.162) did not mediate the reduction of tobacco use after treatment.

3.3.2. Serial mediation

First, we analyzed motivation as a precursor of self-efficacy. GSC direct effects were statistically significant (c'=-11.66; 95%CI=-14.89, -8.42; p < 0.001), as well as the path to motivation to quit ($a_2=1.95$; 95%CI = 1.34, 2.56; p < 0.001), and the path from motivation to quit to self-efficacy ($a_3=0.38$; 95%CI= 0.05, 0.71; p=0.03). As illustrated in Figure 4, GSC appears to improve motivation, which in turn increased self-efficacy; however, mediation effects were non-significant when motivation acted as a precursor of self-efficacy for reducing tobacco use ($a_1a_3b_2=0.09$; 95%CI=-0.61, 1.45; Z=0.43; p=0.666).

We then examined self-efficacy as a precursor of motivation to quit. As observed in Figure 4, serial mediation was statistically significant ($a_1a_3b_2=-0.29$; 95%CI=-1.1, 0.03; Z=-4.36; p < 0.001). In this case, GSC therapy increased self-efficacy ($a_1=1.19$; 95%CI = 0.47, 1.91; p=0.002), which contributed to increased motivation ($a_3=0.27$; 95%CI = 0.01, 0.53; p=0.039) and consequently helped reduce daily tobacco use ($b_2=-0.88$; 95%CI=-2.13, 0.36; p=0.159). GSC direct effects of pre-post tobacco use were c'=-12.95 (p < 0.001) suggesting that, besides motivation and self-efficacy, other mechanisms of behavior change contribute to reducing tobacco use. See Figure 4.

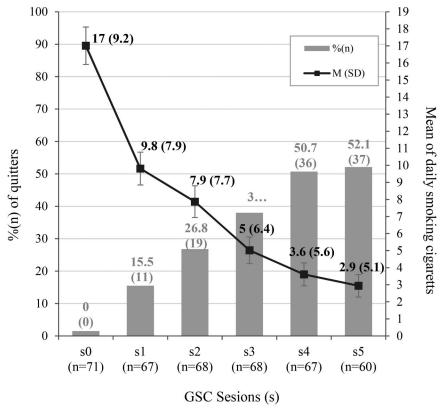


Figure 2. Percentage of quitters (%) and reduction of daily tobacco use during the Guided Self-Change (GSC) therapy in participants who attended therapy (≥3 sessions). n: number of participants; M: Mean of daily cigarettes with standard error bars; SD: Standard deviation; s: session of GSC therapy.

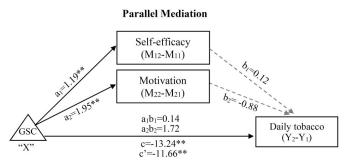
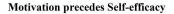


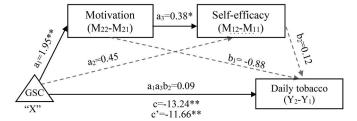
Figure 3. Parallel mediation of self-efficacy (M₁) and motivation (M₂) over tobacco reduction (Y) between baseline and post Guided Self-Change (GSC). e. Continuous lines represent significant paths whereas dashed lines represent non-significant paths. a_1 and a_2 : effect of GSC therapy over self-efficacy and motivation; b_1 and b_2 : effect of self-efficacy and motivation changes over tobacco reduction; a_1b_1 : indirect effects of self-efficacy in tobacco reduction; a_2b_2 : indirect effects of motivation in tobacco reduction; c: total effects of GSC therapy over tobacco reduction including mediators' indirect effects; c': direct effect of GSC therapy over tobacco reduction controlling mediators' effects. Reported effects are unstandardized. *p < 0.05; **p < 0.01

4. Discussion

The aims of this study were to analyze GSC effectiveness for smoking cessation, and to examine mediation effects of self-efficacy and motivation to quit. Our results confirmed the hypothesis that GSC therapy contributes to smoking cessation, partially due to the serial mediation between self-efficacy and motivation.

Participants reduced tobacco use during GSC therapy and the abstinence rates among those who initiated intervention





Self-efficacy precedes Motivation

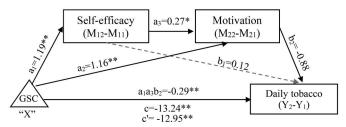


Figure 4. Serial mediation models between self-efficacy (M_1) and motivation (M_2) over tobacco reduction (Y) between baseline and post Guided Self-Change (GSC). *Note.* Continuous lines represent significant paths whereas dashed lines represent non-significant paths. a_1 and a_2 : effect of GSC implementation over self-efficacy and motivation; b_1 and b_2 : effect of self-efficacy and motivation changes over tobacco reduction; a_3 : effect of the first mediator over the second mediator; $a_1a_3b_2$: serial indirect effects of the first mediator through the second mediator over tobacco reduction; total effects of GSC therapy over tobacco reduction including mediators' indirect effects; c: direct effect of GSC therapy over tobacco reduction controlling mediators' effects. Reported effects are unstandardized. *p < 0.05; **p < 0.01.

reached 41.6% (37/89). Interestingly, around 15% of participants quit tobacco before starting treatment, which could be due to initial levels of motivation to quit (Piñeiro et al. 2016; Klemperer et al. 2020). Besides this, tobacco reduction after GSC therapy was significant despite the effect of varenicline, which supports GSC effectiveness. This result concurs with previous studies, where implementation of GSC therapy increased quit attempts and reduced tobacco use in a short period of time regardless of pharmacotherapies (Zarghami et al. 2019). On the other hand, the percentage of participants who completed GSC therapy concurs with the attendance patterns of previous studies, in which receiving at least 3 therapy sessions increases the likelihood of successful attempts to quit (Garey et al. 2020).

Mediation analyses revealed that GSC increased motivation to guit and self-efficacy, and that the interaction of these dimensions contributed to reducing tobacco use, as previously stated (Sobell and Sobell 2005). Consistently with SCT, motivation and self-efficacy showed a reciprocal relationship (Bandura 1977; Bandura 1989), and only the serial path from self-efficacy to motivation demonstrated changes in smoking behavior. These results concur with previous studies where the implementation of self-control tasks to quit tobacco increased the motivation to quit (Weinberger et al. 2022). In this sense, our findings suggest that although increasing motivation to change represents a key mechanism of treatment success (Hopkins et al. 2022), smokers might need to feel highly efficacious in achieving abstinence in order to change their behavior.

Conversely, results showed that self-efficacy on its own would not change smokers' behavior, perhaps because they need to consider the reward for quitting as a sufficient motivation to change (Bandura 1977; Martins et al. 2021). Therefore, both motivation and self-efficacy act as mechanisms of change, however, self-efficacy appears to drive the dynamic process of behavior change and boost motivation to quit.

Previous studies have analyzed the mediation effects of self-efficacy and motivation jointly, concluding that self-efficacy has a greater impact on quitting than motivation (Hendricks et al. 2010; Vidrine et al. 2015; Hoeppner et al. 2017). However, our results indicate that mediation analyses need to consider the interaction of these two dimensions, rather than treating them individually. Although the perspective of serial paths expands theorized mechanisms of change (Catley et al. 2021), more empirical studies are needed to examine the longitudinal interaction of motivation and self-efficacy, and their impact on addictive behaviors.

Several limitations of this study should be considered. First, the within-participants design limited mediation effects with a comparison group and the examination of long-term changes in self-efficacy and motivation. Consequently, this may limit a comprehensive understanding of how self-efficacy and motivation could influence treatment outcomes in the medium and long term. Future studies should explore how these two mechanisms of change would affect smoking cessation with a comparison group in order to improve methodological weaknesses. Second, although the sample size was adequate to conduct this study, larger samples would perhaps surface other underlying mediational paths of self-efficacy and

motivation over tobacco reduction (Pan et al. 2018). Therefore, these findings should be taken with caution, and further studies with larger samples should be conducted in health services due to the predisposition of patients to quit smoking (Carrión Valero et al., 2022) to support the results obtained, and to reduce the potential limitations commonly found in 'real-life' conditions, such as survivorship bias.

In conclusion, GSC therapy was found to be an effective way of reducing tobacco use over a short period, highlighting its suitability for implementation in public health settings. Findings indicate that strategies that contribute to increasing motivation and self-efficacy are key components to when it comes to improving quitting rates. As such, this study contributes to understanding the treatment mechanisms underpinning the effectiveness of GSC therapy for tobacco cessation. To the best of our knowledge, this is the first study that systematically examines the serial mediation effects between selfefficacy and motivation on treatment effectiveness in tobacco cessation. While both motivation and self-efficacy contribute to behavioral changes, reinforcing smokers' achievements during treatment should be considered as a working basis in behavioral interventions for addictive behaviors (Schuck et al. 2014; Elshatarat et al. 2016; Hopkins et al. 2022).

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Ethical approval

This study was approved by the Clinical Research Ethics Committee of the GUHA (Reference: PI2019/096). All participants were informed of the study characteristics and all participants provided informed consent before starting the study.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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