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A multicentre randomized trial of combined individual and telephone counselling for smoking cessation ☆

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ABSTRACT

Objective. The present study assessed the effectiveness of smoking cessation programs combining individual and telephone counselling, compared to individual or telephone counselling alone.

Method. A randomized, multicentre, open-label trial was performed between January 2009 and July 2011 at six smoking cessation clinics in Spain. Of 772 smokers assessed for eligibility, 600 (77%) met inclusion criteria and were randomized. Smokers were randomized to receive individual counselling, combined telephone and individual counselling, or telephone counselling. The primary outcome was biochemically validated continuous abstinence at 52 weeks.

Results. The 52-week abstinence rate was significantly lower in the telephone group compared to the combined group (20.1% vs. 29.0%; OR, 1.32; 95% CI, 1.1–2.7) and to the individual counselling group (20.1% vs. 27.9%; OR, 1.37; 95% CI, 1.0–2.8). The 52-week abstinence rates were not significantly higher in the combined group than the individual group (OR, 0.97; 95% CI, 0.7–1.4).

Conclusion. Individual counselling and combined individual and telephone counselling were associated with higher 52-week abstinence rates than telephone counselling alone. A combined approach may be highly useful in the clinical treatment of smokers, as it involves less clinic visits than individual counselling alone, thus reducing the program cost, and it increases patient compliance compared to telephone counselling alone.

Introduction

Tobacco consumption remains a major cause of morbidity and mortality worldwide; therefore, implementing effective smoking cessation programs should be a priority. While many ex-smokers have quit smoking without formal aid, a significant percentage of smokers require assistance through smoking cessation programs. Clinical practice guidelines describe several smoking cessation methods, including self-help, proactive and reactive telephone counselling, and group and individual interventions (Fiore et al., 2008). Among smokers in the United States, 70% are interested in quitting, 52% have attempted to quit in the past year, and only 32% did so by using medication and professional counselling (CDC, 2011).

Telephone counselling has been shown to help smokers quit, and a proactive approach can be offered as part of face-to-face interventions or as adjunct to self-help materials (Stead et al., 2003). Two published reviews examined studies of the effectiveness of combining telephone and individual counselling in special population and telephone interventions; they concluded that current evidence does not confirm the benefits of telephone counselling interventions as adjunct to face-to-face interventions, and that further studies are required (Stead et al., 2003, 2006). One meta-analysis found that proactive telephone counselling as an adjunct to minimal intervention was more effective than telephone and minimal intervention alone (Pan, 2006).

In the meta-analysis conducted by Fiore et al. (2008) for their clinical guideline, found that the concomitant use of two different

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methods was observed to doubled the success rates as compared to no intervention; and, consequently, they recommended proactive telephone counselling as an adjunct to minimal advice and self-help materials.

The effectiveness of combining telephone and individual counselling has been studied in a number of special population and telephone interventions reviewed by Stead et al. (2003, 2006).

While the published meta-analyses do not draw firm conclusions, several studies suggest that adding telephone counselling to individual counselling can be a cost-effective adjunct. Two studies recruited patients through healthcare systems in which the usual care comprised advice and support, but telephone counselling was offered independently from clinical visits rather than as a complement to clinical face-to-face intervention, and not all smokers attended clinic visits (An et al., 2006; Lipkus et al., 1999). Several studies observed increased abstinence rates for in-patients who received combined interventions including a single session during a hospital stay and telephone counselling after discharge (Ranney et al., 2006; Rigotti et al., 2003). In a randomized trial where counselling and follow-up via the Internet was combined with telephone counselling (Graham et al., 2011), the combined group showed higher sustained abstinence rates than the control group. In contrast, a study of the effectiveness of an intervention program to prevent smoking relapse after childbirth reported that individual counselling combined with telephone counselling was not more effective than the usual advice and self-help materials (Hannover et al., 2009).

To date, no studies have tested the different intervention formats in the context of out-patient interventions as part of the usual care in cessation clinics. It can be difficult to implement individual counselling interventions for smoking cessation (Borland et al., 2001). The number of sessions attended is associated with success rates, and evidence shows that counselling sessions are most needed during the first weeks of attempting to quit, with compliance to follow-up sessions declining over time (Zhu and Pierce, 1995). However, individual counselling programs are expensive and may not be able to reach a large number of smokers, while group programs may not have the flexibility to adapt to individual needs. It is possible that combining clinic individual counselling with telephone counselling and follow-up could solve these difficulties.

The present study aimed to assess the effectiveness of combining individual and telephone counselling in smoking cessation interventions as compared to individual counselling or telephone counselling alone. We hypothesized that the individual counselling program and the combined program would have the same effectiveness, and that both would be more effective than the telephone-counselling program alone. The results obtained should have implications for the clinical management of smoking cessation.

Methods

Study design

A randomized, multicentre, open-label, parallel-group trial was carried out between January 2009 and July 2011 at six smoking cessation clinics in Spain.

The study was approved by the ethics committee of each centre. Participants provided written informed consent.

Participants

We recruited smokers who attended a Smoking Cessation outpatient clinic between January 2009 and July 2010 to receive medical assistance to quit smoking. The inclusion criteria were as follows: being 18 years or older, having smoked $\geq$10 cigarettes daily for the last month, providing consent to participate, and being available by phone. Exclusion criteria were pregnancy or breast-feeding, diagnosis of a current psychotic disorder, unavailability by telephone, not understanding the Spanish language, alcoholism, and other drug addictions. Smokers with chronic diseases were not excluded.

After baseline assessment, participants were randomly assigned to the treatment arms (individual counselling intervention, combined telephone and individual counselling intervention, or telephone counselling) in a 1:1:1 ratio. For this, we used a computer-generated randomization system based on a permuted block randomization list where each block was used by one centre. An independent researcher in the coordination centre generated a random sequence, and centres were informed about smoker allocation after consent to participation during the pre-quit session.

Sample size was estimated, accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test. A total of 176 subjects per group were necessary to detect a statistically significant difference of $\geq$0.15. A proportion in one of the groups was estimated to be 0.28, and we anticipated a drop-out rate of 0.1.

Procedure

Fig. 1 shows the sessions schedule and study timeline. All participants attended the clinic for baseline assessments, pre-quit sessions, and control visits at week 52. At the baseline assessment visit, we obtained written informed consent, reviewed the inclusion and exclusion criteria, and collected the baseline demographic variables, smoking and medical history. Comorbidity and psychosocial characteristics (depression, anxiety, and social support) were collected in the baseline interview. Anthropometric assessment was carried out at baseline and week 52.

In the pre-quit session, pharmacological treatment was prescribed, a quit day was fixed (within the next three weeks), and participants received instructions and information regarding the medication. The medication was indicated and used at the discretion of the therapist, following standard practice. Pharmacological treatment included nicotine replacement therapy (patches or combined patches and gum or lozenges), bupropion, or varenicline, and was standardized for all centres. Smokers with nicotine patch therapy started on quit day with 21 mg daily for four weeks, followed by 14 mg daily for the next four weeks. Varenicline was taken for 12 weeks, starting one week before quit-day: 0.5 mg once daily for 3 days, then 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 11 weeks. Smokers taking bupropion received a prescription for an 8-week course starting one-week before quit date: 150 mg once daily for five days and then 150 mg twice daily.

In the individual counselling group, the intervention consisted of seven individual sessions at 3, 5, 7, 10, 12, 24, and 52 weeks after the pre-quit session. The combined group received individual counselling interventions at weeks 3, 5, and 12 after the pre-quit session, telephone counselling at weeks 7, 10, and 24, and a control session at the clinic at week 52. The telephone counselling group received intervention calls at weeks 3, 5, 7, 10, 12, and 24, and the control session at the clinic at week 52. Telephone and individual counselling interventions lasted 15–20 minutes each, and were performed by a physician or psychologist specialized in smoking cessation.

Behavioural counselling sessions were previously standardized and based on motivational interviewing. They included practical counselling elements, such as problem solving and skill training, information on withdrawal symptoms, drug adverse effects, and barriers to quitting. All intervention calls were conducted by the same therapist from the coordination centre. After the initial telephone contact (week 3 for telephone group, week 7 for the combined group), the day and hour for the next call were always appointed. When a call was missed, it was repeated at different days and hours up to 10 times. In cases of no response, the smoker was considered relapsed.

Measures

The primary outcome was continuous abstinence, defined as sustained (not smoking throughout the follow-up period) abstinence from week 2 (one week after the quit date) to week 52 (Hughes et al., 2003; West et al., 2005). Continuous abstinence was self-reported by each participant and levels of exhaled CO were measured in all participants at week 52. The criteria for determining continuous abstinence were not having smoked since week 2, and showing CO concentrations of $<$10 ppm at week 52. Drop-outs and subjects who failed to provide self-reports or validation data were considered relapsed (Hajek and West, 2010; West et al., 2005).

The secondary outcome of this study was achieving continuous abstinence for the first 3 and 6 months. Point prevalence was defined as abstinence during the week before the follow-up control at weeks 12, 24, and 52.

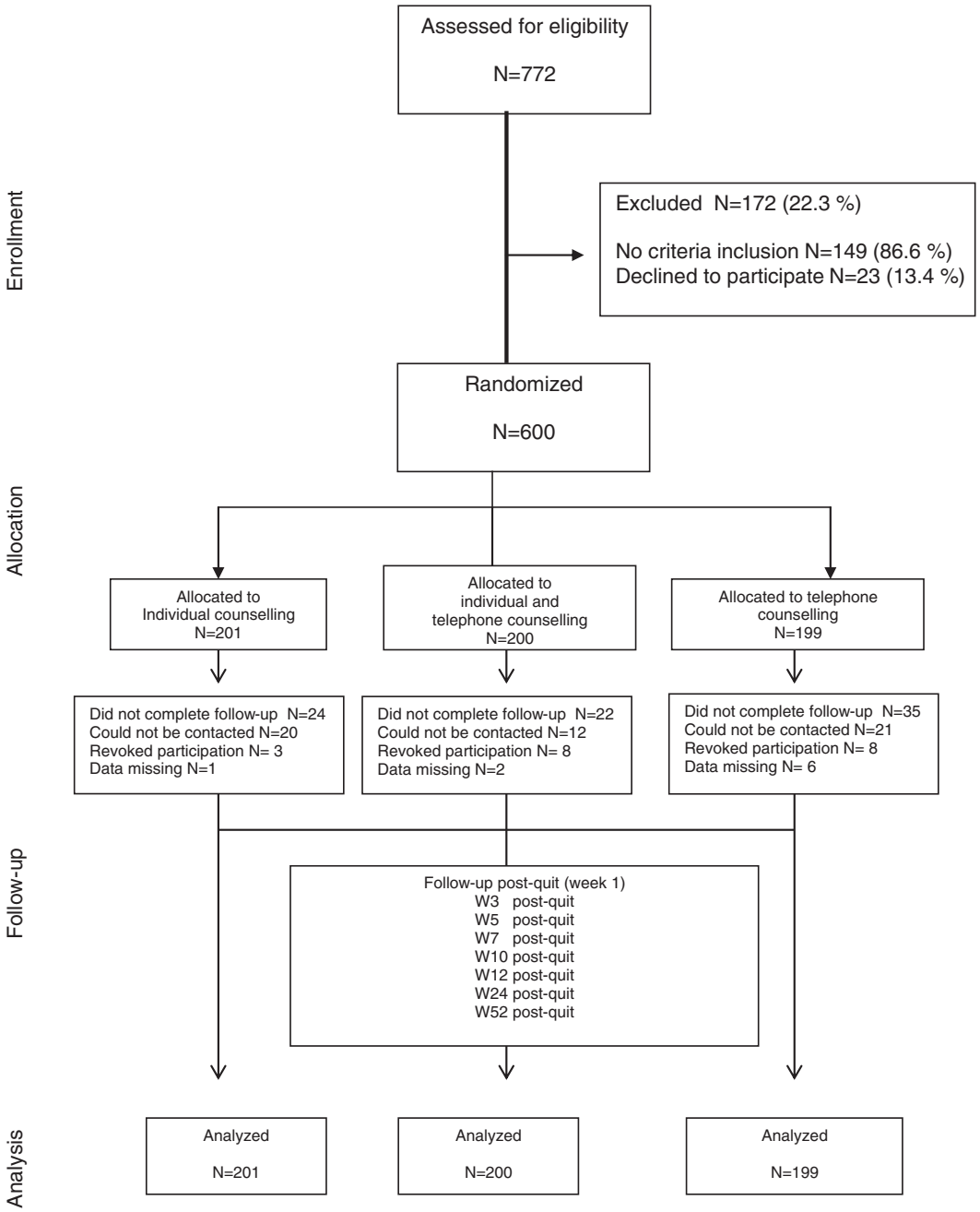

Fig. 1. Flowchart and follow-up of the Spanish multicentre randomized trial, 2009–11.

Compliance with the intervention was assessed as the number of sessions attended. Compliance with the pharmacological treatment was measured as the number of weeks on medication as compared to the number of weeks indicated by the physician.

Statistical analysis

Statistical analysis was performed on the basis of intention to treat. All randomized smokers were included in the analysis. Rates were estimated by including all smokers allocated into the specific group in the denominator. Differences in percentages were assessed using the chi-square test, and means were compared using an approximate analysis of variance test. A logistic regression model was used to test effectiveness across the different arms. The model was adjusted for potential confounding factors, including gender, age, pharmacological treatment, centre, and Fagerström nicotine dependence test (FNDT) score. SPSS version 14 (SPSS Inc., Chicago, Illinois) was used for the analyses.

Results

Attrition

Fig. 1 shows the flowchart for study participant evaluation. Of 772 smokers assessed, 600 (77.7%) were included and randomly allocated to a treatment arm. The inclusion criteria were not met by 149 smokers, and 23 smokers refused to participate. All smokers, regardless of relapse, were asked to come to the clinic at 52 weeks to verify the levels of exhaled CO. A total of 433 smokers (71.2%) completed the follow-up, including expired carbon monoxide validation.

The rate of follow-up and CO monitoring at week 52 was 76.1% (153/201) in the individual counselling group, 75.5% (151/200) in the combined group, and 64.8% (129/199) in the telephone group. The telephone group showed a significantly lower rate of completion of follow-up and monitoring (χ^2, 8.001; DF, 2; p, 0.02). In total, 20 smokers refused to visit the clinic at 52 weeks, including 3 in the individual group, 9 in the combined group, and 8 in the telephone group (χ^2, 3.22; DF, 2; p, 0.19). Of the 433 smokers with CO levels measured at 52 weeks, 8 (1.8%) reported not smoking but had exhaled CO levels above 10 ppm, including 3/153 in individual counselling group, 2/151 in the combined, and 3/129 in the telephonic counselling group, with no significant between-group differences (p, 0.83).

Descriptive statistics

Of the 600 included smokers, 308 (51.3%) were male and 292 (48.7%) were female, and the average age was 47.4 years (SD, 12.1 years). More than 50% of participants reported associated comorbidities. Major comorbidities were history of cardiovascular and respiratory disease and depression. Baseline characteristics were similar between groups with no significant differences observed (Table 1).

Primary outcomes

Table 2 shows the continuous and point abstinence rates. Comparing all three groups regarding the continuous abstinence rate at 52 weeks revealed no significant difference (χ^2, 4.90; DF, 2; p, 0.08). However, significant differences were found between the telephone group (20.1%) and the individual (27.9%; χ^2, 3.79; DF, 1; p, 0.01) and combined counselling groups (29.0%; χ^2, 4.22; DF, 1; p, 0.01). Statistically significant differences were not found between the combined and individual counselling groups (χ^2, 0.02; DF, 1; p, 0.9). Analysis of point abstinence at 52 weeks revealed similar results (Table 2).

Baseline characteristics did not differ between the three groups (Table 1). Two different models were tested—with and without covariates—to assess the robustness of intervention format effect on abstinence at 12, 24, and 52 weeks. The multivariate model included gender and age as covariates because they can be related to increased risk of relapse. On the other hand, FTND score was inversely related to risk of relapse and pharmacological treatment, because it is known to influence the chances of success (Fiore et al., 2008). Although the interventions were standardized for all centres and therapists, it is impossible to ensure the homogeneity; therefore, centre was introduced into the model as a control covariate.

Table 3 shows the effectiveness of the combined and the individual counselling groups compared to the telephone group. Compared to the telephone group, the estimated crude odds ratios for abstinence at 52 weeks were 1.44 (95% CI, 1.2–2.7) and 1.39 (95% CI, 1.01–2.2) for the combined and the individual counselling groups, respectively. The adjusted estimations were similar and differences were significant, although such differences were attenuated by covariates.

Smokers in the combined intervention were 1.1–2.7 times more likely to achieve abstinence at 52 weeks than smokers in telephonic group, independently of covariates introduced into the model (OR, 1.32; 95% CI, 1.1–2.7). Similar results were observed when comparing the individual counselling group with the telephone-counselling group (OR, 1.37; 95% CI, 1.0–2.8). Finally, no differences were observed at 52 weeks (Table 3) between the individual and combined counselling groups (adjusted OR individual vs. combined, 1.02; 95% CI, 0.3–1.4).

Secondary outcome

All subjects attended the pre-quit session. Smokers who received individual counselling had an average of 5.1 ± 1.9 visits to the clinic (71% of predicted) compared to 5.8 ± 1.1 (85.7%) calls and clinic visits among smokers in the combined group, and a mean of 3.8 ± 1.7 (57.1%) counselling calls received in the telephone group. Program compliance significantly differed between groups according to number of sessions attended (F value, 4.260; DF, 2; p, 0.01). Post-hoc testing with the Scheffe test revealed significant differences in the numbers of sessions attended between the combined and the telephone groups (mean difference, −0.82; $p < 0.01$) and between the individual counselling and the telephone groups (mean difference, −0.92; $p < 0.01$), but not between the individual counselling and the combined group (mean differences, 0.40; p, 0.45).

Of 600 smokers, 94% received pharmacological treatment during the study, while 36 (6%) refused concomitant pharmacological

Table 1
Baseline characteristics by treatment group. Spanish multicentre trial, 2009–2011.

	Individual $N = 201$	Combined $N = 200$	Telephone $N = 199$	p value
Gender, n (%)				
Male	94 (46.8)	110 (55.0)	104 (52.3)	
Female	107 (53.2)	90 (45.0)	95 (47.7)	0.24[a]
Marital Status, n (%)				
Married	135 (67.5)	133 (66.8)	136 (68.3)	
Single	35 (17.5)	41 (20.6)	38 (19.1)	
Divorced	30 (15.0)	26 (12.6)	25 (12.6)	0.82[a]
Education, n (%)				
Less than HS graduate	58 (28.9)	49 (24.5)	47 (23.7)	
HS graduate	78 (38.8)	83 (41.5)	76 (38.4)	
College graduate or higher	65 (32.3)	68 (34.0)	75 (37.9)	0.55[a]
Comorbidity, n (%)				
Respiratory disease	32 (15.9)	34 (17.0)	32 (16.1)	
Cardiovascular	43 (21.4)	39 (19.5)	43 (21.6)	
Major depression	22 (10.9)	26 (13.0)	19 (9.5)	
Other	20 (10.0)	11 (5.5)	9 (4.5)	
No	84 (41.8)	90 (45.0)	96 (48.3)	0.10[a]
Age, mean ± SD	47.4 ± 10.8	47.3 ± 11.4	47.6 ± 10.9	0.94[b]
Cigarettes/day, mean ± SD	24.8 ± 10.7	26.7 ± 12.9	24.8 ± 9.7	0.16[b]
Previous attempts, mean ± SD	2.6 ±3.6	2.3 ± 2.2	2.3 ± 2.2	0.57[b]
Maximum previous cessation (days), mean ± SD	353.1 ± 313.3	426.2 ± 412.6	369.8 ± 297.1	0.65[b]
Fargerström score Mean ± SD	6.1 ± 2.2	6.3 ± 2.1	6.5 ± 2	0.10[b]

[a] $\chi 2$ squared test; [b]Analysis of variance test; SD, standard deviation.

Table 2
Continuous and point abstinence rates by treatment group. Spanish multicentre trial, 2009–11.

	Telephone $N = 199$ Abstainers (%)	Combined $N = 200$ Abstainers (%)	Individual $N = 201$ Abstainers (%)
Continuous abstinence (weeks)			
2–12	87 (43.7)	107 (53.5) [b*]	103 (51.2) [*]
2–24	60 (30.1)	89 (44.5) [ab]	85 (42.3) [a]
2–52	40 (20.1)	58 (29.0) [ab]	56 (27.9)[a]
Point Abstinence (weeks)			
12	97 (48.7)	114 (57.0) [b*]	110 (54.7) [*]
24	66 (33.2)	93 (46.5) [ab]	90 (44.8) [a]
52	43 (21.6)	60 (30.0) [ab]	58 (28.8) [a]

[a] $\chi 2$ squared test; $p < 0.05$ vs. telephonic group.
[*] $\chi 2$ squared test; not significant vs. telephonic group.
[b] $\chi 2$ squared test; not significant vs. individual group.

Table 3
Crude and adjusted odds ratios for continuous abstinence. Spanish multicentre trial, 2009–11.

	Telephone N = 199 Reference	Individual N = 201 OR (95% CI) Crude	Adjusted [a]	Combined N = 200 OR (95% CI) Crude	Adjusted [a]	Combined N = 200 Reference	Individual N = 201 OR (95% CI) Crude	Adjusted [a]
Continuous abstinence 12 weeks	1	1.17 (0.7–1.7)	1.11 (0.5–1.3)	1.22 (0.6–2.7)	1.16 (0.5–1.8)	1	0.96 (0.5–1.4)	0.95 (0.4–1.3)
Continuous abstinence 24 weeks	1	1.40 (0.6–2.8)	1.32 (0.5–2.4)	1.47 (1.2–2.8)*	1.39 (1.1–2.3) *	1	0.95 (0.5–1.3)	0.95 (0.5–1.6)
Continuous abstinence 52 weeks	1	1.39 (1.01–2.2)	1.37 (1.0–2.8)*	1.44 (1.2–2.7)*	1.32 (1.1–2.7)*	1	0.96 (0.5–1.3)	1.02 (0.3–1.4)

OR, odds ratio; CI, confidence interval.
[a] Adjusted by gender, age, centre, pharmacological treatment, and Fagerström score.
* Significant.

therapy. Among those receiving drug treatment, 47% received varenicline, 33% nicotine patches, 14% a combination of nicotine patches and gum or lozenges, and 6% bupropion. The type of medication received was homogeneous, with no significant differences among the three groups studied (χ^2, 1.66; DF, 4; p, 0.79). Within the telephone group, 45.3% received varenicline, 49.5% NRT, and 5.2% bupropion. In the individual group, 50.3% received varenicline, 43.6% NRT, and 6.1% bupropion. In the combined group, 45.6% received varenicline, 47.7% NRT, and 6.7% bupropion.

Adherence was measured as the number of weeks in treatment over the indicated time of use (12 weeks for varenicline, and 8 weeks for patches and bupropion). Duration of varenicline use did not significantly differ across groups: 7.42 ± 2.3 weeks for the combined group, 7.40 ± 1.7 for the individual counselling group, and 6.97 ± 2.1 for the telephone group (F value, 0.670; DF, 2; p, 0.56). There were also no significant between-group differences regarding the weeks of use of NRT (5.2 ± 1.3, 4.9 ± 2.0, and 4.0 ± 2.7, respectively) and bupropion (6.0 ± 1.3, 5.9 ± 2.0, and 5.6 ± 2.1, respectively).

Discussion

The major aim of the present study was to assess the effects of different formats for the counselling and follow-up of smokers attending outpatient clinic for smoking cessation. Under realistic situations, we evaluated the effectiveness of combining individual and telephone counselling as compared to individual or telephone counselling alone. We found that the smokers in the combined individual and telephone counselling group showed significantly higher abstinence rates at 52 weeks after the quit day than smokers who received telephone counselling alone. There was an 8.9% absolute difference in the 52-week continuous abstinence rates between the combined and telephonic groups. Similarly, the individual counselling group showed higher abstinence rates than the telephone group, with an absolute difference of 7.8%. However, the combined and individual groups had similar continuous abstinence rates, with an observed difference of only 1.1%. Our results demonstrate that clinical smoking cessation interventions combining individual and telephone counselling required fewer clinical visits and therefore lower cost with equal treatment compliance and adherence compared to individual counselling alone.

The present study is the first to assess the effectiveness of different smoking cessation methods in the context of clinical interventions among smokers attending out-patient smoking cessation clinics. Previous studies have reported that proactive telephone support for smoking cessation increases long-term success rates as compared to brief interventions (Boyle et al., 2005; Tzelepis et al., 2011). In these studies, telephone counselling is commonly integrated into minimal interventions, and the results from several meta-analyses confirm that the use of proactive calls as an adjunct to minimal intervention is more effective than telephone or minimal interventions alone (Fiore et al., 2008; Stead et al., 2006), so the present findings confirm these conclusions. Several clinical trials in special populations have compared the effectiveness of combining telephone counselling and follow-up in usual clinical interventions (Ranney et al., 2006; Rigotti et al., 2003; Wolfenden et al., 2003).

In their first meta-analysis, Stead et al. (2003) concluded that the available evidence neither confirms nor rules out a benefit of telephone counselling as adjunct to face-to-face interventions. In a subsequent update study (Stead et al., 2006), these authors concluded that further research on combining face-to-face intervention and telephone counselling might be useful.

In a study by An et al. (2006) a telephone intervention resulted in an increased use of smoking cessation counselling programs and pharmacotherapy, with significantly improved long-term cessation rates. In another study, Boyle et al. (2005) randomized smokers using smoking cessation medication to receive telephone counselling or no counselling, and observed higher abstinence rates in the telephone-counselling group. Finally, in a trial performed in 26 general practice offices (Aveyord et al., 2007), smokers were allocated either to receive basic support (two nurse visits after baseline assessment and telephone support around the quit date) or weekly support with an additional telephone call at 10 and 21 days after the quit date and an additional nurse visit at two weeks. Abstinence rates at 52 weeks were similar in both groups, showing that the extra support is ineffective in this context. These contrasted with our main results.

One limitation of the present study is the assessment of continuous abstinence only by self-report except during the final control session at 52 weeks. In order to reduce this potential bias, we included measurement of exhaled CO levels at 24 weeks after the quit date in a sample of 50 smokers from the combined and the individual counselling groups. In both groups, the percentage of smokers with exhaled CO levels above 10 ppm who had previously reported themselves to be abstinent was below 1%. Of the 433 smokers with CO levels measured at 52 weeks, self-reported abstinence was only disconfirmed in 1.8%. As reported in a previous meta-analysis by Patrick et al. (1994), our results showed that self-reported smoking status did not differ by group, and was not an overestimate of the actual continuous abstinence. The percentage found in our study is lower than that observed (10%) by Spring et al. (2004) in smokers reporting continuous abstinence. However, our present study did not also measure cotinine levels to assess the accuracy of self-reported smoking status.

Another limitation of this open-label trial is the possibility for biases in the interventions. These were controlled by applying a standardized protocol to all three groups and by having the same therapist to attend the telephone intervention subjects in the combined and telephone group. Counsellors were trained in the standardized study protocol and were experts in smoking cessation. However, the counsellor may still be a source of bias in this study (Miller and Rollnick, 2002). To control this potential source of variation, the centre was introduced in the final model. Finally, it must be noted that the number of drop-outs was higher in the telephone group (35.5%), with fewer sessions, possibly because they had higher relapse rates. Comparing abstinent subjects, the number of sessions was similar in the three groups. It is possible that not all smokers in that group were relapsed and abstinence rates were underestimated.

Conclusion

In real-world smoking cessation clinics individual counselling and combined counselling had better results in terms of abstinence, treatment compliance (number of sessions), and adherence to medication compared to telephone counselling alone and that both individual counselling and combined counselling were equally effective.

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Conflict of interest

JMR, IN, JMC, FA, CP, CM, SM, MB, and AB have received honoraria for conferences from manufacturers of smoking cessation products.

References

An, L.C., Zhv, S.H., Nelson, D.B., et al., 2006. Benefits of telephone care over primary care for smoking cossation. Arch. Intern. Med. 166, 536–542.
Aveyord, P., Brown, K., Saunders, C., et al., 2007. Weekly versus basic smoking cessation support in primary care: a randomised controlled trial. Thorax 62, 898–903.
Borland, R., Segan, C.J., Livingstone, P.M., Owen, N., 2001. The effectiveness of call-back counselling for smoking cessation: a randomized trial. Addiction 96, 881–889.
Boyle, R.G., Solberg, L.I., Asche, S.E., Boucher, J., Pronk, N.P., Jensen, C.J., 2005. Offering telephone couseling to smokers using pharmacotherapy. Nicotine Tob. Res. 7 (Suppl. 1), S19–S27.
CDC, 2011. Quitting smoking among adults–United States, 2001–2010. MMWR 60, 1513–1519.
Fiore, M.C., Jaen, C.R., Baker, T.B., et al., 2008. Treating tobacco use and dependence: 2008 update–clinical practice guideline. US Department of Health and Human Services, Public Health Service, Rockville, MD.
Graham, A.L., Cobb, N.K., Papandonatos, G.D., et al., 2011. A randomized trial of Internet and telephone treatment for smoking cessation. Arch. Intern. Med. 171, 46–53.
Hajek, P., West, R., 2010. Commentary on Smolkowski et al. (2010): Why is it important to assuming that non-responders in tobacco cessation trials have relapsed? Addiction 105, 1016–1017.
Hannover, W., Thyrian, J.R., Röske, K., et al., 2009. Smoking cessation and relapse prevention for postprarten women: results from a randomized controlled trial at 6,12,18 and 24 months. Addict. Behav. 34, 1–8.
Hughes, J.R., Keely, J.P., Niaura, R.S., Ossip-Klein, D.J., Richmond, R.L., Swan, G.E., 2003. Measures of abstinence in clinical trials: issues and recommendations. Nicotine Tob. Res. 5, 13–25.
Lipkus, I.M., Lyna, P.R., Rimer, B.K., 1999. Using tailored interventions to enhance smoking cessation among African-Americans at a community health center. Nicotine Tob. Res. 1, 77–85.
Miller, W.R., Rollnick, S., 2002. Motivational interviewing: preparing people for change, 2nd ed. Guildford Press, New York.
Pan, W., 2006. Proactive telephone counselling as adjunct to minimal intervention for smoking cessation: a meta-analysis. Health Educ. Res. 21, 416–427.
Patrick, D.L., Cheadle, A., Thompson, D.C., Diehr, P., Koespell, T., Kinne, S., 1994. The validity of self-reported smoking: a review and meta-analysis. Am. J. Public Health 84, 1086–1093.
Ranney, L., Melvin, C., Lux, L., McClain, E., Lohr, K.N., 2006. Systematic review: smoking cessation intervention strategies for adults and adults in special populations. Ann. Intern. Med. 145, 845–856.
Rigotti, N.A., Munafò, M.R., Murphy, M.F., Stead, L.F., 2003. Interventions for smoking cessation in hospitalised patients. Cochrane Database Syst. Rev. CD001837.
Spring, B., Doran, N., Pagoto, S., Schneider, K., Pingitore, R., Hedeker, D., 2004. Randomized controlled trial for behavioral smoking and weight control treatment: effect of concurrent versus sequential intervention. J. Consult. Clin. Psychol. 5, 785–796.
Stead, L.F., Lancaster, T., Perera, R., 2003. Telephone counselling for smoking cessation. Cochrane Database Syst. Rev. 1, CD002850.
Stead, L.F., Perera, R., Lancaster, T., 2006. Telephone counselling for smoking cessation. Cochrane Database Syst. Rev. 3, CD002850.
Tzelepis, F., Paul, C.L., Walsh, R.A., McElduff, P., Knight, J., 2011. Proactive telephone counselling for smoking cessation: meta-analyses by recruitment channel and methodological quality. J. Natl. Cancer Inst. 103, 922–941.
West, R., Hajek, P., Stead, L., Stapleton, J., 2005. Outcome criteria in smoking cessation trials: proposal for common standard. Addiction 100, 299–303.
Wolfenden, L., Campbell, E., Walsh, R.A., Wiggers, J., 2003. Smoking cessation interventions for in-patients: a selective review with recommendation for hospital-based health professionals. Drug Alcohol Rev. 23, 437–452.
Zhu, S.H., Pierce, J.P., 1995. A new scheduling method for time-limited counselling. Prof. Psychol. Res. Pract. 26, 624–625.