

Brief Advice and Lozenge Group Telephone Counseling Manual

Session 1 (Day 0)

Before call, determine lozenge dose by following instructions on lozenge tracking form.

- Ask for the participant

“Hello, may I please speak to _____.”

- Re-introduce yourself

“Hi, this is _____. I’m calling from the Nicotine Lozenge Study. As you know, I’m a smoking cessation counselor, and I’m going to talk with you twice on the phone to offer some help with quitting smoking. My first phone call with you will take about 10 minutes and the second will last about 15 minutes. Is this a good time to talk for about 10 minutes?”
(If not, schedule another time.)

- Clarify the help they will receive

“Let me begin by telling you about what you’ll receive from this program. As you know, participants in this study are assigned by chance to one of three groups. You’ve been assigned by chance to the group that will receive brief advice and nicotine lozenges. That means that I’ll send you free nicotine lozenges to help you quit and stay quit, and I’ll talk with you one time after your quit date to provide support. Another counselor may be the one to call you if I am not able to. Do you have any questions at this point?” (Answer questions.)

- Assess plans to quit

“So, I’m wondering, is it still your plan to quit smoking?”

(If yes: Reinforce decision. If no: Tell them that that would remove them from the study, and we wouldn’t be able to give them free lozenges and support. Ask if they would like to reconsider. If no, thank them, tell them they can call again up to two weeks from now if they change their mind, otherwise we will not be able to give them free lozenges and support; end call.)

- Do timeline follow-back (TLFB)

“I’d like to get a clear sense of your cigarette smoking over the past week beginning with the number of cigarettes you smoked a week ago.” (Plug in timeline follow-back instructions here and record smoking. Take average cigs per day from past week and record as baseline CPD on counselor log)

- Emphasize that the best way to quit is by setting a quit date

“We know that the way most people successfully quit is by setting a quit date and using medication like the nicotine lozenge. I’m going to send you the nicotine lozenges, so what we

need you to do is set a quit date. It would be best if the quit date is at least 7 days from now so I can be sure to get the lozenges to you, but within 21 days, so that your motivation to quit is still strong. What would you like to pick as your quit date?"

"Great, so your quit date will be on (day of week and date). I'm going to write that date down so I keep track of it. You might jot it down as well. I also want to mention that if you decide to postpone or delay your quit date, it may mean that you are not able to get more lozenges from us."

- Review what you've talked about today and schedule next call

"You've already made some headway toward quitting by setting a quit date for _____. Before that date, I'm going to send you a brochure that gives some suggestions for quitting smoking, and a questionnaire that I'd like you to fill out and mail back to us right away. I'll also send you your first batch of nicotine lozenges. You'll be receiving a supply of _____ mg lozenges. You'll get these a few days before your quit date, but please don't start using the lozenges until your quit date. Also, please read the information that comes with the lozenges. I'll be available to answer any questions about the lozenges at our next phone call."

"Someone else from our study will be calling you 3 days before your quit date to ask some questions about your smoking. I'd like to call you again a couple of days after your quit date to see how it's going. I'd like to talk with you no matter what happens. Could we schedule a call for _____ at _____?" (If that won't work, arrange another.)

- End conversation

"I've enjoyed talking with you I look forward to talking with you again on _____."

- Complete counseling log
- Email Joanne and Amy with participant ID#, QD, date to send QD -7 day mailing (should be business day before QD -7), study group and lozenge dose.

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Session 2 (QD + 2 days)

- Ask for the participant and introduce yourself

“Hello, may I please speak to _____. Hi, this is _____ from the Nicotine Lozenge Study. I’m calling to check in with you to see how you’re doing with your smoking. Is this a good time to talk for about 15 minutes?”

(If it’s not, schedule another time.)

- Assess smoking status

“The first thing I need to do is get a clear idea of how you’re doing with quitting. Have you tried to quit smoking since we last talked?”

If yes: “When did you quit?” (Write down the date) “How many cigarettes have you smoked since you quit?” (Acknowledge response and write it down)

If no: “How many cigarettes a day are you currently smoking?” (Write this down)

Ask everyone: “How many lozenges a day are you using?” (Write this down)

IF PERSON SAYS TRIED TO QUIT BUT HAS SMOKED 1 OR 2 CPD SINCE QD, skip to Page 4.

IF PERSON SAYS DID NOT QUIT AT ALL OR THEY ARE SMOKING 3 OR MORE CPD, skip to Page 6.

IF PERSON IS ABSTINENT, continue here:

- Congratulate them on quitting and ask how it’s going

“Congratulations, you’re no longer smoking. Good job. How’s it going? What kinds of difficulties are you having?”

(Acknowledge response; use problem-solving process to help them deal with any difficulty.)

- Ask about cravings and problem-solve

“Have you been getting any cravings to smoke? What have you been doing to handle the cravings? How has that been working for you?” (Acknowledge responses.)

(If using at least 9 lozenges per day: Reinforce use. Ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they're using fewer than 9/day. Also ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: "I'd like to encourage you to continue to use the lozenges for at least 6 weeks after your quit date. After 6 weeks, you can either stop using them completely or you can slowly decrease your use, whichever you prefer. Very few smokers get withdrawal symptoms from stopping the lozenges after 6 weeks, so that shouldn't be a problem for you. However, we can provide lozenges to you for up to 12 weeks after your quit date provided that you aren't smoking. Do you have any questions about that?" (Address questions.)

- Discuss the use of self-rewards

"One way to see direct benefits from quitting is to come up with ways to reward yourself for not smoking. For example, some people take the money that they've saved each day and use it to buy something for themselves or to go out to dinner or to do something special they wouldn't otherwise do. Others find ways to include fun things into their days, like talking with a friend, watching a movie, working on a hobby. Can you think of some ways you can reward yourself for stopping smoking?"

- Ask about any high risk for smoking situations coming up in the next several days

"As you think about the next four or five days, can you think of any situations that are likely to put you at risk for smoking?" (Problem-solve the most risky situation mentioned.)

- Review what you've talked about and end conversation

"You're doing a great job stopping smoking. You've gotten through the difficult first couple of days, you've got ways to manage cravings including use of the nicotine lozenges, you've got ideas about how to reward yourself for staying quit, and you've anticipated risky situations that may arise over the next several days. Do you have any questions or concerns at this point? (Address them.)

This is my last call to you, so I want to wish you much success in your efforts. I really believe you can do it. I also want to mention that someone else from our program will be calling you in a couple of weeks to ask you some questions about your smoking and to see if you need more nicotine lozenges. You're still in our study, so we'd appreciate it if you'd continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It's been good talking with you and I wish you success."

- Record information on Telephone Counseling Log.

IF PERSON TRIED TO QUIT BUT HAS SMOKED 1-2 CPD SINCE QUITTING:

- Acknowledge smoking situation and ask what happened

“Okay, so it sounds like you’ve made some good headway with quitting, but you’ve also smoked. What’s going on?” (Ask about the specific situation in which they smoked, where were they, what motivated the lapse, what were they thinking or feeling, how did they get the cigarette, what did they try to do to avoid smoking?)

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation right now?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up when you have a slip; to just decide that you’re not ready to do this or this is too hard. The best treatment for those thoughts is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed.)

“The good news about this experience is that you’ve caught it early and you can recover from it, but it’s going to be important to find a way to avoid these slips because they are very risky. They’re what lead people back to smoking. Are you up for finding a way to manage them?”

- Problem-solve what they could have done differently to resist smoking in that situation

“What kinds of things could you have done differently to have avoided smoking?” (Reinforce these and add others as needed.)

- Ask about cravings and problem-solve

“Have you been getting many cravings to smoke? What have you been doing to handle the cravings? How has that been working for you?” (Acknowledge responses.)

(If using at least 9 lozenges per day: Reinforce use. Ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve.)

(If using less than 9/day: Ask why they’re using fewer than 9/day. Also ask: “Have you had any problems since I last talked with you that might be due to the use of the lozenge?” Use adverse events sheet to document problems and then problem-solve. Correct any misconceptions and encourage use, especially ahead of time when they know they will be facing a difficult situation. Remind them that the lozenges help decrease withdrawal symptoms such as anxiety, depression, difficulty concentrating, restlessness, hunger and impatience, as well as cravings to smoke.)

For everyone: “I’d like to encourage you to continue to use the lozenges for at least 6 weeks after your quit date. After 6 weeks, you can either stop using them completely or you can slowly decrease your use, whichever you prefer. Very few smokers get withdrawal symptoms from stopping the lozenges after 6 weeks, so that shouldn’t be a problem for you. However, we can provide lozenges to you for up to 12 weeks after your quit date provided that you aren’t smoking. Do you have any questions about that?” (Address questions.)

- Discuss the use of self-rewards

“One way to see direct benefits from quitting is to come up with ways to reward yourself for not smoking. For example, some people take the money that they’ve saved each day and use it to buy something for themselves or to go out to dinner or to do something special they wouldn’t otherwise do. Others find ways to include fun things into their days, like talking with a friend, watching a movie, working on a hobby. Can you think of some ways you can reward yourself for stopping smoking?”

- Ask about any high risk for smoking situations coming up in the next several days

“As you think about the next four or five days, can you think of any situations that are likely to put you at risk for smoking?” (Problem-solve the most risky situation mentioned.)

- Review what you’ve talked about and end conversation

“You’re making good progress. You’ve had some difficulty, but you sound resolved to keep going. You’ve got ways to manage cravings, you’ve got ideas about how to reward yourself for staying quit, and you’ve anticipated risky situations that may arise over the next several days. Do you have any questions or concerns at this point?” (Address them.)

This is my last call to you, so I want to wish you much success in your efforts. I really believe you can do it. I also want to mention that someone else from our program will be calling you in a couple of weeks to ask you some questions about your smoking and to see if you need more nicotine lozenges. You’re still in our study, so we’d appreciate it if you’d continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It’s been good talking with you and I wish you success.”

- Record information on Telephone Counseling Log.

IF PERSON DID NOT QUIT AT ALL OR THEY ARE SMOKING 3 OR MORE CPD

- **IF PERSON HAS RELAPSED (BEEN SMOKING 3 OR MORE CPD)**

- Acknowledge smoking situation and ask what happened

“So it sounds like you’ve been smoking. Can you tell me what’s going on?”

- Ask how they’re feeling about the situation and emphasize the value of the experience

“How are you feeling about your smoking situation?”

(Acknowledge response. If they sound discouraged, mention the tendency to want to give up. The best way to renew your motivation is to remind yourself why you wanted to quit in the first place. Ask if those reasons have changed. Reinforce them.)

“The thing we know about quitting smoking is that people often try multiple times before they’re successful. Each time you make an attempt is like a practice session, and you get a better idea of what it’s going to take to be successful. You have the nicotine lozenges to help with that; however, I just want to let you know that we can continue to supply them only if you quit

smoking completely. The best strategy still remains getting focused on setting a new quit date. I'm wondering if you're up for doing that?"

(Acknowledge response. If they don't want to set a new quit date now, acknowledge that and go to "end conversation". If they do want to set a new quit date, reinforce that and continue below.)

- Set a new quit day

"It's usually a good idea to set a quit day fairly soon while your interest is still high. Could you pick a day in the next few days as your quit day?"

(Praise them for their commitment to a quit date; tell them you're going to write that date down and encourage them to do the same.)

- Prepare for quit day

"Knowing what you know now, what do you think will be most helpful in getting you through your quit day?"

- Ask about problems with lozenges

If reported problems with lozenge at prior call, ask about past symptoms or problems with lozenge: "Last time we spoke you mentioned _____. Is this still occurring?" If no problems from previous call, ask: "Have you had any problems since I last talked with you that might be due to the use of the lozenge?" Use adverse events sheet to document problems and then problem-solve.)

- Identify high risk for smoking situation

"When you think about your quit day, what do you think is going to be the most difficult part of the day to get through without smoking? (Problem-solve around that situation.)

- Review what you've talked about today

"It sounds to me like you're ready to give this another try, and that's excellent. You're better prepared for your quit day than you were before because you know more. We can continue to provide you with nicotine lozenges to substitute for your cigarettes and to help you with cravings provided that you are not smoking. Do you have any questions or concerns at this point?" (Address them.)

- End conversation

This is my last call to you, so I want to wish you much success in your efforts. I really believe you can do it. I also want to mention that someone else from our program will be calling you in a couple of weeks to ask you some questions about your smoking and to see if you are eligible for more nicotine lozenges. You're still in our study, so we'd appreciate it if you'd continue to answer questions about your smoking periodically. You will be compensated \$15 for each of those follow-up calls. It's been good talking with you and I wish you success."

- Record information on Telephone Counseling Log.