Preventive Medicine **31,** 68–74 (2000)
doi:10.1006/pmed.2000.0683, available online at http://www.idealibrary.com on IDEAL®

Free Nicotine Patches plus Proactive Telephone Peer Support to Help Low-Income Women Stop Smoking[1]

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Background. **This study tested the impact of free nicotine patches plus proactive telephone peer support to help low-income women stop smoking.**

Methods. **A total of 214 Medicaid-eligible women smokers of childbearing age were randomized to receive free nicotine patches through the mail or free nicotine patches through the mail plus the provision of proactive support by telephone from a woman ex-smoker for up to 3 months. Assessments were conducted by telephone at baseline, 10 days, and 3 and 6 months after enrollment.**

Results. **At the 3-month follow-up, significantly more women in the patch plus proactive telephone support condition were abstinent (42%) compared to the patch only condition (28%) ($P = 0.03$). Similarly, more women in the experimental condition were abstinent at both the 10-day and 3-month assessments (32 v 19%, $P = 0.02$). However, differences were not found at the 6-month follow-up, suggesting that the addition of proactive telephone peer support enhanced short-term, but not long-term cessation.**

Conclusions. **This is the first study to demonstrate a beneficial effect for the addition of proactive telephone support as an adjunct to free nicotine replacement in a low-income population.**

Key Words: **smoking cessation; nicotine replacement; telephone support; low-income women.**

INTRODUCTION

The rate of cigarette smoking within the United States is disproportionately high among women of childbearing age and of low-income [*1*]. This is of particular concern because the consequences of smoking can be harmful not only to the women, themselves, but also to their children [*2*]. Like smokers of all ages and income levels, many of these women would prefer to stop smoking; however, the challenges of cessation loom large given their limited resources and the likelihood that they are embedded within a smoking culture [*3*].

Numerous studies document the efficacy of transdermal nicotine replacement for smoking cessation [*4,5*], with nicotine patches typically doubling quit rates over placebo patches. This doubling occurs regardless of the intensity of behavioral support [*4*]; however, studies of nicotine patches provided over-the-counter (OTC) without behavioral support reveal lower abstinence rates at 3- and 6-month follow-up compared to studies where nicotine patches were provided with the provision of even brief counseling [*6,7*].

One way to provide behavioral support is via telephone. During the 1990s a number of studies documented the efficacy of proactive telephone support, initiated by the support person, to help smokers stop smoking [*8–12*]. A meta-analysis of many of these studies by Lichtenstein and colleagues [*13*] revealed that proactive telephone support increased quit rates by 20–30% above control conditions.

To date, only one published study by Lando and colleagues [*14*] has examined the provision of free nicotine patches with and without proactive telephone support. In this study, subjects were smokers from an HMO population who received free nicotine patches from the pharmacy and were randomized to receive one of the following: (a) a 90-min group orientation session; (b) the orientation session plus a toll-free nicotine patch hotline number to call; or (c) the orientation session plus the hotline number plus four proactive support calls scheduled to occur within 1, 4, 9, and 12 weeks of a designated quit date. Process data revealed that less

[1] This research was funded in part by the Vermont Department of Health.

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0091-7435/00 $35.00

than 1% of the subjects called the hotline number, while subjects in the proactive telephone support condition received a mean of 3.8 calls, each averaging 10–15 min. Outcome assessments at 2 and 5 weeks and 2, 3, 6, and 12 months post-quit date revealed no significant differences in abstinence rates among conditions. By 2 weeks post-quit date, 35% of subjects in all three conditions had relapsed. This finding suggests that the timing of the support calls may have been inadequate to prevent the rapid decline in abstinence that is well documented in the smoking literature [*15*].

The current study builds upon the work of Lando and colleagues, but focuses on low-income women of childbearing age, where smoking prevalence is high and resources for cessation are limited. Like the Lando *et al.* study, our purpose was to test the efficacy of free nicotine patches with and without proactive telephone support; however, we did not include an initial orientation session in our design. Instead, we initiated the support calls prior to the quit day and increased the overall frequency of the calls, especially early in the quitting process to ensure that support was available when the risk for relapse was greatest. In our study, the staff had no face-to-face contact with the participants during the intervention, a model that could have widespread public health implications if proven efficacious.

METHOD

Participants

Potential participants were 435 women who called a local office telephone number in response to flyers posted in health care facilities, human service agencies, and public bulletin boards offering free nicotine patches to women smokers who met study guidelines. Of the women who called and were screened over the telephone, 219 met the following eligibility criteria: were 18–50 years of age; were Medicaid income eligible; smoked greater than four cigarettes per day; had adequate command of English; had high intentions of quitting smoking in the next 2 weeks; had a home telephone; lived in Chittenden County, Vermont; had no plans to move in the next 6 months; were not currently using nicotine replacement; and had no contraindications for the use of nicotine patches (e.g., history of heart disease, pregnant or intending to become pregnant in the next 3 months, breast-feeding). The major reasons for exclusion were: not 18–50 years of age (26%); income too high (25%); lived outside of Chittenden County, Vermont (14%); had no home telephone (11%); planned to move within 6 months (8%); smoked fewer than five cigarettes per day (7%); currently pregnant or breast-feeding (3%); history of heart disease (3%); and unable to reach for baseline assessment (3%). Five eligible women were subsequently removed from the study for the following reasons: lived in the same household as another study participant (two women); became pregnant during the study (one woman); and died during the study (two women).

The 214 women participants had a mean age of 33 years (SD = 8.5); a mean education level of 12.5 years (SD = 1.9); and a mean annual household income of $12,806 (SD = $6,481). Ninety percent were Caucasian; they smoked a mean of 23.7 cigarettes per day (SD = 11.8). Thirty-one percent reported a history of depression; 46% currently lived with at least one other smoker; and 66% had at least one child living in their household.

Procedure

Women responding to recruitment flyers called a local office telephone number to be screened for study eligibility by a female interviewer. Eligible women were read and sent two copies of a consent form through the mail with instructions to return one signed copy if interested in participating. Upon receipt of a signed consent form, the interviewer called the woman to complete a baseline assessment over the telephone. At the end of the baseline assessment, the woman was randomized into either the experimental (n = 106) or comparison condition (n = 108). This study was approved by the University of Vermont Institutional Review Board.

All women received free nicotine patches (NicoDerm CQ by SmithKline Beecham) through the mail with instructions to quit smoking the day after their patches arrive. Women who reported smoking greater than 10 cigarettes per day at baseline received 6 weeks of 21-mg patches, 2 weeks of 14-mg patches, and 2 weeks of 7-mg patches. Women who reported smoking 5–10 cigarettes per day at baseline received 6 weeks of 14-mg patches, followed by 2 weeks of 7-mg patches. Patches were mailed out in three batches. The first batch included a 1-month supply of patches. The second and third batches were sent out contingent upon receipt of a flyer attached to the earlier batch on which the woman indicated whether or not she was currently smoking. If the woman failed to return the flyer or indicated that she was currently smoking, no further patches were sent to her. In the latter case, we sent her a letter stating that we could not take the medical responsibility for supplying her with patches while she was smoking. This letter was sent to 8% of the participants.

Women randomized into the comparison condition received the free nicotine patches through the mail. Women randomized into the experimental condition received the free nicotine patches through the mail plus proactive telephone support provided by one of five women ex-smokers who had received 7 h of training for the support role. Each woman in the experimental condition was assigned to one of the support persons after the baseline assessment. The support person initiated all support calls. The first call usually occurred

before a designated quit day; the second occurred on or shortly after the quit day; the third call was about 4 days later; and subsequent calls were typically on a weekly to bi-weekly basis for up to 3 months. Each call lasted an average of 9 min. During the support calls the support person provided encouragement, guidance, and much reinforcement for quitting smoking, and helped the woman cope with high risk for smoking situations using semi-structured protocols. The support person negotiated a schedule of contact with the woman, and the woman was told she could end the calls at any time. Participants received a mean of seven support calls over the 3-month period. For each call, the support person recorded on a log sheet the date and duration of the call, the woman's current smoking status, whether or not she was currently using the patches, and the major issues discussed during the call. Brief quality control checks were conducted by telephone by a research assistant with a sample of women in the experimental condition (46%) over the course of the intervention period. During these brief contacts, the research assistant asked whether the participant had been receiving telephone support from a woman ex-smoker and how she felt about the calls.

Assessments

Three research assistants conducted the screening and baseline, 10-day, 3-month, and 6-month follow-up assessments by telephone. The baseline assessment addressed: (a) demographic characteristics (age, education, annual household income, race, number of children in the home); (b) smoking history and current smoking behavior (age began smoking, cigarettes per day, nicotine dependence, number of quit attempts in the past year, length of longest quit attempt, prior use of nicotine patches and gum); (c) smoking attitudes (motivation to stop smoking and motivation to continue, confidence and intentions to quit smoking); (d) smoking environment (number of other smokers in the home, smoking among friends and family, anticipated support for quitting); and (e) mental health concerns (self-reported lifetime experience of feeling depressed nearly every day for 2 or more weeks, report of feeling downhearted and blue in the past month, current anti-depressant medication use, current stress level, and current concerns about weight). The questions about motivation, proportion of friends/family who smoke, anticipated support for quitting, and feeling downhearted and blue in the past month were all scored on 4-point scales from "not at all" or "none" = 1 to "a lot" = 4. The confidence measure consisted of four items (confidence could quit in the next month, could handle feeling stressed, feeling sad, or being around other smokers without smoking), each scored on 4-point scales from "not at all" = 1 to "a lot" = 4. A mean score was calculated as the confidence index (Cronbach's $\alpha = 0.60$). The question about intentions to quit in the next 30 days was scored on a 3-point scale from "possibly" = 1 to "definitely" = 3, as women having lower intentions to quit were excluded from the study. The questions assessing stress level and weight concerns were scored on 11-point scales from "no stress" (or weight concern) = 0 to "extreme stress" (or weight concern) = 10. Nicotine dependence was measured by the Fagerstrom Test for Nicotine Dependence [*16*] consisting of six items; the total score could range from 0 to 10 with a higher score indicative of greater nicotine dependence.

Ten days after the baseline assessment, a research assistant contacted each subject to determine receipt of the nicotine patches through the mail, use of the patches, problems with the patches, smoking status, and receipt of the first telephone support call (if in the experimental condition). Three and 6 months after the baseline assessment, a research assistant conducted follow-up interviews addressing most of the variables assessed at baseline. The motivation, confidence, and intention questions were framed in terms of quitting (for continuing smokers) or staying quit (for women who were abstinent). Self-reported abstinence was defined as no smoking in the past 7 days [*17*]. Those women reporting abstinence at the 3- or 6-month follow-up were asked to provide a carbon monoxide reading at a home visit for which they were offered a \$15–\$25 incentive payment (the amount increased over the course of the study to enhance participation). A reading of $\leq$8 ppm was considered indicative of nonsmoking. Process data collected at the 3-month follow-up assessment included number of days used the nicotine patches, perceived usefulness of the patches and likelihood of recommending them to a friend, each scored on a four-point scale where 1 = "not at all useful" (not likely to recommend) and 4 = "extremely useful" (extremely likely to recommend). Experimental subjects were asked about the usefulness and likelihood to recommend the telephone peer support using the same four-point scales. All subjects were asked whether or not they called a toll-free number provided on the patch boxes to reach the pharmaceutical company if they had questions about the patches.

Statistical Analysis

χ^2 analyses (for dichotomous variables) and *t*-tests (for continuous variables) were used to determine significant differences by condition at baseline and at each follow-up assessment. Abstinence rates at each follow-up assessment were based on an intention-to-treat model and counted women not reached for follow-up as smokers. Logistic regression analyses were conducted using baseline variables and experimental condition as predictors of abstinence at 3- and 6-month follow-up.

RESULTS

Baseline characteristics by condition are presented in Table 1. No significant difference was observed between conditions on any baseline variable.

Of the 214 participants, 96% were reached for the 10-day post-baseline telephone assessment. Of those reached, 95% had received their first batch of nicotine patches, and 73% had begun using them; these proportions did not differ significantly by condition. Seventy-six percent of the women in the experimental condition had received at least one peer support call. No significant difference was observed in quit rates between conditions at the 10-day contact, with 70% of experimental subjects and 60% of comparison group subjects reporting abstinence when women we were unable to reach were counted as smokers.

For the 3-month follow-up assessment, we reached 95% of women in the experimental condition and 85% of women in the comparison condition. This association was significant ($P = 0.01$), indicating a greater success in contacting experimental condition women. The 3-month follow-up process data are presented in Table 2. Regarding use of nicotine patches, 96% of women in the experimental condition and 95% in the comparison condition reported using them during the study. Mean numbers of days of use were 38.6 and 38.3, respectively. Perceived usefulness of the patches was comparable between conditions; however, women in the experimental condition were significantly more likely to recommend them to a friend ($P = 0.03$), and a significantly greater proportion of women in the comparison condition (21%) versus in the experimental condition (8%) called the toll-free pharmaceutical company number with questions about the patches ($P = 0.02$). We did not specifically ask whether women who called SmithKline Beecham enrolled in their "Committed Quitters" program. However, since significantly more women in the comparison condition reported calling, it is likely that any enrollment into that program would only make the test of our proactive telephone peer support more conservative. Ninety-five percent of women in the experimental condition reported receiving our telephone peer support calls. These women rated highly their usefulness and the likelihood they would recommend them to a friend.

Three-month outcome data are presented in Table

TABLE 1

Baseline Characteristics by Condition[a]

	Patch plus support ($n = 106$)	Patch only ($n = 108$)
Demographics		
Age (years) ($M \pm$ SD)	32.9 ± 8.0	33.2 ± 9.1
Education (years) ($M \pm$ SD)	12.6 ± 2.0	12.4 ± 1.7
Annual income ($) ($M \pm$ SD)	12,438 ± 6,474	13,166 ± 6,496
Race [Caucasian, % (n)]	90% (95)	91% (98)
≥ 1 child in home, % (n)	66% (73)	67% (72)
Smoking history		
Age started (years) ($M \pm$ SD)	15.6 ± 3.3	15.2 ± 4.3
Cigs/day ($M \pm$ SD)	23.0 ± 12.0	24.3 ± 11.5
Fagerstrom score ($M \pm$ SD)	5.7 ± 2.3	5.6 ± 2.3
Quit attempts past year ($M \pm$ SD)	1.6 ± 1.7	1.4 ± 1.6
Longest attempt (days) ($M \pm$ SD)	32.6 ± 68.2	29.1 ± 48.0
Ever used nicotine patches, % (n)	35% (37)	36% (39)
Ever used nicotine gum, % (n)	22% (23)	19% (21)
Smoking Attitudes		
Motivation to quit ($M \pm$ SD)	3.9 ± 0.2	3.9 ± 0.5
Motivation to smoke ($M \pm$ SD)	1.7 ± 0.9	1.7 ± 0.9
Confidence to quit ($M \pm$ SD)	3.1 ± 0.6	3.0 ± 0.6
Intentions to quit ($M \pm$ SD)	2.7 ± 0.5	2.6 ± 0.6
Smoking environment		
≥1 other smoker in home, % (n)	40% (42)	52% (56)
Friends/family smoke ($M \pm$ SD)	3.1 ± 0.9	3.0 ± 0.9
Support for cessation ($M \pm$ SD)	3.7 ± 0.6	3.6 ± 0.7
Mental Health		
Self-reported depression ever, % (n)	30% (32)	32% (34)
Down and blue past month ($M \pm$ SD)	2.3 ± 0.9	2.2 ± 1.0
Taking antidepressant meds, % (n)	21% (22)	14% (15)
Stress level ($M \pm$ SD)	5.0 ± 2.6	5.0 ± 2.8
Weight concerns ($M \pm$ SD)	5.8 ± 3.7	5.6 ± 3.6

[a] No significant differences were found between conditions at baseline.

TABLE 2

Three-Month Follow-Up Process Data

Variable	Patch plus support	Patch only	*P* value
Response rate, % (*n*)	95% (101/106)	85% (92/108)	0.01
Reported use of patches, % (*n*)	96% (97/101)	95% (87/92)	ns
Days used patches (*M* ± SD)	38.6 ± 26.5	38.3 ± 23.8	ns
Usefulness of patches (*M* ± SD)	3.7 ± 0.6	3.5 ± 0.9	ns
Recommend patches (*M* ± SD)	3.8 ± 0.4	3.6 ± 0.8	0.03
Called toll-free patch No % (*n*)	8% (8/101)	21% (19/92)	0.02
Received support calls, % (*n*)	95% (96/101)	—	—
Usefulness of calls (*M* ± SD)	3.2 ± 1.0	—	—
Recommend calls (*M* ± SD)	3.5 ± 0.9	—	—

3. At 3 months, we observed a significant association between abstinence and condition ($P = 0.03$), with 42% of experimental women and 28% of comparison group women reporting no smoking in the past 7 days. Analysis of period prevalence, defined as abstinence at both the 10-day and 3-month assessments, also revealed a significant association ($P = 0.02$), with 32% of women in the experimental condition and 19% of women in the comparison condition reporting abstinence at both assessments. When women not reached for follow-up were eliminated from the 3-month point prevalence analysis, quit rates were 44% in the experimental condition and 33% in the comparison condition. This difference was not significant due to the smaller sample sizes. Among continuing smokers at the 3-month assessment, no significant differences were found between conditions for cigarettes per day or Fagerstrom dependency score, although the means were in the predicted direction. Among mediating variables assessed at 3 months, we observed a significant difference in confidence in ability to quit or stay quit between conditions ($P < 0.05$), with women in the experimental condition reporting greater confidence ($M = 3.2$) than women in the comparison condition ($M = 2.9$). No other differences in mediating variables were significant.

A simultaneous logistic regression was run with all subjects testing all baseline variables and experimental condition as predictors of abstinence at 3-month follow-up. Experimental condition was the strongest predictor of 3-month abstinence (odds ratio 2.0; 95% CI 1.09, 3.68). The odds of being abstinent were twice as great for women in the experimental versus comparison condition. Concern about weight at baseline was the only other significant predictor of abstinence (odds ratio 1.1; 95% CI 1.01, 1.2). The odds of being abstinent at 3 months were 1.1 times greater for each unit increase on the 11-point scale indicating concerns about weight.

The response rate at the 6-month follow-up was about 73% in each condition. By this time, all significant differences in reported abstinence had disappeared. As presented in Table 3, nearly twice as many subjects in the experimental condition had relapsed back to smoking for an abstinence rate of 23 vs 19% in the comparison condition. Among continuing smokers at 6 months, a borderline significant difference was observed in mean number of cigarettes smoked per day ($P = 0.055$), with continuing smokers in the experimental condition smoking fewer cigarettes ($M = 11.3$) than continuing smokers in the comparison condition ($M = 14.9$). As at the 3-month follow-up, we found a significant difference

TABLE 3

Three- and Six-Month Follow-Up Outcome Data

Variable	Patch plus support	Patch only	*P* value
3-Month Follow-Up			
Reported abstinent (all Ss), % (*n*)	42% (44/106)	28% (30/108)	.03
Quit at 10-day and 3-month, % (*n*)	32% (34/106)	19% (21/108)	.02
Cigs/day (smokers only) (*M* ± SD)	9.5 ± 10.3	13.1 ± 12.0	ns
Fagerstrom score (*M* ± SD)	3.2 ± 2.1	3.6 ± 2.6	ns
Confidence score (*M* ± SD)	3.2 ± 0.9	2.9 ± 0.9	.05
6-month follow-up			
Reported abstinent (all Ss), % (*n*)	23% (24/106)	19% (20/108)	ns
Quit at 3- and 6-month, % (*n*)	20% (21/106)	15% (16/108)	ns
Cigs/day (smokers only) (*M* ± SD)	11.3 ± 7.7	14.9 ± 10.7	.055
Fagerstrom score (*M* ± SD)	3.4 ± 2.3	3.9 ± 2.4	ns
Confidence score (*M* ± SD)	3.1 ± 0.8	2.7 ± 0.9	.01

between conditions in confidence in ability to quit or remain quit ($P = 0.01$), with experimental subjects reporting greater confidence ($M = 3.1$) than comparison subjects ($M = 2.7$). A simultaneous logistic regression revealed no significant predictors of abstinence at 6 months among baseline variables or experimental condition.

The carbon monoxide readings obtained at the 3- and 6-month follow-up tended to corroborate subject reports. At 3 months, we obtained CO readings from 60% of experimental subjects and 66% of women in the comparison condition reporting abstinence. Of these, 80% of experimental subjects and 78% of comparison group subjects had values of 8 ppm or less. At 6 months, we received CO readings from 59 and 67% of experimental and comparison condition women, respectively. Of these, 82% of experimental subjects and 93% of comparison subjects had values confirming abstinence. Women who gave readings greater than 8 ppm were classified in all analyses as smokers.

DISCUSSION

The results of this study reveal a short-term effect for the addition of proactive telephone peer support to the provision of free nicotine patches to help low-income women stop smoking; however, the difference in quit rates between conditions was lost by the 6-month follow-up. This loss appears to be attributable to the near doubling of relapse rates in the experimental versus the comparison condition between the 3- and 6-month follow-up assessments. It is noteworthy that the telephone peer support contacts for women in the experimental condition ended just before the 3-month assessment, suggesting that the support calls maintained abstinence while they were operative and that a longer period of support may be necessary to avoid subsequent relapse.

Our findings are more hopeful than those of Lando and colleagues [*14*] who observed no short- or long-term impact for the addition of four proactive telephone support calls delivered over 3 months to HMO patients who were also receiving up to 8 weeks of free nicotine patches. Differences in subject characteristics between the two studies (low-income women versus more affluent males and females) may account for the differing results, as women with fewer resources who are enmeshed within a smoking environment may find the provision of proactive support to be a more useful adjunct to nicotine replacement therapy than other users of NRT. It is also possible that differences in the number and pacing of the calls could account for the short-term outcome differences. In our study, women received an average of seven calls (59% received more than four) and many of the calls occurred early in the quitting process (56% received three or more calls in the first month). In contrast, subjects in the Lando study received four calls spaced widely over 3 months. Although we did not measure time to relapse, it is possible that our spacing and frequency of calls prevented the high rate of early relapse observed in the Lando study (nearly 50% by 5 weeks), resulting in a higher abstinence rate at 3 months in our experimental condition (42%) compared to theirs (26%). This possibility is further supported by Zhu and colleagues [*12*] who observed that six proactive telephone contacts within 30 days of a designated quit date prevented relapse better than a single proactive telephone contact when outcomes were measured at 1-, 3-, and 12-month follow-up, and the results were strongest early in the cessation process. Thus, frequent support contacts during the early process of quitting appear to help both users and non-users of NRT to remain abstinent.

Our finding that the relapse rate back to smoking was nearly twice as high in the experimental than the comparison condition between the 3- and 6-month follow-up raises questions about the optimal duration of telephone support to maintain abstinence. Other researchers have observed that face-to-face maintenance contacts reduce relapse during a 3-month maintenance period, but fail to impact longer-term abstinence rates [*18*]. It is unclear whether continued telephone support beyond 3 months would produce less relapse or whether, conversely, the provision of external support results in external attributions for success, enhancing the likelihood of relapse whenever the support is terminated. Although we did not measure attributions directly, we did measure confidence in ability to quit or remain quit at the 3- and 6-month assessments. Our findings revealed significant relationships between condition and overall confidence, with women in the experimental condition expressing greater confidence in their ability to quit or remain quit at both assessments. This suggests that the provision of telephone support did not diminish subjects' beliefs about their ability to manage their smoking; instead, it appeared to enhance these beliefs. Therefore, it seems reasonable to entertain the possibility that support for a longer duration might mitigate the relapse we observed between 3 and 6 months. This should be tested in future research.

Process data collected at 3 months indicated that both the nicotine patches and the telephone peer support were received favorably and that women in the two conditions used the patches for the same amount of time. Interestingly, experimental subjects reported being significantly more likely to recommend the patches to a friend, suggesting that the telephone peer support enhanced satisfaction with the patches, perhaps by addressing users' concerns. The fact that significantly more women in the comparison condition called the toll-free pharmaceutical company telephone number with

questions about the patches supports this interpretation. Thus, proactive telephone support for NRT users may not only encourage, assist, and reinforce changes in smoking, but may also provide a convenient way to address questions and concerns about patch use. The relative importance of these content components in enhancing abstinence rates should be examined in future studies.

This study demonstrated a short-term benefit for proactive telephone peer support in conjunction with free nicotine patches to help low-income women of childbearing age to stop smoking. Because of the magnitude of the smoking problem with this segment of our population, further examination of this intervention is warranted.

ACKNOWLEDGMENTS

Nicotine patches were provided by SmithKline Beecham. We are grateful to Kerstin Lipke and Ellen Torabi for conducting the assessment interviews and to Leanne Ponder, Jill Carberry, Julie Bristol, Alexi Potter, and Deb Shell for their work as telephone peer support staff.

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