

From Research to Practice:  
Improving Medication Adherence in Persons with HIV

Judith A. Erlen, PhD, RN, FAAN  
Professor, Doctoral Program Coordinator, and  
Associate Director, Center for Research in Chronic Disorders  
University of Pittsburgh  
School of Nursing  
440 Victoria Building  
Pittsburgh, PA 15261  
Telephone: 412-624-1905  
FAX: 412-624-8521  
E-mail: jae001@pitt.edu

Susan M. Sereika, PhD  
Associate Professor; Director, Center for Research and Evaluation;  
And Director, Data Management and Analysis Core,  
Center for Research in Chronic Disorders  
University of Pittsburgh  
School of Nursing  
360 Victoria Building  
Pittsburgh, PA 15261  
Telephone: 412-624-0799  
E-mail: ssereika@pitt.edu

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### Abstract

**Background:** Successful management of HIV/AIDS requires that patients reliably take their prescribed drugs. The challenge for researchers is to demonstrate the efficacy of interventions, and the challenge for health care providers is to enable patient adherence. Interventions tested in clinical trials need to be examined for their usefulness in clinical practice.

**Objectives:** This study examined the delivery of a 12-week structured telephone intervention based on social cognitive and self-efficacy theories designed to improve medication adherence in persons with HIV infection who were prescribed and taking antiretroviral therapy. Second, this study examined what factors (race, gender, socio-economic status) are related to participation in the 12-week nurse-delivered structured telephone intervention.

**Methods:** Adherence to delivery of the intervention in a sample of 99 subjects with HIV infection in the treatment arm of a larger intervention study was assessed according to 1) the number of intervention sessions delivered, 2) the duration of each intervention session, 3) the number of telephone attempts to reach a subject for an intervention session, 4) the time elapsed between intervention sessions, 5) number of instances that multiple interventions were delivered in a session (i.e., “doubled up”), and 6) the attrition from the intervention.

**Results:** The average number of intervention sessions delivered was 8.1 (SD=4.07). Subjects were more likely to receive the first five intervention sessions (n=77, 77.8%). Twenty-one (21.2%) subjects dropped out of treatment before it was completed. Nearly one-quarter (n=24, 24.2%) of the sample had interventions “doubled up”. Intervention sessions lasted on average 11.3 minutes. Typically more than one attempt was needed before contacting the subject (Mean = 1.2). The mean number of days between sessions was 11.5. Women were more likely to have

“doubled up” interventions ( $p=.036$ ). For some sessions, more attempts were necessary to contact women and sessions tended to be shorter for women than men. For one session, the duration was longer for subjects in the \$10,000-\$19,999 income level ( $p=.049$ ). When examining interaction effects between the demographic factors considered, a race by income effect was observed for mean number of attempts to contact the subject ( $p = .044$ ).

**Discussion:** These results suggest that despite efforts to prevent nurse interventionist drift from the study protocol, factors beyond the interventionist’s control may have influenced the subject’s level of participation in the intervention protocol.

**Key Words:** HIV infection, Medication adherence, Intervention research

## From Research to Practice: Improving Medication Adherence in Persons with HIV

Antiretroviral therapy has dramatically changed the management of HIV/AIDS and increased the survival of patients with this illness; however, successful management of HIV/AIDS requires that patients reliably take their prescribed drugs. Researchers have demonstrated that near perfect medication adherence, as high as 95%, may be required to decrease viral load, increase CD4 counts, and decrease drug resistant mutant strains of HIV (Paterson et al, 2000; Wu, 2000). Investigators report that not unlike other chronic disorders, adherence rates to prescribed medications in persons with HIV/AIDS range from 30% to 90% (Gifford et al, 2000; Golin et al, 2002); higher rates have been found when self-report is used to assess adherence (Wutah, 2001). A survey of 219 persons with HIV infection showed an average self-reported adherence rate of 70% over the previous week and 80% during the last 24 hours (Cook et al, 2001). Erlen and colleagues (2002) found that 60% of 61 female subjects with HIV/AIDS self-reported high levels of adherence to antiretroviral therapy; however, only 57% of those subjects thought it was dangerous to miss a dose. Documented evidence of medication non-adherence in persons with HIV/AIDS supports the need for intervention studies to enhance medication taking behavior.

Adherence among persons with HIV/AIDS is related to beliefs that treatment prolongs life (Samet et al, 1992), mood changes and greater depression (Paterson et al, 2000; Wagner et al, 2001), forgetting or taking less medication than prescribed (Chesney, Morin, & Sherr, 2000), side effects (Bartlett, 2002), and substance abuse (Wagner et al, 2001). Gifford's research team (2000) found that race, symptoms, and stress were associated with poorer adherence; increased access and social support were associated with greater adherence. Others have shown that nonadherence is related to living a "marginal" lifestyle (Morin & Moatti, 1996) and barriers such

as being reminded of having HIV/AIDS, not wanting others to know, and forgetting to ask questions (Catz , Kelly, Bogart, Benotsch, & McAuliffe, 2000).

Social cognitive theory (Bandura, 1986) provided the theoretical basis for the intervention examined in this study; this theory offers one explanation for understanding health behavior. The focus of social cognitive theory is modeling, problem solving, and self-control; learning occurs when behavior is reinforced (Bandura, 1986). This theory addresses adopting new behaviors, using them when circumstances vary, and maintaining them over time (Bandura, 1986). One learns to be a problem-solver, to use strategies to increase the desired behavior, and to gain a sense of mastery. Problem solving and self-management are skills necessary for developing and maintaining adherence. Social cognitive theory recognizes that environmental factors stimulate behavior and that one's personal characteristics and beliefs (self-efficacy) interact with each other to influence behavior (Bandura, 1986).

The principle underlying self-efficacy theory is that people believe that their ability and the efficacy of the treatment is influenced by and influences their behavior (Bandura, 1997). Self-efficacy influences one's use of knowledge, skills, and resources to manage changing situations. It can be enhanced when persons master a specific behavior, are confident that they can achieve, and have supportive relationships (Bandura, 1997). Once developed, self-efficacy regulates choices about health behavior and becomes a significant predictor of health behavior like medication adherence (Bandura, 1986, 1997).

Long-term regimen adherence is difficult to sustain. Reasons for non-adherence include the complexity of the regimen, side effects, forgetting, not understanding the instructions, depression, limited social support, and stigma associated with HIV. In addition, given that there is an increasing incidence of HIV infection among women, minorities, and those of lower socio-

economic status (Centers for Disease Control [CDC], 2002; Hall, Song, & McKenna, 2003), researchers need to examine whether selected socio-demographic factors among the HIV/AIDS population are related to adherence to medication regimen. Therefore, the challenge for researchers is to demonstrate the efficacy of interventions, and the challenge for health care providers is to enable patient adherence. Interventions that are tested in randomized clinical trials need to be examined for their usefulness in clinical practice.

One way to examine this fit between a research protocol and its potential usefulness in clinical practice is to examine the adherence to the intervention protocol that was designed specifically for the study. Therefore, the primary purpose of this study was to examine the delivery of a 12-week structured telephone intervention based on social cognitive and self-efficacy theories designed to improve medication adherence in persons with HIV infection who were prescribed and taking antiretroviral therapy. Secondly, this study sought to examine what factors (race, gender, socio-economic status) are related to participation in the 12-week nurse-delivered structured telephone intervention.

## **Methods**

After the study protocol and consent documents for the parent study were reviewed and approved by the University of Pittsburgh Institutional Review Board (IRB), subjects were recruited from local HIV/AIDS clinics and through self-referral. Potential subjects who desired to participate contacted the project director. Arrangements were made for the individual to be seen in a private conference room in the clinic or in the School of Nursing in order to obtain informed consent and screen the volunteer for study inclusion.

## **Sample**

Study participants had to be 18 years of age or older, diagnosed with HIV infection, prescribed and taking antiretroviral medications; have access to a telephone; be able to speak, read, and write English; and be living in a private residence or apartment in the community. Subjects were excluded if they had evidence of cognitive impairment as evidenced by their score on the HIV Dementia Scale (Power, Selnes, Grim, & McArthur, 1995), were living with someone already enrolled in the study, had motor impairment of their upper extremities, had a hearing impairment or did not have a hearing enhanced telephone, or were blind.

One of the subject's antiretroviral medications was then randomly selected for monitoring. Subjects were taught how to maintain the diary and use the cap containing an electronic event monitor (EEM). They were asked to use a standard pill bottle with the EEM for the randomly selected medication and a paper and pencil diary for one month so that baseline adherence could be determined. After the one month period, the subject returned for baseline data collection. The downloaded data from the electronic event monitor and the diary were reviewed. Subjects with less than 100% adherence were then randomized to either the treatment or usual care/control arm.

The sample consisted of the 99 subjects in the treatment arm of the parent study. Two-thirds of the sample was men and slightly more than half were white. The average age was 39.68 (SD=7.98) years. Subjects had an average of 13.1 (SD=2.30) years of education. Two-fifths of the subjects had an income of \$10,000 or less and one-fifth had an income of \$20,000-\$49,999. Refer to Table 1.

Insert Table 1 about here.

## Procedure

The participants in this study were those individuals with HIV/AIDS who were assessed to be less than 100% adherent at baseline and who were randomized to the treatment arm. These participants received a 12 week telephone-delivered structured intervention given by a registered nurse with a minimum of a bachelor's degree in nursing. The weekly intervention sessions were intended to be provided in 15-20 minutes. Intervention sessions included topics such as self-assessment of habits, self-assessment of medication taking, developing habits, side effects, social support, problem solving, developing a plan, and reinforcement. The interventionist tailored the sessions to the person's particular situation. Each of the 12 sessions also included a self-efficacy statement, homework, and knowledge questions.

The interventionist was formally trained in the delivery of the study protocol. The methods for training included simulation and role play. Training sessions were audio-recorded and reviewed by the project director who discussed her observations with the principal investigator. This information was then provided as feedback to the interventionist.

The intervention sessions were audio-recorded throughout the study unless the subject had not consented to the recordings. The interventionist also took notes during each session. Initially, all sessions were reviewed for adherence to the protocol by the project director. Subsequently, sessions were randomly selected for monitoring. Feedback and additional training were provided by the project director as needed.

## Data Analysis

Oracle 9i (Oracle Corp., Redwood Shores, CA) was used for the data management and SPSS version 13.0 (SPSS, Inc., Chicago, IL) was used for the analysis of data. The major endpoints examined in terms of the delivery of the intervention were 1) the number of

intervention sessions delivered (maximum=12), 2) the duration (in minutes) of each intervention session, 3) the number of telephone attempts to reach a subject for an intervention session, 4) the time elapsed (in days) between intervention sessions (expected=7 days), 5) number of instances that multiple interventions were delivered in a session (“doubling up”); and 6) the attrition, or drop-out, from the intervention. In addition to session-specific summary statistics for the delivery outcomes, endpoint data were aggregated over the sessions and summary statistics (mean, standard deviation, minimum, and maximum) were computed to summarize the major distributional characteristics of the identified endpoints for each intervention subject. Appropriate descriptive statistics (i.e., means, medians, standard deviations, minimums, maximums for continuous variables and frequency count and percentages for categorical variables) were calculated to characterize the summarized endpoints for the intervention group (n=99). Group comparative statistics (two sample t-tests/ANOVA or Mann-Whitney U-tests/Kruskal Wallis tests for continuous endpoints; chi-square tests of independence for categorical endpoints) were computed to investigate bivariate whether the intervention delivery endpoints varied by key sociodemographic characteristics [gender (male, female), race (nonwhite, white), income (under \$10,000, \$10,000 to \$19,999, and greater than \$20,000)]. Factorial analysis of variance (ANOVA) was used to investigate the joint effects of the identified demographic factors on summarized intervention delivery endpoints. The level of statistical significance was set at .05 for two-tailed hypothesis testing. Findings greater than .05 but equal to or less than .10 were also identified for potential trends in the data that need further exploration.

## **Results**

The average number of intervention sessions delivered was 8.1 (SD=4.07). Forty-three (43.4%) subjects received the entire 12 sessions. Subjects were more likely to receive the first five intervention sessions (n=77, 77.8%). Less than half received the last three sessions. In regard to attrition, twenty-one (21.2%) subjects dropped out of treatment before it was completed; of those 21 subjects two (2.0%) received none of the 12 intervention sessions. (See Figure 1)

Insert Figure 1 about here.

As shown in Figure 2, nearly one-quarter (n=24, 24.2%) of the sample had interventions “doubled up” (two sessions were delivered during the same call) over the course of the 12 weeks of the telephone-delivered intervention. For one subject (1%), two sessions were delivered out of order, i.e., a later session was delivered before an earlier session.

Insert Figure 2 about here.

In general an intervention session lasted on average 11.3 minutes (Median = 10.0; Range = 4.7-26.7) and typically more than one attempt was needed before contacting the subject (Mean = 1.2, Median = 1.0, Range= 0-4). The mean number of days between sessions was 11.5 (Median = 8.9, Range = 3-84). Figure 3 shows the distribution of the mean duration and mean number of attempts for each of the twelve intervention sessions. The mean durations of the intervention sessions ranged between 9.3-15.2 minutes across the intervention sessions. The first session focusing on the review of the current regimen and clarifying misconceptions was the longest, taking on average 15.2 minutes (SD = 8.56). Even though the time and date for the next session was set at the end of the session, the interventionist typically contacted subjects more than one time to deliver an intervention session. The mean number of attempts to contact a subject ranged from 0.5-1.7 across the intervention sessions. Subjects who participated in all 12 sessions were more likely to be available for the session when the interventionist called. Given that on average

subjects had to be contacted more than once, the mean times between sessions ranged from 5.3-12.0 days across the sessions, with the shortest and longest inter-session intervals being between sessions 11 and 12 and between sessions 2 and 3, respectively. (See Figure 4).

Insert Figure 3 about here.

Insert Figure 4 about here.

When examining the number of intervention sessions received (i.e., “dose” of intervention) by gender, women were more likely to have “doubled up” interventions ( $p=.036$ ). More attempts were necessary to contact women in Sessions 3 ( $p=.070$ ) and 8 ( $p=.027$ ). Sessions 7 ( $p=.036$ ), 10 ( $p=.058$ ), and 12 ( $p=.053$ ) tended to be shorter for women than men. The intervals between sessions tended to be of similar duration between men and women. There was a marginally significant difference in the dose of intervention received between whites and non-white, with whites (Mean = 8.8, SD=3.9) receiving slightly more sessions compared to nonwhites (Mean = 7.24, SD = 4.2) ( $p = .075$ ). Nonwhites (Mean = 1.1, SD = 1.8) also required more attempts by the interventionist to contact the subject for the last session compared to whites (Mean = 0.2, SD = 0.6) ( $p = .059$ ). Sessions tended to be of similar duration between white and nonwhite subjects, except for Session 6 which may have lasted longer for white participants (Mean = 11.8, SD = 6.9) compared to nonwhite participants (Mean = 9.3, SD = 4.8) ( $p = .084$ ). The duration between sessions was similar for white and nonwhite subjects. The only difference noted when examining income was that Session 9 was longer (14 minutes) for those whose income was \$10,000 - \$19,999 ( $p = .049$ ). When examining interaction effects between the demographic factors considered, a race by income effect was observed for mean number of attempts to contact the subject ( $p = .044$ ). As displayed in Figure 5, for white participants the

mean number of attempts seems to be fairly constant over level of income, whereas for nonwhite participants the number of attempts varies inversely with income (partial eta-squared=.072).

Insert Figure 5 about here.

## **Discussion**

One means of assessing quality is by examining adherence to a research or clinical protocol that has its basis in theory and scientific evidence. Effective delivery of a treatment protocol requires adherence on the part of both the interventionist/clinician and the patient. In this study, there was monitoring of the intervention; feedback was provided in order to maintain treatment fidelity. While the intervention was designed to promote and improve medication adherence, patients had to assume responsibility for their own participation in and adherence to the study protocol.

Adherence is the degree to which one follows or conforms to the prescribed therapeutic regimen (Haynes, 1979; Wright, 2000) or to the delivery of the planned intervention protocol. The intervention was designed as 12 weekly pre-scripted sessions given in a pre-determined order with each session averaging 15 minutes. The components of the intervention were guided by social cognitive and self-efficacy theories (Bandura, 1986). Clearly, the planned treatment protocol was not followed for all subjects in regard to number of sessions delivered and the length of time between sessions. Over half of the participants received less than the planned treatment. Because there was a greater likelihood that they received the first five sessions, earlier sessions may need to address the most important topics related to medication adherence since they are more likely to be delivered and received. Possibly at the end of the fifth session subjects either thought they had received the information that they needed or they were burdened by the

study protocol with its weekly sessions and homework. If the early content focused on issues with which they were familiar, subjects may have thought that the later sessions would not be any different. Thus, they may have perceived that the intervention was not helpful to them. Participants in randomized clinical trials do not always understand that they may not receive any benefit even if they are in the treatment arm (Erlen, 2000).

Also of concern when examining adherence to the intervention protocol was the attrition rate. One-fifth of the subjects dropped out of treatment, and two subjects received no treatment. During enrollment subjects were told about the study expectations. Possibly they were unclear as to what they would be asked to do if they were randomized to the treatment arm. There is also the possibility that the lifestyles of the subjects were too chaotic and there was not time for study participation. Maybe they ended the intervention early or did not participate in all sessions because of other factors such as stigma, substance abuse, or mood disorders. Other researchers (Catz et al, 2000; Wagner et al, 2001) have identified that such factors can interfere with a person's ability to adhere to their medication regimen. Quite possibly these factors also influence adherence in other areas of a person's life as well.

Maintaining a weekly schedule for delivering the sessions was difficult. Although the interventionist scheduled a day and time for the next intervention, there were numerous instances when the subject was unavailable. At least two attempts to contact per session, on average, were necessary. The subject was given the focus of the next session when the current session was ending. This content area may not have been of interest to the subject; therefore, the person was unavailable when contacted. When the interventionist was unable to speak with the subject a benign message was left by the interventionist if there was an answering machine. The message often included the day and time when the interventionist would call back in order to increase the

likelihood that the person would be there to answer the telephone. There were occasions when telephones were disconnected or subjects changed cellular telephone companies. These instances necessitated contacting the health care provider or clinic for new contact information. In this study, the consent form had a clause that gave permission for the researchers to contact the clinic or health care provider for such information if it was necessary to do so.

If no contact was made, the intervention was missed or “doubled up” at the next session. “Doubling up” of sessions occurred as a way to cover the content. However, while “doubling up” met the goals of the interventionist to deliver the content, this may have been more information than participants were able to manage at the time of the call. “Doubling up” may have increased the length of the session. Participants may not have had that additional time and may have just wanted to end the session. Content from two sessions may have been condensed to some degree and therefore was not presented in as much detail or subjects may not have had the time to ask as many questions or to get additional clarification. Thus, the participant may not have received the full benefit of the intervention session.

A 12 week intervention may be too long; some sessions may be unnecessary, particularly for each person. Sessions may need to be tailored according to a person’s needs and life situation. Even though, the intervention sessions addressed topics that are generally considered to impact adherence, all sessions may not be necessary for all individuals because of their previous experience with managing medications. Subjects may not have been dealing with the particular issue at the time that the topic was discussed. The problem may have already occurred and strategies developed so that the subject was no longer experiencing the problem. Possibly subjects may need to be more involved in identifying the topics to be discussed.

Particular socio-demographic characteristics did not demonstrate any significant differences despite the fact that HIV/AIDS disproportionately affects marginalized groups (CDC, 2002; Hall, Song, & McKenna, 2003). While these characteristics have the potential to influence the sessions to include, the amount of time needed to deliver the intervention, and potential barriers to intervention delivery, the degree of participation and specific components of the intervention received were not different. Quite possibly the lack of significant differences in this study may be due to the fact that patients had chosen to participate in the study and therefore “bought into” the intervention.

In order to achieve adherence to an intervention protocol, a quality control mechanism needs to be in place. In this study the researchers had carefully trained the interventionist and regularly monitored the delivery of the intervention protocol (Rudy et al, 2005). If the interventionist strayed from the protocol, feedback or additional training was provided. In this study, there was no indication that additional training of the interventionist was needed. Ongoing random monitoring is one way to prevent drift. Researchers need to incorporate explicit documentation of their quality assurance program in order to assure that the protocol is delivered correctly.

However, the subjects also needed to be adherent to the intervention protocol since the premise was that the full intervention would enable subjects to be adherent to their medication regimen. Statements promoting self-efficacy were given to participants at the end of each session. The interventionist expressed confidence in the individual’s ability to include this aspect in managing their medication regimen. The question remains as to whether or not the subjects viewed themselves as gaining more confidence in their ability to adhere to their medication regimen.

The interventionist was limited as to actions to take to decrease subjects' non-adherence to the intervention protocol. Their participation was voluntary; they had the right to withdraw or to not fully participate. The interventionist could verify the telephone number, make additional telephone calls, or leave messages in an attempt to contact the person. Telephone calls were made from a university telephone or with a calling card. Therefore the telephone number was blocked when subjects had "caller ID". In these instances, subjects may have been reluctant to answer the telephone.

Interventions that are tested in randomized clinical trials and found to be effective cannot be used in clinical practice without examining the various components of the protocol for their relevance to the clinical situation. Issues that need to be considered are the amount of time the intervention takes, the availability of a dedicated interventionist, the fact that pre-determined sessions may not be appropriate for all, and the cost of implementing such a program even though there are benefits to patients. Feedback from participants in a clinical trial regarding the intervention, as well as a careful analysis of the protocol, the audio-recorded sessions, and the field notes can provide the information that is needed to make decisions about the usefulness of a protocol in clinical practice. Similar testing and evaluating of the revised protocol need to be conducted once health care providers implement the intervention protocol in the clinical setting.

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Table 1: Sample Characteristics

<u>Sex</u>	<u>n</u>	<u>%</u>
Male	66	66.7%
Female	33	33.3%
<u>Race/Ethnicity</u>		
White	54	54.5%
Nonwhite	45	45.5%
<u>Income</u>		
under \$10,000	41	42.3%
\$10,000 to \$19,999	35	36.1%
> \$20,000	21	21.6%
<u>Age (years)</u>		
Range = 19-61	Mean = 39.68	SD = 7.98
<u>Formal Education (years)</u>		
Range = 8-20	Mean = 13.09	SD = 2.30

### Captions for Figures

Figure 1: Distribution of Number of Intervention Sessions Received

Figure 2: Distribution of the Number of Occurrences of “Doubling Up” of Intervention Sessions

Figure 3: Distribution of the Mean Duration and Number of Attempts by Intervention Session

Figure 4: Distribution of the Mean Number of Days Elapsed between Intervention Sessions

Figure 5: Plot of Interaction Effect of Income by Race for Mean Number of Attempts to Contact

Figure 1

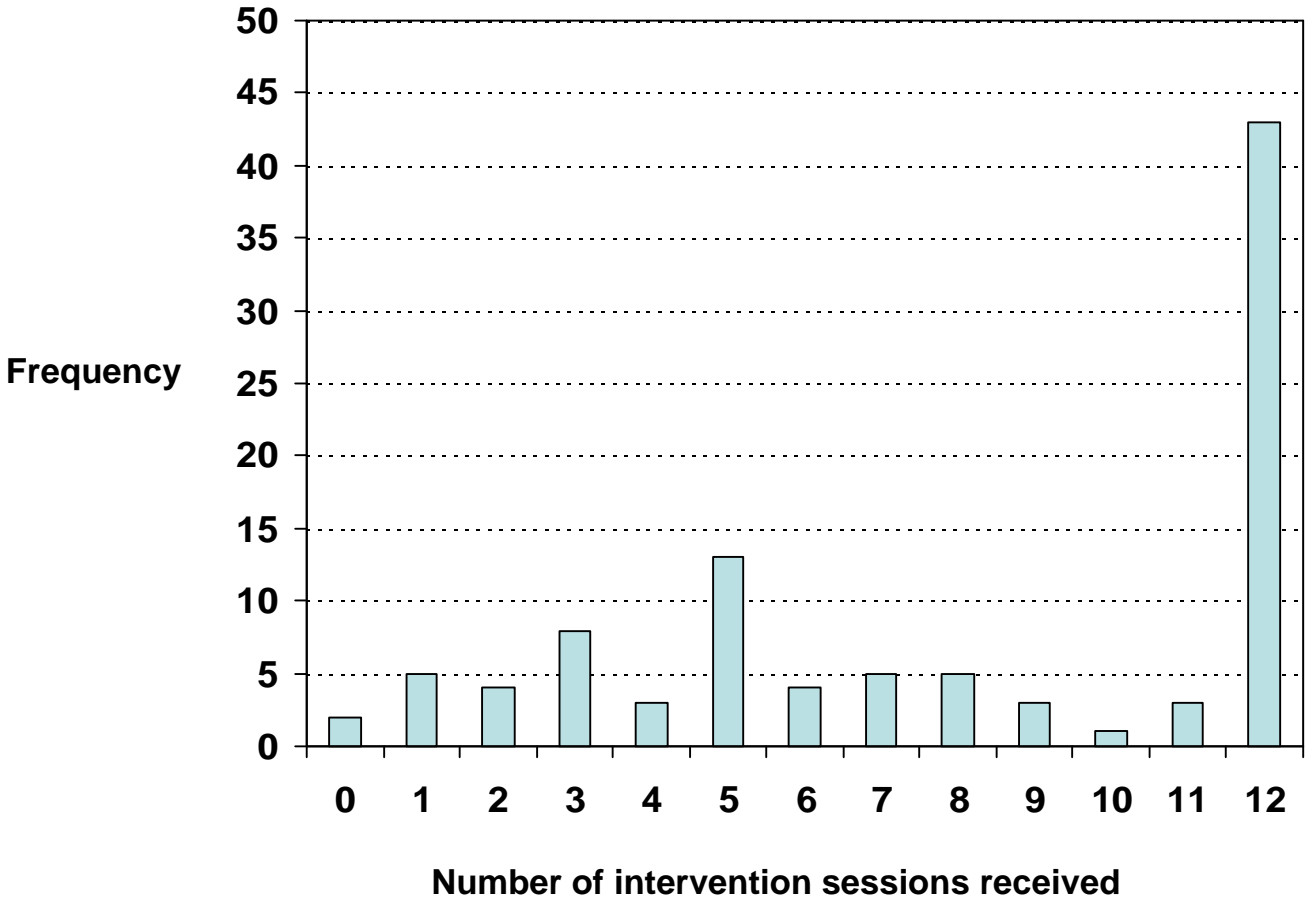


Figure 2

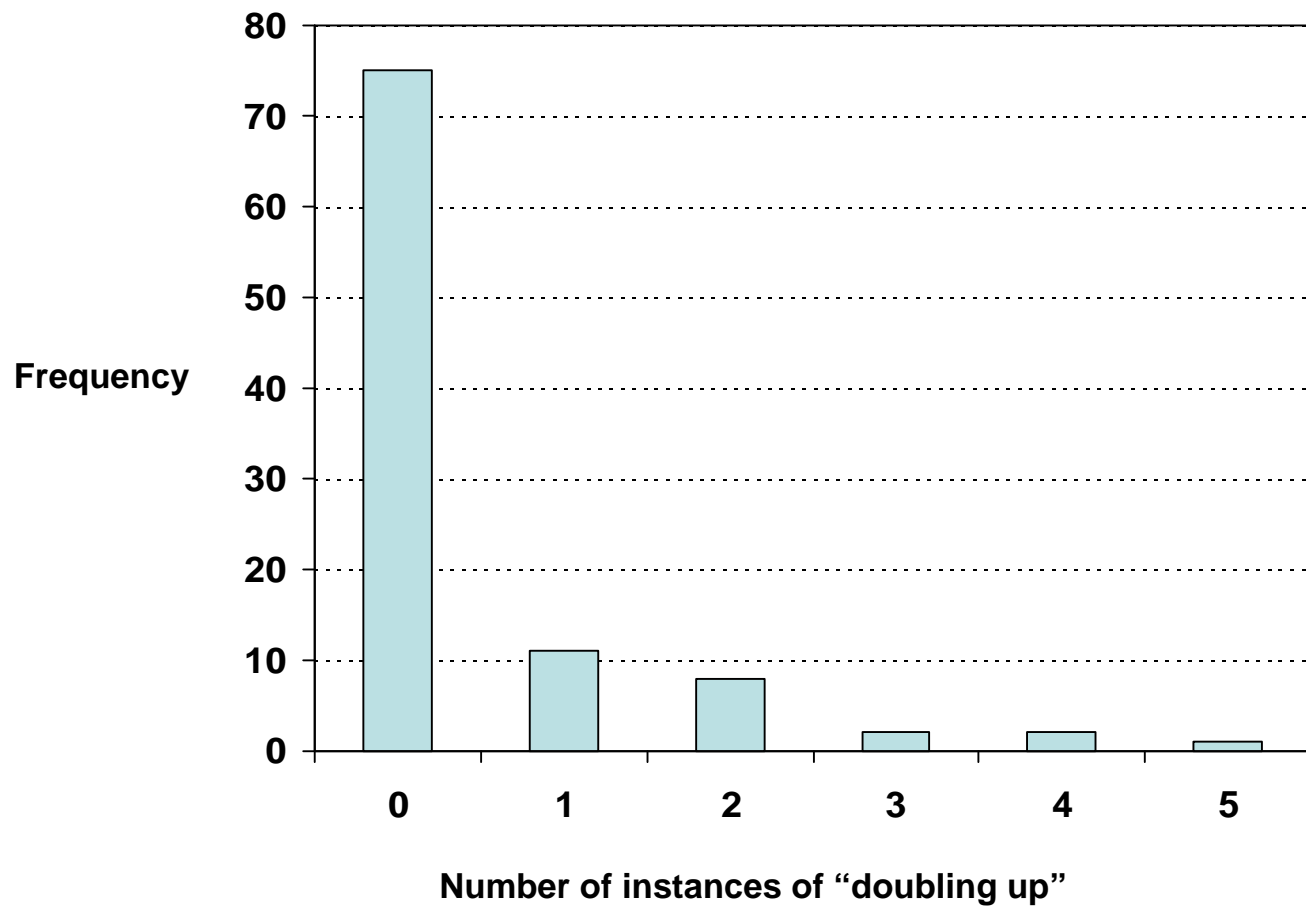


Figure 3

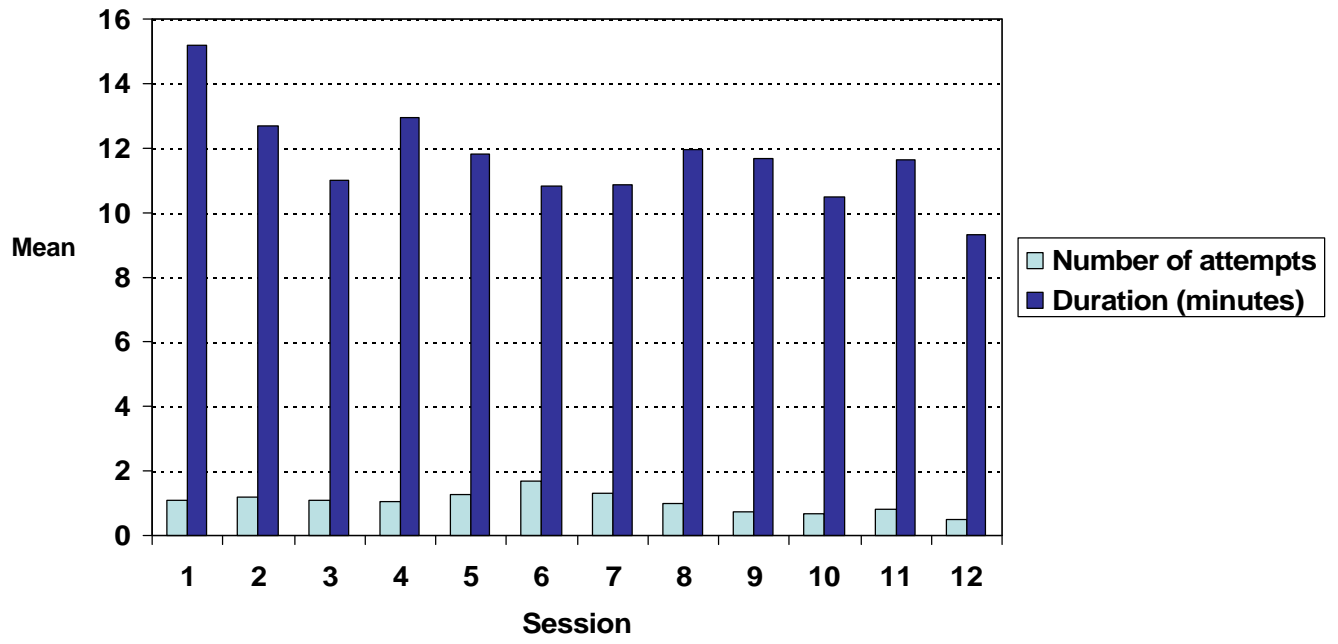


Figure 4

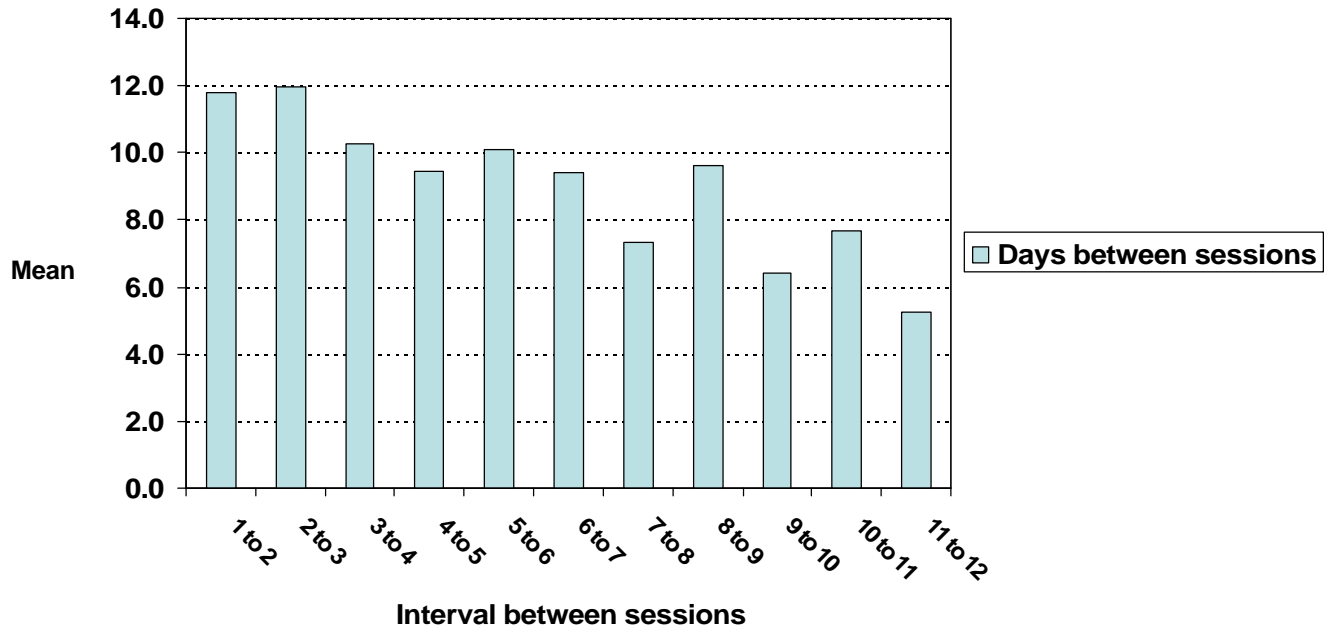


Figure 5

