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A PDA Intervention to Sustain Smoking Cessation in Clients With Socioeconomic Vulnerability

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ABSTRACT

This manuscript describes a pilot study to examine feasibility of a personal digital assistant (PDA) in clients in the hospital setting with social economic status vulnerability (SES) and tobacco addiction. The purpose of this research program is to make a positive impact on the health and quality of life of the target population by assisting them to make a permanent change and sustain smoking cessation after discharge through use of an innovative smoking cessation program called the Follow-up Relationship Intended to END Smoking Personal Digital Assistant (FRIENDS PDA). The aims are to explore: 1) Acceptance of the technology based intervention by evaluating utilization, perception of use, ease of use, satisfaction and technical difficulties, 2) Feasibility of the study by examining the attrition rate and methods for recruitment and retention; and 3) Data collection methods for treatment protocols and the reliability of instruments for primary (smoking cessation verified by biomarker of saliva cotinine) and secondary (depression, weight, and self-efficacy temptation situations) outcomes for a future larger study.

The sample was 31 medical surgical clients with a mean age of 47.35 (\pm 13.3), an average education of grade 11, average income of \$13,629 and average household between 2 and 3 people. They were enrolled in a hospital smoking cessation program and invited to participate in a relapse prevention program (FRIENDS PDA) after discharge. The results showed after 2 months there was high utilization of the PDA. The participants viewed the PDA as useful and easy to use, had high satisfaction and would recommend use to other smokers. Numerous technical problems were identified and indicated areas for future improvements. The feasibility of the study methods was demonstrated. There were 73 potential participants referred over six months with 31 meeting the inclusion criteria who were entered into the study. The attrition rate was 21% at 2 months. A power analysis showed 192 clients would be needed for a fully powered study which would require additional data collection sites. The data collection time was 1 hour or less. Cronbach Alphas for the instruments ranged from .72 to .96. The FRIENDS PDA treatment protocol was successfully implemented in all 31 participants. There was a continuous abstinent rate of 33% (n=10) at two months. A future study is warranted in a larger sample.

Key words: Smoking cessation interventions, personal digital assistant, SES vulnerability

On admission to the hospital, clients are asked about their smoking status and because hospitals are smoke-free, most clients achieve smoking cessation during the hospitalization period (Fiore, Jaen, & Baker, 2008). However, a large number of clients will relapse and start smoking again soon after discharge. Smoking will thus remain a significant health problem and impact the health and quality of life of individuals unless new ways are found to deliver relapse prevention strategies (Thorpeir, Geller, Sulem et al, 2008; USDHHS Surgeon General Report, 2004). The purpose of this study is to explore a method to decrease relapse, as an extension of the counseling and medication treatment started in the hospital, during the first two months after discharge in medical surgical clients with socioeconomic status (SES) vulnerability of low income and education. The overall goal is to improve the addicted smoker's health and quality of life through permanent change to a non-smoker. The first two months after discharge is a beginning step and was chosen because it represents a high risk time for relapse. The target population of clients with tobacco addiction with SES vulnerability was chosen because these clients find it more difficult to quit, are a target of advertising and promotions by tobacco companies, and have fewer resources and social support networks after discharge.

The aims of the study are to explore: 1) Acceptance of the technology based relapse prevention intervention by evaluating utilization, perception of use, ease of use, satisfaction and technical difficulties, 2) Feasibility of the study design by examining the attrition rate and methods for recruitment and retention; and 3) Data collection methods for treatment protocols and the reliability of instruments for primary (smoking cessation verified by biomarker of saliva cotinine) and secondary (depression, weight, and self-efficacy temptation situations) outcomes for a future larger study.

LITERATURE REVIEW

Best Practice Interventions for Smoking Cessation

Clients who smoke, including those with SES vulnerability, are recommended to receive multicomponent therapy with medication and counseling. (Fiore, 2008). There are 7 first line medications and the medication choice is made after a careful history and physical assessment. Client

preferences, past experiences, and costs are important and should be considered when choosing the best medication for each individual client.

After clients have been assessed for the best medication choice, it is a good time to discuss behavioral change therapy. The literature demonstrates that a skills focus is helpful in building self-efficacy for smoking cessation and is needed for making a permanent change (Fiore, 2008). Another consideration in therapy is the delivery method. The most common delivery methods for skills based smoking cessation relapse prevention interventions are the self-instructional method, individual counseling, or group therapy formats (Rigotti, Munafo, & Stead, 2007; Stead, Lancaster, & Perera, 2004). Any of these can be delivered in person, by telephone or by internet. The intervention discussed in this study is the FRIENDS intervention which can also be delivered in various formats. Early studies used a self-instructional delivery format and showed smoking cessation success rates of about 25 percent at 2 months in clients after discharge from the hospital (Buchanan & Likness, 2008; Buchanan, El-Banna, Siedlik et al, 2004). This study will explore the use of another delivery format for the FRIENDS intervention, that of a PDA.

The PDA delivery device for the FRIENDS intervention used in this study is a fairly new option and as such it is important to discuss how clients with SES vulnerability will react when given this device as an aid for relapse prevention after discharge. One of the first factors that was considered before adopting this type of delivery was the capability of PDA technology. Factors that were considered included the memory and the size. The memory had to be large enough to support all of the applications while the size needed to remain small to insure portability. The device had to be perceived by the user as useful to them and having the ability to improve performance and productivity at maintaining smoking cessation after discharge. The device also had to be perceived as being easy to learn to use. All of these are critical factors in the client's decision to accept or reject a new technology.

The technology acceptance model (TAM) explains that acceptance of new technology is dependent on specific belief systems which determine a person's intention to use. Two belief subsets in the TAM model are perceived ease of use and perceived usefulness (Davis, 1989, Davis, Bagozzi, Warshaw, 1989). The intention to use is determined by the perceived ease of use (defined as the extent to which a

person believes the technology will be easy to use and effortless) and by the perceived usefulness (defined as the extent to which the person believes the technology is appropriately designed to the task). Clients who perceive ease of use of a technology and believe it will help them attain their goal are more likely to work hard to learn to use it and to sustain use over a longer period of time (Venkatesh, Morris, Davis et al, 2008; Venkatesh, 2000).

The field of information technology has exploded and may be a viable method for delivery of health promotion and health behavior change interventions including smoking cessation relapse prevention (Fiore, 2008; Lenert, Munoz, Stodard et al, 2003; Etter, Houszecz, Landfeldt, 2003; Etter & Perneger, 2001). It has been suggested as a viable way to reach vulnerable populations who tend to be mobile and difficult to reach using conventional methods (Fiore, 2008; Chang, Bakken, Brown, et al, 2004).

A PDA technology has advantages over larger desk top models and web based intervention because in addition to adequate program memory and portability, it is fairly easy to learn to use and has low cost. One of the biggest benefits to PDA technology is the ability to do daily logging and to receive tailored feedback to responses which has been shown to be useful when making a behavior change (Fiore, 2008; Yon, Johnson, Harvey-Berino et al, 2007; Chang, Omery, & Mayo, 2003). The guidelines to ensure a properly tailored program include: an assessment of individual smoking characteristics and patterns, use of extensive algorithms to produce interventions tailored to the specific needs of the user; and use of a method that delivers the tailored messages back to the individual in a clear, interesting and precise manor (Strecher, Schiffman & West, 2005; Strecher, 1999). For the SES vulnerable client, the comprehension of the device should be leveled at the 6th to 8th grade.

There is evidence the client with SES vulnerability receives substantial pressure to smoke not only from tobacco company advertisements and promotions but also from friends, spouses and co-workers who smoke. Clients discharged from the hospital need a reminder about their skills, need distraction from cravings, and a way to daily monitor and receive information to manage cravings and nicotine withdrawal symptoms. The literature suggests relapse prevention therapy that is focused on skills to

develop self-efficacy perceptions is effective (Park, Schultz, Tudiver, et al, 2004; Chandola, Head, & Bartley, 2004; Stoffelmayr, 2003; Velicer, Declemente, & Rossi, 1990; Cohen & Lichtenstein, 1990).

A portable device may also provide a distraction to smoking triggers and temptations to smoke through games. In one sense, the device may itself become a source of positive partner support or become a “buddy”. One key is to make sure the device is not a nuisance but a positive force. A positive perception of partner support that is received is related to higher smoking cessation rates while a negative view has the opposite effect (Park, Schultz, Tudiver, et al, 2004; Cohen & Lichtenstein, 1990).

The person who delivers the intervention to the client is another consideration. The Nurse in the hospital setting is in an optimal position to carry out the discharge teaching and relapse prevention education and skills training (Fiore, 2008; Chouinard, Robichar-Ekstrand, 2005). Nurses not only have strong teaching and counseling backgrounds, but studies also show they have access to the client at a time when they are highly motivated to quit because of acute illness (Chouinard, Robidhaud-Ekstrand, 2005). The best time to do the discharge teaching is when the Nurse has assessed the client and determined they are stable and pain free. The delivery method should be standardized and delivered by Nurses with the necessary cognitive and psychomotor skills, acquired through classroom and simulation teaching.

Conceptual Framework

There is a large body of knowledge showing that behavioral change is more likely to occur if clients perceive self-efficacy. An appropriate conceptual framework to increase self-efficacy is Social Learning Theory (Bandura, 1997). The definition of self-efficacy for smoking cessation for this study is an adaptation of Bandura’s definition and is: a perception of a judgment by the client of the possession of capabilities, skills, and resources to organize and perform a course of action to attain smoking cessation in the hospital and to stay on this course of action after discharge by continuing to use these capabilities, skills, and resources. Self-efficacy for smoking cessation beliefs are derived from 4 major sources (performance accomplishment, vicarious experiences, verbal persuasion, and emotional and psychological arousal) which are contained in the FRIENDS PDA programs. Interaction with the FRIENDS PDA boosters self-efficacy for smoking cessation after discharge, is a daily reminder of what the client has

learned and is a resource for when they feel lack of confidence or are in a tempting situation to smoke. The FRIENDS PDA represents a continuous source of self-efficacy for smoking cessation beliefs. The FRIENDS PDA provides a mechanism for carrying the skills, teaching, and resources to the individual's personal environment and temptation situations where they are the most vulnerable for relapse.

An assumption of the conceptual frameworks is that regular use of the FRIENDS PDA will bolster and continue the feeling of self-efficacy for smoking cessation beliefs thereby increasing the perception of a judgment of possession of capabilities, skills, and resources to manage personal symptoms, temptation situations, and barriers that increase the probability for relapse.. The content is shown in Table 1.

Insert Table 1 here.

METHODS

This study was designed to implement the aims and fulfill the purpose of this study which is the prevention of relapse after discharge from the hospital in order to make a positive impact on the health and quality of life of the client with SES vulnerability and tobacco addiction. The study protocols were approved by the institution's Internal Review Board and participants voluntarily consented to participate.

Sample and Study Design

Participants were accrued from a large Midwestern teaching hospital and were referred by healthcare providers who heard about the study or saw a posted advertisement. Inclusion criteria were: adults aged 19 or older, current smoker with a puff of cigarette in the last 7 days before admission, history of smoking at least 10 cigarettes 5 of 7 days for the last year, live within a 100 mile radius of the medical center, in stable medical condition, not pregnant or planning on getting pregnant, no contraindications to use of nicotine patch, and wanted to quit smoking (or had quit in the 7 days before admission). Women who were breast feeding or pregnant were excluded because the nicotine patch is a category D drug and not recommended as first line therapy. Participants were also asked about annual household income using the Federal Family Poverty Income Guidelines which ask about total household income and total number of people in the family. For example, an income of \$22,050 or less in a family of four is considered to be poverty level. The income level is adjusted up or down for number in household using the guideline

parameters (USDHHS Federal Family Poverty Income Guidelines, 2008). Stability of condition was assessed by measuring blood pressure and apical heart rate which had to be less than or equal to 140/90 and no arrhythmias. This is because the study medication (NRT patch) could make these conditions worse. Depression symptoms were evaluated before admission into the study because the literature showed depression can be worsened by smoking cessation and nicotine withdrawal. Figure 1 provides the study design and participation from recruitment through completion of the study at two months.

Development and Description of the PDA

The development of the PDA was done in collaboration with information technology faculty who had extensive experience. A graduate assistant was instructed in the development of the programming using a blueprint of content provided by the principal investigator. It took about 15 months for development and testing before the PDA was ready for the pilot study. The development consisted of a focus group of smokers who provided input into the development of the programs. There were also pilot tests by former smokers who used the PDA for several weeks and then were interviewed.

The program files consisted of a “No Smoking Plan” template which was completed at the beginning. There were also 9 symptoms which could be monitored every day. The participants rated the symptoms on a Likert scale of 1 (not present) to 5 (high). There were also 7 skill modules which were self-instructions on various skills including how to obtain positive partner support, how to manage barriers, and tips for relapse prevention. There were also 4 teaching modules on standard topics including positive health effects of quitting, negative effects of smoking, effects of NRT, and sabotage. The details of the content in these files was shown and can be reviewed in Table 1.

There was a written protocol for loading the program which was taught to a Research Nurse who was able to learn to load the program and to download the post-data of utilization time and time of use of individual components after 2 months of use. The PDA had the capability to store the raw data scores from daily symptom monitoring but was not retrieved as part of this feasibility study. There was a template for recording time when the PDA was turned on and when it was turned off. There was also a

template that could record time of use of selected individual components of treatment. This data was retrieved to give an estimate of use.

The PDA in this study was purchased wholesale from a large manufacturer. It was a Classic Handheld model and contained 64 MB of SDRAM and 256 MB Flash ROM. The cost was \$250.00 per device. The operating system was a Microsoft Windows Mobile 6 Classic, with a 624 MHz Marvell PXA310 processor. The PDA utilized a SQL Server Mobile 2.0 to store and retrieve application related data. The server was used to keep a master database of all records made on the PDA in the field through replication. The PDA included an integrated microphone, receiver, and speaker, as well as a headphone jack. The PDA was a wireless Bluetooth 2.0 with EDR. It weighed 3.86 ounces, was 2.71 inches wide, .54 inches thick in diameter, and 4.59 inches in height. The reflective touch screen was 3.5 inches with LED backlight. It had a rechargeable Lithium-ion battery and was powered by AC adaptor. A picture with size compared to a pack of cigarettes is shown in Figure 2.

Insert Figure 2 here.

Measures

Demographics. Demographic characteristics of interest (e.g. age, gender, marital status, income, education) were collected using a Demographic Tool. To measure income, the U.S. Department of Health and Human Services-USDHHS Federal Family Poverty Income Guidelines were used (USDHHS, 2008). This definition used family income and family size. For example for a family of one the income threshold was \$10,830, for a family of two \$14,470, family of three \$18,310, family of four \$22,050 and so on.. For measurement of education, participants were asked to name number of years (0 kindergarden , 12 years graduation from high school).

Other tools were used to collect data about smoking behaviors using standard questions about pack years, reasons for tobacco use, and past quit attempts (Chabrol, Niezborala, Chastan et al, 2003). Sample questions included “How long have you been smoking”, “Do you use other forms of tobacco”, “How many times have you tried to quit in the past”. Data was collected using the Fagerstrom Test for Nicotine Dependence (FTND) (Chabrol, 2003; Heatherton, Kozolwski, Frecker et al, 1991). The total score

possible is 10 and scores of 6 or greater indicate dependence. The internal reliability has been reported as .61 and .64 in two studies and test/retest reliability at .88 (Pomerleau, Solange, Lutzke et al, 1994; Heatherton, 1991;). For this study the Cronbach Alpha was .71.

A screening and tracking tool was used to collect feasibility data including number referred, number screened, and number meeting inclusion criteria and number who were entered and not entered into the study and why.. Notes were kept on any issues with the instruments or areas with confusing questions.

Acceptance of PDA Technology. Clients were assessed to determine perceptions surrounding the use of technology. A tool was used to assess whether they thought the technology was easy or complex, whether they felt the PDA technology was well adapted to the task of smoking cessation, and if performance and productivity were improved after use. The tool was adapted from the literature based on the TAM framework (Venkatesh, 2000; Davis, 1989). In this study a 7 point Likert scale was used to measure the responses (1 extremely likely) to (7 extremely unlikely). Lower scores reflected improvements in the perception of usefulness and ease of use. The participants were also asked about attitude, satisfaction with the various components, and technical difficulties. The Cronbach Alphas in this study for the PU and PEOU subscales were .92 and .96 respectively.

Smoking Level. Smoking level measures are typically used as primary outcomes to evaluate the effectiveness of an intervention. In this study two time points were used. Although research studies typically use longer time intervals such as 6 and 12 months, this was a feasibility study and two time points were considered adequate to test data collection protocols. Data was collected using self-report and the 7 day point prevalence rate by asking “Have you had a puff of a cigarette in the last 7 days”?

All participants were also asked to provide a saliva sample to measure the saliva cotinine using measures described in the literature (Montalto & Wells, 2007; Etter, VuDuc, Perneger, 2000). The saliva was collected using a standard protocol and was analyzed using a bioassay to test for the nicotine metabolite using a standard test (NicAlert® test, Jant Pharmacal Corporation, 2005). All samples were collected at 8 days after completion of the NRT so that NRT did not contaminate the saliva samples. The cotinine test is expressed as levels which represent equivalents of cotinine (ng/mL) and allows

comparison across samples estimating number of cigarettes. The scale runs from 0 to 6. A score of 0 represents 1-10 cotinine equivalents and indicates no current smoking. A level of 1 reflects 10-30ng/mL and indicates current use of tobacco products. A score of 6 represents greater than 1000 cotinine equivalents and indicates the heaviest smoker. Cotinine is the major metabolite of nicotine, is an indicator of tobacco smoke exposure, has a long half life (18 hours), stays in the saliva, blood, and urine for about 5-7 days after smoking, is proportional to the quantity of nicotine absorbed and has sensitivity and specificity equal to other biochemical tests (Etter, VuDuc & Perneger, 2000; Jant Pharmacal Corporation, 2005). A reduction in the level baseline to two months would reflect improvement.

Depression. Depression was measured using the Center for Epidemiologic Studies Depression (CES-D) scale which measures current symptoms of depressive state (Coulehan, Schulberg & Block, 1989). Participants used a 4 point scale from 0 (rarely or none of the time) to 3 (most or all of the time) to rate the degree to which each of 20 statements is self-descriptive. Total scores can range from 0 to 60 with higher total scores reflecting greater endorsement of depressive symptoms. Test/retest reliability and construct and content validity have been supported (Coulehan,1989). The CES-D correlates highly with other measures of depression including the Beck Depression Inventory (Coulehan,1989). Sample questions include: "I was bothered by things that usually don't bother me." "I did not feel like eating; my appetite was poor." For this study, the Cronbach alpha was .93. A change (reduction) of depression scores or stability over time would be an improvement or expected outcome at two months..

Weight (Body Mass Index). A calibrated scale that had a height and weight measure was used to collect data on current weight and height and was used to calculate body mass index. In this study, stable weight/body mass index over time is a positive outcome.

Self-Efficacy Temptations Scale. This data was collected using the Smoking Cessation Temptation Scale (Velicer, DiClemente, & Rossi, 1990). A confirmatory factor analysis indicated three subscales and one overall general construct called skill ability to resist temptation to smoke situations (Velicer, 1990). Level of confidence is indicated on a 5-point scale: 1(not at all tempted) to 5 (extremely tempted) so lower scores would indicate improvement in skills. This instrument has acceptable construct and

predictive validity and internal consistency (Cronbach's Alpha ranges from .88 to .92 in published studies). For the present study the Cronbach Alpha coefficients were .86 for the positive/social subscale, .93 for the negative/affect subscale and .88 for the habit/craving subscale. A positive change (reduction) in scores from baseline to two months would indicate increased self-efficacy for management of temptation situations and a reduced probability for relapse. As a preliminary exploration of the relationships between the variables based on the conceptual framework would expect to see a positive correlation between smoking and self-efficacy temptations.

Procedures

Clients were referred to the study through advertisement and referrals. A screening form was used to assess if the client met the inclusion criteria. If they did, they were given an on-site appointment with the Research Nurse who explained the study and did a history review, a blood pressure and an apical pulse check. If they agreed to participate and met the inclusion criteria they signed the form and were entered into the study. After consent the baseline data collection was done using the written protocol. After data collection, they were provided with the intervention as described below. At two months they were interviewed in their homes or at a place of convenience using the similar written procedures.

Intervention

The NRT patch dose was started in the hospital and was based on number of cigarettes smoked per day in the last week. If smoking more than 10 per day in the 7 days before admission, a step down patch system was given starting with 21 mg for 4 weeks, 14 mg for 2 weeks, and 7 mg for 2 weeks. If smoking 10 or less per day in the 7 days before admission, they were given 14 mg for 6 weeks followed by 7 mg for 2 weeks. They were instructed to use the patch for 24 hours, received education about the patch, and had to return demonstrate correct use.

They were also provided the brief 5A counseling by a Smoking Cessation Nurse (SC Nurse) using the guidelines in the CPG (Fiore, 2008). The brief 5A counseling is for the client who is willing to quit. It takes about 15 minutes. The steps are: Ask (identify all tobacco users at every visit), Advise (strongly urge all tobacco users to quit), Assess (determine willingness to make an quit attempt), Assist (provide

counseling and medication), and Arrange (ensure follow-up contact). For this study the follow-up was the FRIENDS PDA intervention. Clients were given the national quit line network number (1-800-Quit Now) at the end of the two months. They were asked not to participate in any other studies or to use any other resources during the 2 months.

Within 2 days before the anticipated discharge, when the participant was stable and comfortable, they were taught use of the FRIENDS PDA by two SC Nurses who had been educated in a University teaching simulation lab. Each SC Nurse was given a copy of the teaching protocol called the “Instructor Teaching Curriculum” at least 48 hours before the teaching simulation lab session. The teaching session was standardized and was 4 hours long. The SC Nurses were tested after the teaching session on level of attainment of 6 cognitive and 8 psychomotor skills. These results and the details of the curriculum and the teaching simulations are reported in another unpublished manuscript (Buchanan & Murcek, 2009). The SC Nurses were observed at random intervals during delivery of teaching/counseling sessions at the bedside using a written observation tool. This insured reliability of the delivery of the content over multiple clients over time and decreased “slippage” in content delivery. The reliability between the 2 SC Nurses in delivery of the teaching curriculum was 94 percent.

Participants were evaluated after each teaching/counseling session with the SC Nurse using a post-test which measured cognitive and psychomotor skill levels. The participant had to demonstrate correctly all of the cognitive and psychomotor skills which were considered basic to use of the PDA. They were given 60 minutes of instruction time broken into six 10 minute teaching sessions to assist them to meet all of the performance objectives before they were discharged. All of the participants achieved all of the learning objectives before discharge.

Data Analysis

The data was collected by a research nurse or the principal investigator. Data were entered into SSPS PC (version 12) using double entry technique. Descriptive statistics, scatter plots, frequencies, and bar graphs were used to evaluate normal distribution of the data. A Spearman Rho Rank Order correlation

was used to evaluate relationships between variables. Cronbach Alphas were calculated for the study instruments as previously reported.

RESULTS

Background Characteristics

The sampling pool was medical surgical patients from an acute care teaching hospital. Seventy three potential participants were screened and referred for an appointment with the Research Nurse. At this meeting, 31 were found to meet the inclusion criteria and these signed the consent form and comprised the study sample. The reasons for exclusion are shown in Figure 1 and included elevation in blood pressure, presence of an arrhythmia, or refusal to use birth control-BC. There were no exclusions for NRT patch contraindications and all agreed to use the study NRT patch. Those who did not meet study criteria were referred to other hospital or community based programs including the national quit line number (1-800 Quit Now) . All of the participants received the same intervention protocol (brief counseling and the NRT patch medication in the hospital) plus the relapse prevention intervention of the FRIENDS PDA for use for 2 months after discharge. All stated they completed the NRT protocol.

The study sample, as shown in Table 2, was slightly more female than male, was predominantly Caucasian (74%) and ranged in age from 19 to 69 years with an average age of 47.35 (\pm 13.1). Participants were married/living together (37%), unmarried living with someone (34%) or unmarried/living alone (30%). The average income was \$13,692 (\pm 8204), the average number in the household was 2.67 (\pm 2.22) and the average education years completed was 11.69 (\pm 2.25). The mean pack years was 38.39 (\pm 22.69), mean number of times quit in the past was 3.31 (\pm 2.3), mean age of first cigarette was 13.82 (\pm 5.87), and mean Fagerstrom Test for Nicotine Dependence was 6.16 (\pm 2.17) indicating heavy dependence.

Insert Table 2 here

Acceptance of Technology

The mean experience level of years using a PDA was 97 (\pm 1.6). The internal time logs showed the average hours of use per day over the 2 months was 1.16 (\pm 2.67). This data only showed time of turned

on and time of turned off over each day of the 2 month study period. The investigators were able to determine that each PDA was turned on for at least a few minutes for most days during the 2 months but were not able to determine if it was the participant or someone else who was using it.

Table 3 shows the data for technology acceptance responses including perceived use, perceived ease of use, and attitude. These are all part of the TAM framework and are measured before and after use of technology. The perceived usefulness (PU) and perceived ease of use (PEOU) were measured at baseline before use and then assessed again at 2 months to see if the responses had changed. The PU showed lower or better scores after use indicating participants were more likely to perceive the PDA as useful for smoking cessation after they had used it. For example the question “the PDA improved my performance” was $4.06(\pm 1.05)$ at baseline and $2.70(\pm 1.40)$ at follow-up indicating a perception of improved performance after 2 months of use. The perceived ease of use (PEOU), with the exception of the first question (learning to use a PDA was easy) decreased at two months indicating general improvement in feelings about ease of use. However the results are conflicting as the response to “learning to use a PDA was easy” was higher at two months indicating a perception of more difficulty. The attitude scores were generally more favorable after use. The PDA was perceived as fun but the data also supports the PDA may be anxiety producing. This could impact both learning and smoking behavior so this is important to learn more about. Boredom feelings increased indicating the need for more variety in delivery of teaching/learning modules in the PDA.

Also shown in Table 3 are the portability, technical difficulty, skill and knowledge, and overall satisfaction ratings which were measured after 2 months of use. The portability was rated high and in general participants felt the PDA was easy to carry, was there when needed and was comforting to have.

The technical difficulty scores indicated the screens were easy to read and move through. When asked to expand on the difficulties encountered the participant reported the screen would go blank in the middle of a learning session, the battery would run out in the middle of a learning session, the battery time was not enough, the touch wand got lost, the touch screen was not sensitive or did not work necessitating

multiple touches, the games would freeze when playing. Four times during the study period, the Research Nurse had to travel to the home and get the PDA to bring it to the research office to be reprogrammed because it crashed. Some participants also stated they became bored playing the same 2 games. In one case, a child took the PDA and loaded personal programs which caused it to work very slowly and to eventually crash.

The education modules were rated most highly, next was the symptoms monitoring, then the skills modules, the temptation situation scenarios, and lastly the games. The overall satisfaction rating at two months was assessed by asking if they would recommend the PDA to someone quitting and if it was an essential tool for smoking cessation with scores of 2.38 (± 1.38) and 2.73 (± 1.03) respectively.

Insert Table 3 here

Primary and Secondary Outcomes

Table 4 shows the primary outcome of the physiological biomarker, the saliva cotinine (mean, \pm S.D.). The mean level at admission to the study was 4.76 (± 2.12) indicating heavy smoking in the days before admission to the hospital. Many of the participants had quit the night before admission. At 2 months the level had decreased to 2.87 (± 1.52). The self-reported quit rate (verified by cotinine) at 2 months was 33% with 10 continual abstainers.

Insert Table 4 here

The secondary outcomes are also shown in Table 4. In general, all of the secondary outcomes showed stability or improvement. Depression was 22.39 (± 10.45) at baseline and 24.89 (± 9.22) at follow-up. These levels indicate a risk for depression episode. The participants with high screening values may need careful evaluation for the development of depression symptoms which can occur during and after quitting smoking (Glassman, Covery, Stetner et al, 2001). The sample was also obese with weight/BMI at 30.67 (± 9.33) and 29.92 (± 9.97) baseline to follow-up. Studies show that weight gain is a barrier for relapse and should be treated (Filozpf, Fernandez, Fernandez-Cruz, 2004). However, these participants had not as yet experienced any weight gain so information should be tailored to provide preventive messages.

There was considerable change in the self-efficacy temptation scores. Higher self-efficacy temptation scores indicated there was higher temptation to smoke and lower confidence in ability to manage temptations to smoke. Lower self-efficacy scores indicated lower temptation to smoke and more confidence in ability to manage temptations to not smoke. In general, the total score, a reflection of the ability to resist temptation to smoke was 39.56 ± 7.01 and at follow-up at 2 months had lowered or improved to 28.92 ± 9.69 . This change indicated more confidence in ability to manage temptations and lowered probability for relapse at two months. The most change was in the positive social and negative affect temptation situation subscale suggesting skills learning to manage social and negative temptation situations which was a focus of the intervention.. There was a relationship between high smoking levels and high self-efficacy temptations scores ($r = .39, p < .05$). This is congruent with the conceptual framework stating a relationship between self-efficacy for smoking cessation and behavior change.

DISCUSSION

This study provides evidence of the acceptance of PDA technology to deliver the FRIENDS relapse prevention intervention in this small sample of smokers addicted to tobacco with SES vulnerability. The sample had an average education of 11th grade and an average income of \$13,629. The results indicate the PDA was utilized fairly regularly, however it cannot be assured it was only the participant using the PDA.. The perceived usefulness scores improved after 2 months of use as were most of the perceived ease of use scores. There was a positive attitude toward the use of a PDA and the results demonstrated the device to be perceived as highly portable. However, there were numerous technical difficulties reported that need to be attended to. The education and symptom monitoring daily logging were rated highly and used frequently. This is a positive finding as the literature shows that daily logging is related to positive changes in behavior. The overall satisfaction ratings demonstrated that the participants would recommend the FRIENDS PDA to others who are quitting smoking.

These findings are similar to others who have found daily logging and tailored messaging to be effective when making a behavioral change (Fiore, 2008; Yon, Johnson, Harvey-Berino et al, 2007; Chang, Omery, & Mayo, 2003). The education and skills programs were useful to the participants but the

participants probably got bored with the repetition. For the future, other methods should be incorporated in order to increase interest including short video clips of “talking head” experts discussing important points.

The feasibility of the research methods for the FRIENDS PDA intervention in participants with SES vulnerability were demonstrated. The sample was accrued in 6 months and there were about 10 potential participants that were referred each month with about 4-5 participants entered each month from the available pool. On-site assessment of blood pressure and apical pulse should be part of the study procedures for all clients in the hospital setting. The attrition rate was 21% at 2 months and would be expected to increase as longer time intervals are incorporated into the study design. A future experimental study with a control group would need at least 192 participants which does not include a calculation for attrition. The study procedures also need methods to retain the participants especially as most experimental designs with a control group use a time period of at least 6 months to determine if behavior change has occurred. There were 3 participants who moved and left no forwarding address.. A questions in the screening procedures should ask if the potential participant is planning on moving in the next 6 months. To attain the sample for a fully powered study, multiple data collection sites would needed.

About one third of the participants in this study were able to maintain continuance of abstinence for a 33% smoking cessation rate. This rate of continual abstinent rate is similar to other intensive interventions reported in the literature (Fiore, 2008; Strecher et al, 2005). The CPG (Fiore, 2008) states a favorable attitude toward the use of technology based interventions and recommends them as a potential way to reach a larger percentage of smokers.. The participants had respectable smoking cessation rates suggesting a PDA may have benefit for clients with SES vulnerability. This may be due to the portability and ease of use or to some other unknown effect. In the present study, the participants perceived the PDA as having some technical difficulties but perceived it as a productive tool with a potential to help them quit smoking. As shown in previous studies, participants will work harder to learn how to use a tool if they perceive it as useful (Gardner & Amoroso, 2004; Kwon, 2000).

These participants made a significant change in their smoking behavior. There were 10 continual abstainers (verified by saliva cotinine). As a group the mean saliva cotinine went from 4.76(\pm 2.1) to 2.87(\pm 1.52). Future study should focus on the mechanism of the treatment in order to make it stronger. In this study, those who perceived more skill ability to manage temptation situations had more reduction in smoking levels. This relationship is consistent with the conceptual framework which states that self-efficacy for smoking cessation is assistive when making a behavior change and can be increased through skills teaching and participant learning. The level of learning attained by the participants was uniform and a teaching curriculum was utilized by the SC Nurses to standardize the intervention. It is not known how long the treatment effect lasts and if self-efficacy for smoking cessation was stable or changing over the 2 months.. However, this is yet another study verifying the effects of self-efficacy as an aid for sustaining smoking cessation begun in the hospital (Stoffelmyer, 2003; Fiore et al, 2000; Velicer, 1990;). Not much has been published about the effects of newer portable technologies and smoking cessation self-efficacy. Newer technologies allow more interaction and tailoring than the traditional self-instructional manuals and paper diaries. Because this is a field of rapid change the future may provide even more useful and effortless interactive methodologies.

Although this study can only be generalized to the participants of the study, it is important that certain findings are considered for practice and research. Despite being a vulnerable population with lower income and education, participants perceived the technology-based intervention to be both easy to use and useful in the task of quitting smoking. The concept of vulnerability needs to be further examined for efficient and effective tailoring to be utilized.

The findings of this study are important as it corresponds to the recommendations made by Fiore (2008) that all interventions found to be effective should be offered to all individuals who use tobacco regardless of SES, education, or income. In addition to the information that those with a low-income status and/or those who have a limited formal education status endure a disproportionate burden from

tobacco, these findings may aid in the development of future studies assessing the appropriateness of technology use as an intervention for smoking cessation.

Further research needs to be done to evaluate client's smoking cessation and relapse rates at timed intervals of 6 month and 1-year and their feelings about the technology after these extended periods of time. Future studies also need to implement randomization and larger sample sizes to increase the strength of the findings. The results of this study are promising because they suggest those with SES vulnerability are accepting of a technological-based intervention. The mechanism is likely perception and continuance of self-efficacy for smoking cessation obtained through skills based learning.

CONCLUSION

As a group, these participants substantially changed their smoking behavior. It cannot be emphasized enough that smoking cessation is one of the best behavior changes that can be made to improve health and quality of life. This sample, despite being vulnerable economically, also had limited support and lower confidence at baseline in their ability to manage temptations to smoke. It appears they were accepting of technology via the PDA but it is not known if it was truly the effects of the intervention because the limitations of the study including the lack of a control group and a small sample size. It is intriguing to attribute the change in behavior to the relapse prevention intervention but that remains to be proven in a future larger study with multiple data collection sites. This program of research should continue to explore interventions for clients with SES vulnerability and explore the latest technological advances that are available which is congruent with the current CPG. The study results are promising and if proven may provide new interventions and delivery mechanisms in hopes of reaching those who are most burdened by smoking and tobacco related disease.

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Figure 1: Recruitment and Retention

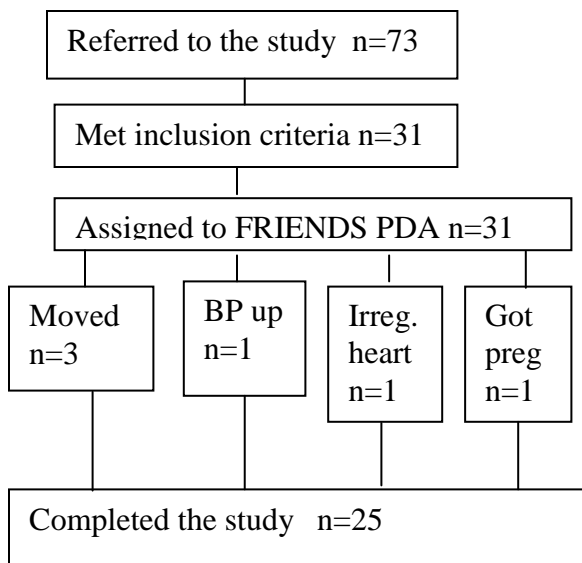




Figure 2: Picture of FRIENDS PDA compared to pack of cigarettes.

Table 1:
The 4 Major Sources of Self-Efficacy for Smoking Cessation Information

<u>Source of Self-Efficacy</u>	<u>Intervention Components</u>	<u>Performance Criteria</u>	<u>Outcome</u>	<u>Evaluation Measures</u>
Performance Attainment (feel repeated successes of abstinence)	Authentic mastery experience	Discuss past successes	Abstinence	Saliva cotinine, self-report
	In hospital treatment	Perceive support	Perceived support	Partner Interaction Questionnaire
	5A counseling	Learning	Knowledge	Post-test
	NRT	Demonstrate NRT use	Correct daily use	Observation and utilization
	Positive support	Verbalize support	Perceived support	Partner Interaction Questionnaire
	FRIENDS intervention	Daily use	Mastery of use	Post-test/observation
	Continue NRT	Daily NRT use for 8 wks	Correct use	Utilization rate
	FRIENDS program skills:			
	Symptom monitoring skill	Demonstration	Symptom Management	Questionnaire
	Symptom management skill	Demonstration	Symptom Management	Withdrawal Symptoms Score (↓)
	Weight management skill	Demonstration	Weight Management	Weight, height (BMI)
Depression management skill	Demonstration	Depression Management	CESD score (↓)	
Temptation management	Demonstration	Temptation Management	Self-efficacy Temptation Scale (↓)	
Partner support management	Demonstration	Perceived support	Partner Interaction Questionnaire	
Games	Demonstration	Distraction	Self-report, questionnaire	
Vicarious Experiences (seeing or visualizing others perform successfully)	Knowledge to seek pos partner	Demonstration	Positive support (↑)	Partner Interaction Questionnaire
	Temptation situation scenario	Demonstration	Temptation (↓)	Self-Efficacy Temptation Scale
Verbal Persuasion/social influence (talking to persuade belief in capabilities)	Partner Support	Obtain a support partner	Positive support	Partner Interaction Questionnaire
	Messages to not smoke Persuasive messages Education sheets	Demonstration	Knowledge (↑)	Post-test
Physiological arousal state Recognizing cues to arousal	Daily Symptom Monitoring	Monitor daily	Symptoms (↓)	Withdrawal Symptoms Score
	Symptom management skills	Demonstrate skill use	Symptoms (↓)	

Table 2:
Baseline Characteristics of the Sample Mean (\pm S.D) or Percentage (n=31)

<u>Variable:</u>	
Age	47.35(\pm 13.3)
Average Income	13,629 (\pm 8204)
Average number in household	3.2 (\pm 2.20)
Average Education Years completed	11.39 (\pm 2.25)
Gender % Female	54%
Gender % Male	46%
Caucasian	72%
Married/living together	38%
Unmarried/living with someone	30%
Unmarried/live alone	30%
Employed (part/full time)	60%
Regular exercise (3x wk)	35%
Drink alcohol < 3x week	42%
Taking antidepressants	30%
Diagnosis of heart disease	52%
Diagnosis of depression	36%
Diagnosis of COPD/Emphysema	23%
Diagnosis of lung cancer	12%
Diagnosis of arthritis	11%
Diagnosis of diabetes	11%
Diagnosis of surgery	9%
Hospitalized in past 2 months	30%
Partner who smokes	32%
Pack years	38.39 \pm 22.69
Number times quit in past	3.31 \pm 2.31
Age first started	13.82 \pm 5.87
Nicotine Dependence (FTND)	6.16 \pm 2.7

Table 3:
Technology Acceptance and Other Responses of PDA Participants (Mean \pm S.D.)

	<u>Baseline</u> n=31	<u>Two Months</u> n=25
<i>Perceived Usefulness-PU (Productivity) (5Q)</i>		
Enabled me to accomplish tasks quickly	4.11(1.23)	3.39(1.5)
Improved my performance	4.06(1.05)	2.70(1.40)
Made it easier to do task of quitting smoking	4.06(1.16)	2.50(1.20)
Improved my productivity in smoking cessation tasks	3.94(1.04)	2.70(1.5)
Enhanced my effectiveness at quitting smoking	4.00(1.97)	2.80(1.47)
<i>Perceived ease of use-PEOU (Effortlessness) (4Q)</i>		
Learning to use a PDA was easy	3.70(1.03)	4.17(1.0)
It was easy to get to what I need to do my tasks	4.16(.83)	3.80(1.2)
It was easy to become skillful at using	4.22(1.03)	3.89(1.4)
It was easy to use	4.00(1.1)	3.37 (1.2)
<i>Attitude-ATT (5Q)</i>		
I had fun	3.39(.85)	2.92(.78)
Provided enjoyment	4.56(.765)	3.50(1.3)
Made me feel anxious	4.32(2.02)	3.56(2.1)
Made me feel bored	1.83(1.3)	2.83(1.38)
Made me have negative feelings	3.32(1.2)	3.88(1.6)
<hr/>		
<i>Portability (2 months)</i>		
The PDA was easy to carry around	-	1.40(.516)
PDA was always there when I needed it	-	2.10(1.49)
It felt comforting to have the PDA with me at all times	-	2.40(.843)
<i>Technical Difficulty (2 months)</i>		
The screens were easy to read	-	1.82(1.27)
The screens were easy to move through	-	2.56(0.99)
At times I became frustrated with the PDA	-	3.37(1.59)
I encountered many technical problems	-	2.96(1.09)
<i>Skill and Knowledge Components (2 months)</i>		
The games were useful	-	3.54(2.3)
The symptom monitoring was helpful	-	2.43(1.35)
The education modules were useful	-	2.19(1.27)
The skill modules were useful	-	2.89(1.67)
The temptation situation scenarios were helpful	-	3.26(1.89)
<i>Overall Satisfaction Rating with PDA (2 months)</i>		
I would recommend the PDA to someone quitting	-	2.09(1.13)
The PDA is an essential tool for smoking cessation	-	2.29(1.45)

Scale:1 (Extremely likely) to 7 (Extremely unlikely)

Table 4:

Primary and Secondary Outcomes: Mean (\pm S.D.)

	<u>Baseline(admission)</u> (n=31)	<u>2 Months</u> (n=25)
<u>Percent Current Smokers</u>	100%	67%
<u>Primary Outcome Saliva Cotinine</u>	<u>Mean (\pmS.D.)</u>	<u>Mean (\pmS.D.)</u>
	4.76 (2.1)	2.87 (1.52)
<u>Secondary Outcomes</u>	<u>Mean (\pmS.D.)</u>	<u>Mean (\pmS.D.)</u>
Depression (CESD)	22.39 (10.4)	24.89(9.22)
Weight (BMI)	30.67(9.33)	29.92(9.97)
Self-Efficacy Temptation Total*	39.56(7.01)	28.92(9.69)
Self-Efficacy Positive/social	12.02(3.36)	9.64(2.57)
Self-Efficacy Negative/affect	14.39(2.90)	9.29(3.01)
Self-Efficacy Habit/craving	12.45(3.89)	11.01(4.34)

*Higher self-efficacy temptations scores indicates lower confidence in ability to manage temptations to smoke. There was a relationship between high smoking levels and high self-efficacy temptations/low confidence in ability to manage temptations to smoke scores ($r = .39, p < .05$).