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AASAP: A PROGRAM TO INCREASE RECRUITMENT AND RETENTION IN CLINICAL TRIALS

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Abstract

Objective—To evaluate a theory based, subject-centered, staff/subject communication program, AASAP (Anticipate, Acknowledge, Standardize, Accept, Plan), to increase recruitment and retention in RCTs.

Methods—AASAP was evaluated with logistical regression by comparing rates of recruitment (at telephone screening, baseline assessment, initial intervention) and intervention retention (over 16 weeks) before (−AASAP) and after (+AASAP) it was introduced to a 3-arm RCT to reduce disease distress among highly distressed subjects with type 2 diabetes.

Results—Included were 250 subjects in −AASAP and 338 in +AASAP. Significant improvement in recruitment occurred at each of the 3 recruitment stages: agreed at screening (OR=2.52, p<.001), attended baseline assessment (OR = 1.91, p<.001), attended initial intervention (OR = 1.46, p<.03). Higher education and shorter diabetes duration predicted better recruitment in −AASAP (OR = 2.23, p<.001), but not in +AASAP. AASAP also improved intervention retention over 16 weeks (OR = 3.46, p<.05).

Conclusion—AASAP is a structured program of subject/staff communication that helps improve external validity by enhancing both subject recruitment and retention.

Practical Implications—AASAP can be taught to non-professional staff and can be adapted to a variety of health settings. It can also be used by clinicians to engage patients in programs of ongoing care.

Keywords

clinical trials; recruitment; retention; diabetes

1. Introduction

Problems with subject recruitment and retention in observational and interventional studies pose major threats to external validity [1]. These problems limit the generalizability of study findings, they increase study costs by requiring larger samples to maintain power, they

necessitate the use of statistical procedures to account for lost data, and they reduce research staff morale and productivity [2–5]. Poor retention is common in studies with demanding protocols and among high risk, distressed or vulnerable participant groups [4,6]. Yet these can be the very high risk and poorly managed populations to which many interventions are directed.

Attrition varies considerably from study to study, with ranges reported between 5% and 70% [7]. “Acceptable” attrition rates are usually considered to be in the 20%–30% range [8]. Even at this relatively low rate, however, per subject costs in terms of staff time, energy and other study resources devoted to subjects who were subsequently lost to the study can be considerable.

In this report we describe the background and rationale of AASAP, a practical strategy of communication to improve subject recruitment and retention in clinical studies. We then present quasi-experimental data on the effectiveness of AASAP as applied to a recent three-arm RCT to reduce distress and improve self-management among adult patients with type 2 diabetes.

1.1 Approaches to subject recruitment and retention

Because of major threats to external validity, it is frequently recommended that all studies include a detailed plan to maximize the breadth of recruitment, reduce attrition and manage lost subject data [9]. Types of plans that address these problems generally fall within four overlapping categories. First are statistical plans that address missing data after the study has been complete [10]. While effective, most statistical approaches are based on the questionable assumption that the data are missing at random, or that the pattern of change in a subject’s score recorded over time prior to attrition will continue in the same trajectory if the subject had remained in the study. Second are plans that focus on improving patient tracking over time [11,12], particularly those with highly mobile, difficult to follow samples. Third are plans that make the research protocol as patient-friendly as possible, e.g., enhanced flexibility in time and place of subject appointments, training a friendly and empathetic staff [4,6].

A fourth approach, which is the focus of the current report, adds a subject-centered, staff-subject communication focus to the previous three [7,13,14]. Using elements of social exchange theory [15], motivational interviewing [16] and social ecology [7], we call the program AASAP (*Anticipate*, *Acknowledge*, *Standardize*, *Accept*, *Plan*).

1.2 AASAP rationale

A subject’s decision to join or continue in a research study is often accompanied by a variety of contradictory motivations [17,18]. These contradictory experiences can lead to a complex interplay of mixed feelings, realistic and unrealistic expectations that influence decisions to engage in or terminate a relationship with a study. In motivational interviewing terms, subjects are markedly “ambivalent” about their participation [16].

Subjects vary in their awareness of the ambivalence that contributes to their decision to join and to remain in a research study, and some have little language to label and describe these experiences even to themselves. Furthermore, their ambivalence can easily shift over time in response to engagement in different stages of the study protocol: for example, between recruitment and assessment, between assessment and intervention, and between intervention and follow-up. Thus, because the ambivalence is often hidden from awareness and because it changes over time, it is difficult for many subjects to articulate clearly and share with study staff the conflicting (pro and con) emotions and expectations that lead them to join, refuse or remain in a study. For example, an obese subject may accept a telephone invitation

to join a weight loss study because s/he sincerely wants to lose weight (pro), but quit the study after baseline assessment and prior to starting the intervention, saying that s/he is simply too busy to participate. The subject may not share or may be unaware that a powerful contrasting reason (con) driving their decision not to participate is a fear of another weight loss failure, a fear that intensifies over time as the intervention approaches.

1.3 Goals and steps of AASAP

AASAP is a practical communication strategy that labels overtly the emotions and expectations that may underlie both sides of the subject's ambivalence. A staff-subject interchange can defuse subject resistance as it contextualizes the subject's experience. For example, some patients express their resistance by missing appointments or by neglecting to complete a critical step of the intervention, complaining that they do not have the time due to the demands of family or work ("I forgot."). AASAP involves verbally reflecting the underlying ambivalence (e.g., "So you would really like to participate because you are concerned about your weight…, but you also may be worrying if this is right for you – or you may be concerned that the program might not be helpful for you…."). This helps begin a conversation between subject and staff that provides a realistic appraisal of the pros and cons that surrounds the ambivalence by normalizing the experience as both not unexpected under the circumstances and as frequently shared by others in the program. It also allows the subject to express other aspects of their ambivalence, consciously recognize aspects of their complex feelings of which they had not been aware, or clarify their attitudes and feelings if the staff's labels are not accurate. The push-pull tensions that often accompany a structured staff-subject discussion about recruitment and retention are then defused as subject and staff realistically examine the issues in context without feeling pressured or defensive. Then the subject can make a more realistic decision about what is best for them.

The five steps of AASAP follow directly from this theoretical rationale. *Anticipate* reminds participants that they may experience a particular feeling or change in feeling as they approach a particular stage of the project. For example, one project included the following in their "welcome to the project" letter: "We have learned that many patients initially look forward to their first project meeting with considerable enthusiasm, but as the date approaches they begin to feel some hesitancy, wondering if the program is going to be too demanding, given other programs they have tried before. You too may feel this way. These are very common feelings and if you feel them, please know that others experience them also." *Anticipate* also helps subjects adjust to upcoming changes in the research protocol. For example, in one recent study we noted an increase in attrition during a period with less staff-subject contact than previously. We learned that many subjects felt disappointed by the less frequent contact, felt abandoned by project staff, or felt ashamed that they had not been as successful as they had wanted to be. By anticipating program changes and explaining their purpose well in advance, we reduced the potential for subjects' misattributions and misperceptions.

Acknowledge labels the feelings and expectations overtly, rather than leaving them hidden or out of awareness. Labeling reduces distortions and allows for a candid conversation between subject and staff. In the above subject letter example, we overtly labeled feelings of hesitancy and apprehensiveness, and hinted at a "fear of failure."

Standardize "normalizes" the labeled feelings as common and to be expected under the circumstances, e.g., "Many people we work with feel this way," or "From what you have told me it would make sense that you would feel this way." These statements re-cast the feelings as understandable reactions and place them into a context that is acceptable and shared by others, not as something to be hidden or to be ashamed of. These three steps (A,

A, S) form the core of AASAP and they can be used in face-to-face, telephone and written contacts with subjects.

The remaining two steps, *Accept* and *Plan* are brief and highly structured, and are frequently used in discussions with subjects after recruitment. *Accept* helps subjects to see how the ambivalence they experience can be tied to their behavior. Although it may appear obvious to an outside observer, many subjects do not recognize the linkages between their feelings on the one hand and their behavior on the other. For example, a fear of failure that might be generated by remaining in a weight-loss program can be directly linked to a subject's decision to withdraw from a study. *Accept* examines these feeling-behavior linkages so that a subject can make a clear and conscious decision about what might be best, rather than making a decision without being aware of the multiple contributing factors. For example, an *Accept* script might include: "What have you been feeling that has led you to have missed so many appointments recently? And why now?" Focusing on the feeling-behavior sequence that results from enhanced labeling, recognition and normalizing, highlights sequence with greater subject awareness that allows for alternative behaviors to be considered. "So perhaps your missing appointments may have something to do with your feeling like you have not done as well as you would have liked."

Plan helps subjects to make their own best decision about what to do next. Following from the above example, "I wonder if we can address your very legitimate feelings in another way? What other options might you have?" This kind of question, phrased in empathic terms, helps subjects acknowledge the ambivalence and then view their alternatives in a realistic and examined way.

2. Methods

AASAP was developed during data collection for a three-arm RCT called REDEEM (REducing Distress and Enhancing Effective Management), an intervention for patients with type 2 diabetes designed to test the efficacy of two diabetes distress-reduction programs against an attention control group. Included in the initial subject-friendly protocol was a plan to manage missing data and a system for subject tracking. After approximately 12 months of the study, however, we realized that we were not reaching our goals for both subject recruitment and 16-week intervention retention. In response to this problem, the investigators initiated a series of research team meetings to develop a program to help research assistants (RAs) verbalize some of the perceived processes and barriers they experienced as they interacted with resistant subjects at each stage of the trial. Through these brain-storming discussions, the team developed a list of staff-perceived subject "feeling scenarios," verbal descriptions of the emotional ambivalence subjects experienced during the course of the study (Table 1). The team then developed written phrases and sentences ("scripts") for each subject scenario, following AASAP, that RAs could use to normalize the feelings, and help subjects acknowledge ambivalence and anticipate what might occur next. The scripts were also included selectively in written correspondence with subjects as a preventive intervention. All research staff then attended two, two-hour workshops, led by the investigators, to review and expand upon the scripts and to assist each RA in translating the scripts into their personal style. This included role paying interactions with hypothetical subjects and developing skills and experience in responding to subject feelings with AASAP in an empathic, non-judgmental style. Subsequently, a portion of each weekly staff meeting was devoted to a review of the previous week's application of AASAP with current subjects.

2.1 Study design

We used a pre-post, before and after design to test the efficacy of AASAP. Comparisons were undertaken between the relative rates of subject recruitment and intervention retention

during the first 12 months of the study without AASAP (−AASAP) with similar rates during the remaining months of the study with AASAP (+AASAP), following a 4-month interval between −AASAP and +AASAP to reduce between-group contamination.

2.2 Subjects and protocol

Subjects with diabetes were identified from the patient registries of two community based health care systems. Subjects received a letter describing the project and were provided with a number of opt-out options prior to receiving a phone call for screening. Inclusion criteria included diagnosis of type 2 diabetes for 12+ months, age 21 or over, speak and read English, score above the cut-point for diabetes distress and below the cut point for depression, and display a deficit in diet, exercise or medication use. Based on a modification of the Summary of Diabetes Self-Care Activities [19], a deficit was defined as five or fewer days in the last week when the subject failed to follow their diet or exercise plan, or more than one day in the last week in which they failed to take their prescribed medication.

If eligible and interested, a home or office visit was scheduled within 2 weeks to sign informed consent and complete baseline assessment. Subjects were then randomized into one of the three trial arms using a computer-generated protocol. Upon completion of baseline assessment, subjects were scheduled for a baseline intervention visit within 2 weeks. Telephone screening took 10–15 minutes, baseline assessment 60–90 minutes, and each of the three interventions required 60–80 minutes.

Those subjects randomized to Computer-Automated Self-Management (CASM) received assistance with diet, exercise and medication adherence using a web-based behavioral change system. Those in the Computer-Automated Problem Solving (CAPS) arm, the most intensive of the 3 arms, received CASM plus live problem solving therapy to address distress-related problems. Those in the control arm received feedback from a comprehensive, diabetes-neutral health risk evaluation. As part of each intervention, all subjects received live 10–20 minutes telephone calls at weeks 2, 4, 7, and 12 to provide enhanced support and assistance for CASM or CAPS. Control subjects discussed additional health-related topics. Telephone screeners, recruiters, assessors, and interventionists were college-educated RAs who were trained and closely supervised by the investigators. The study was approved by the IRB at UCSF.

2.3 Measures and data analysis

Recruitment of eligible subjects was defined as a sequence of the three separate stages that led to a subject's attendance at the baseline intervention appointment: (1) verbally agreed to attend baseline assessment after successful completion of screening, (2) attended baseline assessment and (3) attended the baseline intervention appointment. Intervention retention was defined as completing 16 weeks of intervention, and a brief telephone call to collect follow-up information. Logistical regression analyses were used to examine differences between −AASAP and +AASAP rates of recruitment at each of the three stages (screening, baseline assessment, baseline intervention), controlling for age, gender (0=male, 1=female) education, ethnicity (0=white, 1=non white), duration of diabetes, and marital status (1=partnered, 0=non partnered). Similar logistical regression analyses examined differences in intervention retention over 16 weeks including the follow-up phone call. Intervention retention analysis within each study arm was conducted with chi square.

3.0 Results

3.1 Recruitment

A total of 588 subjects were screened as eligible, with 250 in the −AASAP group and 338 in the +AASAP group (Table 2). Average age was 55.7 (9.5) years, 56.5% were female and diabetes duration was 7.2 (5.90) years. Of the demographic variables, the −AASAP and +AASAP groups differed only by education ($p<.01$), with the −AASAP group reporting on average more college education than the +AASAP group. All subject demographics and diabetes duration were controlled in adjusted analyses.

Table 3 shows both the unadjusted and adjusted values for the logistic regression analyses that compared recruitment of the eligible sample at each of the 3 stages of the recruitment process by AASAP group, such that higher ORs indicated a higher probability of being recruited. The unadjusted ORs indicated significant improvement due to AASAP in recruitment at each of the three recruitment stages: 87.6% (n=219) of eligible subjects in the −AASAP group vs. 94.7% (n=320) in the +AASAP group agreed to attend baseline assessment (OR = 2.52, $p<.001$); 64% (n=160) of subjects in the −AASAP vs. 77.2% (n=261) in the +AASAP group actually attended baseline assessment (OR = 1.91, $p<.001$); and 53.6% (n=134) of subjects in the −AASAP vs. 62.7% (n=212) in the +AASAP group (OR=1.46, $p<.03$) attended the baseline intervention session. The adjusted ORs followed a similar pattern, with greater probability of retaining subjects in the recruitment process for +AASAP compared to −AASAP subjects (screening OR=2.69, $p<.001$; baseline assessment OR = 1.77, $p<.01$; baseline intervention appointment OR = 1.33, $p<.11$). In both adjusted and unadjusted analyses, the effect of AASAP was greatest at screening.

We also explored whether subject demographics were related to subject recruitment at each of the three stages of the recruitment process separately by AASAP group. For −AASAP, both higher education and shorter duration of illness were significantly associated with better recruitment at all three recruitment stages: telephone screening (OR=2.23, $p<.001$; OR=.89, $p<.001$), baseline assessment (OR=1.46, $p<.05$; OR=.91, $p<.001$), and baseline intervention appointment (OR=1.31, $p=.07$; OR=.91, $p<.001$). For +AASAP subjects, in contrast, no demographic variable or diabetes duration was significantly associated with recruitment at any stage, with one exception: higher education was associated with better recruitment only at telephone screening (OR=1.98, $p<.01$).

3.2 16-week intervention retention

A total of 291 subjects were included in the intervention retention analysis (Table 2): 79 in −AASAP and 212 in +ASSAP. Note that fewer subjects were included in the AASAP intervention retention analysis than in the +AASAP analysis because only subjects who completed the 16-week intervention before the introduction of AASAP were included in the −AASAP group to protect against between-group contamination. There were no significant differences between +AASAP and −AASAP in intervention retention over 16 weeks on any baseline demographic variable or on diabetes duration. Significant between-group differences occurred in the analysis unadjusted for control variables, with greater intervention retention in the +AASAP than −AASAP groups (OR = 2.60, $p<.05$) (Table 3). Similar results occurred in the analyses that adjusted for demographic variables and diabetes duration (OR = 3.46, $p<.05$). In both cases, more than twice the number of subjects were retained in the +AASAP than −AASAP groups.

We also analyzed retention separately for each study arm to determine if the intensity of the three interventions was related to intervention retention over 16 weeks. We considered CAPS the most intensive intervention, followed by CASM and the control condition, respectively. Of the 9 subjects in the −AASAP group who were lost during the 16-week

intervention, 78.0% were from CAPS, 0% from CASM and 22.0% from the control group ($X^2 = 7.39$, p = .03). Significantly more drop-outs came from the most intensive intervention arm than the other two. Of the 10 subjects from the +AASAP group who were lost to the study during the 16-week interval, 40% came from CAPS, 30% from CASM and 30% from the control group, with no significant between-arm differences ($X^2=0.85$, p = .85). Not only were the attrition rates during intervention significantly lower in +AASAP than −AASAP (4.7% vs. 11.4%, respectively), but the intervention intensity effect found in the −AASAP group was no longer significant in the +AASAP group.

4. Discussion and conclusion

4.1 Discussion

The introduction of AASAP into an ongoing behavioral intervention for distressed subjects with type 2 diabetes led to a significant increase in the percent of eligible subjects recruited. Furthermore, we find a significant increase in subject retention during the 16-week intervention. Last, we find that the significant effect of intensity of intervention on attrition during the intervention found in the −AASAP group is not significant in the +AASAP group. Thus, AASAP is successful in significantly increasing subject recruitment and intervention retention in a study of distressed subjects.

In addition to evaluating the number of subjects who might otherwise be lost to a study due to limited recruitment or attrition over time, we also consider whether lost subjects constitute a unique group whose absence might limit the generalizability of results. We find that subjects with short diabetes duration and high education are more frequently retained, especially during the early stages of recruitment. This effect, however, is found primarily in −AASAP and not in +AASAP, suggesting that AASAP helped retain significantly larger numbers of some high risk subgroups than would have been the case otherwise. This suggests that AASAP increases sample diversity and makes the sample more representative of the target community.

We, along with others [7], find that most subjects are lost during the early stages of recruitment. This is the time when the most diverse group of subjects is encountered but when each subject's relationship with staff is just beginning. It is noteworthy that AASAP has its greatest effect during this early study period. Addressing subject ambivalence in written correspondence prior to live contact and during live telephone screening, even when subject-staff relations are undeveloped, has a notably positive outcome.

Although the between-group AASAP differences are statistically significant, the number of subjects actually lost to our study at each stage of recruitment and during intervention may appear to be relatively small and inconsequential. When combined, however, the total number of subjects lost at each stage of recruitment to the end of intervention, can be considerable. For example, if 20% of eligible subjects at screening refuse to participate and are lost to recruitment, and an additional 25% are lost during intervention, then for every 100 subjects identified at screening as eligible, 60 will actually complete the intervention (100 eligible subjects less 20% = 80; 80 subjects less 25% = 60). The introduction of a successful and robust attrition prevention program like AASAP might be expected to reduce subject loss during recruitment and intervention by perhaps 20%, 30%, or even 50%. This leads to an increase of 8, 12, or 20 subjects per 100 subjects, respectively. If, as in our study, the expected sample size is 300, a program such as AASAP can prevent the loss of 24, 36, or even 50 subjects overall, when subjects potentially lost to recruitment and during intervention are aggregated. This adds up to a meaningful contribution to external validity.

Most empirical studies of attrition reported in the literature, as well as our own, use a pre-post, study-within-a-study format [11,12], as investigators realize after study initiation that recruitment and retention have become challenging problems. Thus, most studies of this kind, including ours, are initiated as an after the fact adjunct to ongoing research, rather than as a test of the effects of different recruitment and retention strategies as part of the original research plan.

Several study limitations are noteworthy. First, this was relatively well-educated, highly distressed sample of subjects with type 2 diabetes. The effects of AASAP may be more or less limited among less well-educated or less distressed subjects. Second, we used an exploratory pre-post design with no control group. Our results may be biased in part because recruitment and retention could have improve over time simply due to increased RA experience. Third, we defined retention as completion of the 16-week protocol. The longer-term effects of AASAP were not assessed. Thus, applications of AASAP to other populations and study time periods are needed to test its broader efficacy.

4.2 Conclusion

We have described AASAP as a brief, practical, theory based program of communication to improve subject recruitment and retention that addresses subject ambivalence and provides a structure for addressing subject-centered needs at each stage of the project. The empirical evaluation of AASAP reported here provides support for its effectiveness in improving recruitment and retention in an ongoing clinical trial with distressed subjects.

4.3 Practical implications

AASAP can be used in a variety of research settings with both distressed and non distressed subjects; it can be customized to address subject experiences at each stage of the research protocol; and it can be easily adapted to behavioral, pharmacological and general medical research protocols. AASAP can also be used by clinicians to help subjects begin and continue in ongoing programs of care, such as education, disease management and decisions to begin new treatment. AASAP is a structured, subject-centered communication strategy that helps subjects engage in a productive conversation regarding the often contradictory feelings and motivations that influence decisions to join and remain in health-related programs.

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Table 1

Examples of subject pro and con feeling scenarios for each stage of a research project.

Project stage	Pro	Con
Screening	This sounds interesting and it might help me take care of my diabetes better.	I am not sure that this will work for me, and I have tried these things before without much success.
Initial assessment	The staff are nice and maybe this will help me and possibly others too.	They want to find out a lot about me and I am embarrassed about all the problems and failures I have managing my health. Will they blame me?
Intervention	This deals with important stuff and I need to manage things better.	This is complicated: how will this help me, can I stay with this, can I trust them, I am scared that I do not understand all of this and I will appear silly to them.
Ongoing intervention	I hope this works for me, I need to get my diabetes under control.	This is not easy, it takes more work than I thought, I feel guilty that I am not doing as well as I should, I am letting them down.
Follow-up	I need to stay with this even though I am on my own and they are not around as much. This could help me be independent.	They are not in touch as often now because they feel that I did not do well, they are giving up on me, this is not going well – I need more help. I don't want to deal with this.
Final assessment	I owe them this visit, they tried hard. I can tell them what I thought about the project and give them helpful feedback. I can be useful to myself and to others.	I feel very embarrassed that I did not do well. I am angry at them because they did not help me enough and now they have abandoned me. I must have been too much for them – I failed.

Table 2

Description of − AASAP and + AASAP groups.

	Total	− AASAP	+ AASAP	t-test or χ^2
Recruitment	**N=588**	**N=250 (42.5%)**	**N=338 (57.5%)**	**p-value**
Patient Characteristics				
Age	55.74 (9.51)	56.03 (9.81)	55.52 (9.30)	.53
Gender (female)	332 (56.5%)	145 (58.0%)	187 (55.4%)	.52
Education level				.01**
≤ 12th grade	51 (8.6%)	13 (8.4%)	12 (8.7%)	
Some college or vocational school	195 (33.1%)	21 (39.9%)	32 (28.2%)	
≥ Four years of college	342 (58.3%)	13 (51.7%)	14 (63.1%)	
Years since diagnosis	7.18 (5.90)	7.52 (5.52)	6.93 (6.16)	.24
Ethnicity				.27
Asian American	141 (24.0%)	71 (28.5%)	70 (20.7%)	
African American	101 (17.1%)	43 (17.2%)	58 (17.1%)	
Hispanic	63 (10.7%)	23 (9.2%)	40 (11.7%)	
Caucasian	235 (40.0%)	93 (37.2%)	142 (42.0%)	
Other	48 (8.2%)	20 (7.9%)	28 (8.4%)	
Living with partner/married	362 (61.5%)	153 (61.1%)	209 (61.7%)	.87
Intervention Retention	**N=291**	**N=79 (27.1%)**	**N=212 (72.9%)**	**p-value**
Patient Characteristics				
Age	55.37 (9.90)	54.38 (11.07)	55.74 (9.42)	.30
Gender (female)	154 (52.8%)	46 (58.2%)	107 (50.7%)	.25
Education level				.11
≤ 12th grade	29 (8.9%)	8 (10.1%)	18 (8.5%)	
Some college or vocational school	86 (29.6%)	30 (38.0%)	56 (26.4%)	
≥ Four years of college	179 (61.5%)	41 (51.9%)	138 (65.1%)	
Years since diagnosis	6.77 (5.98)	6.02 (4.86)	7.05 (6.33)	.19
Ethnicity				.07
Asian American	63 (21.6%)	21 (26.6%)	42 (19.8%)	
African American	55 (18.9%)	19 (24.1%)	36 (17.0%)	
Hispanic	33 (11.3%)	11 (13.9%)	22 (10.4%)	
Caucasian	113 (38.8%)	20 (25.3%)	93 (43.9%)	
Other	27 (9.3%)	8 (10.1%)	9 (9.0%)	
Living with partner/married	178 (61.2%)	46 (58.2%)	132 (62.3%)	.53

Data are means +/− SD or n (%).

** $p < .01$

Table 3

− AASAP/ + AASAP group effects unadjusted and adjusted for patient demographics

	RECRUITMENT						INTERVENTION RETENTION	
	Telephone screening		Baseline assessment (A1)		Attended initial intervention		Completed 16 week intervention	
	OR	p value	OR	p value	OR	p value	OR	p value
Unadjusted effect								
AASAP group	2.52	<.001***	1.91	<.001***	1.46	.03*	2.60	.05*
Adjusted effects								
Age	1.03	.10	1.01	.92	1.01	.51	0.97	.28
Gender (female)	0.95	.87	0.84	.38	0.81	.23	0.65	.41
Education level	2.01	<.001***	1.24	.04*	1.13	.20	1.22	.45
Years since diagnosis	0.95	.03*	0.97	.10	0.97	.09	0.91	<.01**
Ethnicity (minority)	0.93	.83	1.01	.96	1.04	.84	1.23	.70
Partner status (partnered)	0.67	.23	.78	.22	.96	.81	1.02	.97
AASAP group	2.69	<.001***	1.77	<.01**	1.33	.11	3.46	.02*

* p < .05;

** p < .01;

*** p < .001.