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Randomized Clinical Trial of Computerized PAINRelievelt® for Patients with Sickle cell disease: PAINReportIt® and PAINUCope®

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Abstract

Objective: To compare effects of a tailored multimedia education program versus usual-care on barriers to pain management of adult patients with SCD

Methods: Pretest/posttest randomized controlled trial (RCT) of 228 outpatients with SCD randomized to the tablet-based PAINUCope intervention focused on barriers to pain management, pain, and analgesic adherence or selection of games (control). Outcomes were barriers to pain management, pain, and analgesic adherence.

Results: The barriers to pain management and pain scores did not change significantly from pretest to posttest for either condition. Changes in analgesic adherence rates from pretest to posttest were statistically significant for the intervention group ($p=.046$) but not for the usual care group ($p=.419$). The group difference was not statistically significant.

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Conclusions: This first RCT of a tailored multimedia education intervention with adult patients with SCD did not significantly reduce the outcomes of interest compared to the control group. Findings provide insights for improving intervention delivery and reinforcement of patient behaviors.

Practice implications: Study redesign is warranted with modifications that include theoretical and methodological approaches and patient-centered delivery of the intervention that take advantage of recent technology developments.

Keywords

patient education; sickle cell disease; pain management; pain barriers

Introduction

Patients with sickle cell disease (SCD) have barriers to pain management similar to patients with cancer [1, 2], which may contribute to inadequate adherence to prescribed analgesics and insufficient control of acute and chronic pain of SCD [1, 3]. Episodes of severe intense pain often result in acute care utilization that can last many days [4–7], contributing to the estimated \$2.4 billion annual healthcare costs for the 100,000 Americans living with SCD [8, 9]. Educational interventions designed to improve patient knowledge [10], decrease patient barriers to pain management, and reduce pain severity have been effective for cancer patients [8, 11, 12], but have not been tested in the SCD population. The study purpose was to compare the effects of a multimedia education intervention on pain-related outcomes among adults with SCD.

The Johnson Behavioral System Model [13] suggests that behavior change is facilitated by increasing behavioral choices through change in knowledge and role modeling of the behavioral choices likely to produce desired outcomes. Guided by these perspectives, the intent of our educational intervention was to provide the participants with evidence-based, pain-related behavioral choices and role model implementation of the behavioral choices to improve pain control for patients with SCD.

Patients often minimize or under report aspects of their pain for reasons based on their own understanding about pain or personal factors such as education or ethnicity [14–17]. On a 0–10 scale, patients with SCD experience moderate (>3 to 6) to severe (>6) pain in multiple locations on most days, making barriers to pain management a threat to the adequacy of their pain control [12, 18–21]. Barriers that may be particularly relevant to SCD pain management include patients' understanding of pain as a symptom, fear of addiction or tolerance to prescribed opioid analgesics, and concerns with side effects such as nausea and constipation are examples of knowledge that can influence behaviors [1, 3, 21, 22]. Patients also may lack knowledge of medications required for SCD pain control. These medications include a variety of analgesics (opioid, non-opioid, or adjuvant), which can be prescribed alone or combined and must be individualized to achieve pain control with as few side effects as possible [21–23].

Achieving adequate SCD pain control is difficult, in part, because of the complexity of and variation in individual patients' pain experiences [12, 21–24]. The Composite Pain Index (CPI) was created as a multidimensional representation of such pain and to capture its complexity. Standardized on a scale 0 and 100, the CPI is the average of four sensory dimensions: location, intensity, quality and pattern. For adults with SCD, the CPI produces a SCD pain phenotype [24] that is a reliable predictor of acute care utilization for pain control over 2 years [25]. Support for CPI construct validity comes from studies of cancer pain and outpatient sickle cell pain [8, 9, 26]. Interventions that reduce CPI among outpatients with SCD could have important benefits for patients' comfort and ultimately for reducing SCD healthcare costs.

Patient Education

Barriers to pain management are not systematically measured in clinical practice, which means that the need to increase knowledge and change pain-related behaviors can be missed. A potential solution for reducing barriers to pain management among patients with SCD is to measure each patient's pain and pain barriers and then provide education to improve knowledge and enhance behavior change. Specifically, data about pain and barriers can be used to provide tailored education focused on each barrier with examples to role model behavior change for improving pain control. The specific aim of this study was to compare the effects of a multimedia-education program for adult outpatients with SCD on their barriers to pain management, analgesic adherence, and CPI. We hypothesized that compared to the control group, the intervention group would have decreased barriers to pain management and CPI and increased analgesic adherence.

2. Methods

2.1 Study Design.

With a pretest/posttest randomized controlled study design, we conducted all study activities with the approval of the University of Illinois at Chicago (UIC) Institutional Review Board. The primary outcomes for our study were patient barriers to pain management, analgesic adherence, and CPI per registration with clinicaltrials.gov (). To ensure balance within the groups for low and high pain intensity levels (<5 or ≥5 on a 0–10 scale), we used stratified random assignment of outpatients with SCD in permuted blocks (18 to 22 patients per block) to one of two groups, usual-care or intervention. Automatically, based on patient-reported pain intensity, the study software randomly assigned participants to groups. The programming code resided in a hidden folder within a password-protected database that was not accessible to any study staff with patient contact or data analysis responsibilities. Only the software engineer had access to the hidden folder with the randomization code. Using this randomization method, the principal investigator, coinvestigators, and clinic staff remained blind to patient treatment group assignment until the data for each patient were collected and analyzed. At least one research staff member (usually research nurse) also was blind to the group assignment of each patient. Subjects were blind to study hypotheses throughout the study and to group assignment until they clicked on intervention icon on the tablet desktop.

2.2 Setting.

We recruited participants from the Adult Sickle Cell Clinic of the University of Illinois (UI) Hospital and Health Sciences System in Chicago, IL. The clinic is part of the Comprehensive Sickle Cell Center that serves a panel of more than 500 adults with SCD. Hematologists, medical residents, nurse practitioners, registered nurses, and support staff provided outpatient follow-up care.

2.3 Sample.

Inclusion criteria required that the patient: (a) had a diagnosis of SCD; (b) was scheduled for continuing care at the UI Sickle Cell Clinic; (c) had moderate to severe level of pain (3 on 0–10 scale) related to SCD within the last 12 months; (d) had an ED visit or hospitalization within the previous 2 years; (e) spoke and read English; and (f) was 18 years or older. Excluded were patients who were legally blind or physically unable to complete the study questionnaires. We selected 3 on 0–10 scale as the inclusion criteria because patients with SCD report the average score 3.3 ± 2.2 is a tolerable level of pain, but they report the optimal pain level is 0.98 ± 2.3 score [1].

As shown in Table 1, the sample available for analysis included 228 adults who were aged 18 to 74 years, 62% female, 98% African American heritage, and 45% educated up to high school level and 46% educated beyond high school. The intervention and control groups were similar at pretest on all evaluated demographic variables (Table 1). Figure 1 presents the CONSORT data for study participants. At the 0.05 level of probability and using 2-tailed, independent t test, a sample of 114 patients in each group (228 total) was expected to provide power of 85%.

2.4. Procedures.

The research specialist (RS) recruited eligible patients from the clinic and obtained signed informed consents. The RS told eligible participants that investigators were testing a new computerized tool for pain related to SCD. Following the visit with the provider, the RS introduced participants to the computer where they entered their code on the introduction screen. Participants completed pretest measures. The usual-care participants' study code allowed access to a list of computer games from which the participants could make selections. The intervention participants' study code allowed access to the educational intervention. At their next clinic visit approximately 3 months afterward, the participants completed posttest measures.

Potential risks to the patients of this study were minimal; specifically increased pain could result from focusing on their pain. To reduce risk of increased pain, patients were informed of their right to refuse to participate or to stop participation and rest if needed. Patients also were allowed to take analgesics prescribed for them. Another potential risk included possible loss of privacy. To reduce the risk for loss of privacy, patient confidentiality was maintained through the use of participant codes that were linked to the patient's name to display tailored education with the patient's name. All patient identifiers were removed for data analysis procedures.

2.5 Measures.

PAIN*RelieveIt*®[27]® (Nursing Consult LLC, Seattle Washington) is a suite of computerized touch-screen tools offering longitudinal self-report pain assessment (PAIN*ReportIt*®), decision support for providers (PAIN*ConsultN*®) and tailored patient educations (PAIN*UCope*®). PAIN*ReportIt*®, a software program designed for use on pen-tablet computers, is an electronic version of the McGill Pain Questionnaire (MPQ) [27, 28]. The MPQ is a well-validated tool measures pain location, quality, intensity, and pattern dimensions of sensory pain [27–30]. Aggregated, these data form the CPI. Specifically, the CPI score derives from the average of the four individual dimension scores, each of which is converted to a 0–100 scale [1]. In a cancer sample reliability of the CPI was 0.71 [14]; and in a SCD sample the correlation between CPI at two time points was $r = 0.45$; $P < 0.001$; 95% CI 0.31, 0.57 [8]. Sensitivity of the CPI to detect the effect of an educational intervention was demonstrated in a cancer population [8].

The computerized BQ-13, a 13-item version of the Barriers Questionnaire (BQ) [9] measures patient beliefs about pain management on a 5-point Likert scale (0, do not agree; 5, agree very much). BQ-13 findings from a cancer study show construct validity and high internal consistency [9]. Other investigators reported use of shortened BQ versions containing similar items [15, 31, 32]. Prior to this study, we conducted focus groups and cognitive interviews with SCD patients to assess the BQ-13 validity and findings supported validity in this population [8]. Findings from one report indicate that BQ-13 scores are similar in cancer and SCD samples despite the differences in the disease trajectories [1].

Participants documented their use of analgesics in the 24 hours prior to data collection by selection from an analgesic list embedded within PAIN*ReportIt*®. Included on the list were analgesics from opioid, non-opioid, and adjuvant drug categories. Data for each drug included dose, route, frequency interval prescribed, and times taken in the previous 24 hour, which allow calculation of self-reported analgesic adherence for the previous 24 hours, a time period known for recall reliability [1].

2.6. Intervention.

Participants randomly assigned to the intervention group had access to the PAIN*UCope*® intervention. From data in the PAIN*ReportIt*® database, PAIN*UCope*® generates a list of the barriers to pain management for each participant based on each BQ-13 item response that was greater than 0 or pain intensity that was greater than tolerable to the patient. A set of educational material with facts or scripts tailored to SCD patient barriers to pain management or pain intensity and was available to the participant via the tablet computer. The educational material within PAIN*UCope*® was written at a 6th grade reading level and presented as 21st century best practices, evidence-based facts or scripts for the person living with SCD. The content included video and audio clips, photo illustrations, and animations to reinforce the educational messages and maintain participant interest in the educational materials. Participants could make their selection within the PAIN*UCope*® menu, read or listen to the information on the tablet computer in any order and, if desired, print any or all of the information. Table 2 includes examples of the educational content provided to the participants. Based on formative feedback from focus groups who advised regarding study

processes, use of clinic wait-time as an opportunity for patients to self-administer a tablet-based educational intervention was intended as a way to test an intervention that would fit into the clinic flow and be sustainable with low personnel costs when implemented clinically.

Participants randomly assigned to the usual care group had access to computer games to provide them an opportunity to interact with the same tablet computer as the intervention group participants. Games included instructions to allow participants of all ages to play the games.

2.4 Statistical analysis

Data were imported into the statistical software R for analysis. Descriptive statistics including mean, standard deviation, frequency, and percentage were obtained for patient demographics and various outcome variables of interest at both pretest and posttest. Student t tests, Chi-square tests, and Fisher's tests were used for group comparison. Linear regression analysis was performed on posttest outcomes to allow group comparison controlling for their pretest values. For missing data processing, multiple imputation was used to generate multiple completed datasets, on which the statistical inference was applied and then aggregated to generate a summary. Statistical significance was set at a two-sided alpha of 0.05.

3. Results

3.1.1 Univariate Results—The stratification provided adequate balance of the pain experience context for the sample, as represented by the current pain intensity scores reported by the participants at pretest (Table 1). At pretest 117 (49% of the usual care group and 54% of the intervention group) reported pain intensity less than 5 (middle of the 0–10 scale), and 111 (51% of the usual care and 46% of the intervention group) reported scores between 5 and 10. At posttest, 91 of the participants (48% of the usual care and 50% of the intervention group) reported posttest pain scores less than 5 on a scale of 0–10. Table 3 presents the means and standard deviations (SDs) at pretest and posttest by the usual care and intervention groups for study outcomes, including barriers (BQ-13), pain (CPI), and analgesic adherence.

3.1.2 BQ-13—The mean (SD) BQ-13 scores for the intervention group were 2.15 ± 0.87 and 2.05 ± 0.80 at pretest and posttest, respectively (Table 3). The mean (SD) BQ-13 scores for the control group were 2.39 ± 0.92 at pretest and 2.26 ± 0.86 at posttest. The difference in group means was statistically significant at pretest with the control group fairing worse. The group means did not differ at posttest. Further, neither group's mean score changed significantly from pretest to posttest ($p=.115$ for usual care and $p=.252$ for intervention).

Table 4 presents mean (SCD) scores for each of the BQ-13 items by control group and intervention group and time (pretest, posttest). The intervention and control groups did not have significant pre to post changes in mean scores for any BQ-13 item.

3.1.3 CPI—At pretest, mean CPI scores ranged from 9.1 to 86.5 for the control group and from 4.7 to 73.8 for the intervention group. At posttest, the ranges were 0.0 to 72.2 and 7.1 to 81.0, for the control and intervention group, respectively. Mean CPI scores for neither group changed significantly from pretest to posttest ($p=.691$ for usual care and $p=.509$ for intervention). The mean (SD) for pretest and posttest CPI by group and test statistics for t tests for group comparison appear in Table 3.

3.1.4 Analgesic Adherence—Average analgesic adherence rates were low with considerable variation (Table 3). At pretest, the analgesic adherence rate for the control group was statistically significantly higher than the intervention group. At posttest, between group differences were not statistically significant. The changes in adherence from pretest to posttest were statistically significant for the intervention group ($p=.046$) but not for the usual care group ($p=.419$). The use of step 2 opioids and step 3 opioids was similar between groups. Step 2 opioids use was (72%) for the usual care group and (69%) for the intervention group; step 3 opioid use for the usual care group was 60% and 56% for the intervention group.

3.2 Multivariate Results

Table 5 presents the regression coefficient estimates for group and time effects on the outcomes of interest. Not surprisingly, posttest values for the BQ-13, CPI, and analgesic adherence were significantly associated with their pretest values. Controlling for pretest values, however, posttest scores for the patient outcomes of interest were not statistically different between the intervention and usual care groups.

3.3. Exploratory Results

To understand the lack of statistically significant intervention effects, we conducted exploratory analysis to inform future research. Fidelity of the intervention delivery is an important issue. Table 6 presents the frequency of the actual time spent viewing the content compared to the time required to view all of the content for each tailored education component (one for each of the 13 barriers to pain management). For example in the intervention group, 92 participants' BQ-13 responses demonstrated the need for education regarding addiction, and they were given access to view the tailored education content about addiction. Of those 92 participants, 37 (40%) opened the education on addiction and 16 (17%) left it open the length of time required to complete it. Of the same 92 participants, 51 (55%) requested a paper copy of the material. Overall 75% of the participants accessed the addiction content on the computer or printed it, but only 17% accessed the computer content for enough time to engage it fully. We did not collect evidence of paper content engagement. Overall, Table 6 shows that the intervention delivery was 55% to 81% but less than 30% opened and viewed the content for the full length of time. Additionally, 50% to 61% of the participants requested printed materials, including some participants who viewed the content on the computer and requested printed materials.

We also examined the association of CPI with the intervention delivery among the intervention group participants at pretest. The numbers of the PAIN Ucope items provided (i.e., needed by) to the participants were positively correlated with the pretest CPI ($r=0.30$;

$p=.001$), but the number of items viewed by the participants fully had minimal correlation with the pretest CPI ($r=-0.04$; $p=.66$). This finding shows that the PAINUCope program provided a higher dose of intervention to patients with more pain and hence more needs, however, the dose absorbed (viewed fully) by patients had minimal correlation with their pain and needs, suggesting that other factors such as patient attention span or fatigue might have been the limiting factor. Patients that selected either “Tiring” or “Exhausting” to describe their pain experience on average viewed fully 15.9% (21.3%) of the items shown to them while patients who did not select either viewed fully 19.4% (26.3%) of the items (Table 7). The difference between these two groups of patients was not statistically significant ($p=.49$). While we used an imperfect proxy to identify patient fatigue, this finding seemed to suggest that fatigue was not the major factor in low intervention uptake.

Another factor that may have influenced study results is the length of time between pretest and posttest, a factor controlled by participants’ clinic visits. We found that participants frequently canceled and rescheduled clinic visits. The nature of follow-up clinic visits resulted in some participants not completing posttest assessment at exactly 3 months. To evaluate for the interval between pretest and posttest as a time effect we grouped participants based upon time of posttest. Of 184 participants that completed the posttest, 116 (63%) completed it within 6 months of the pretest, 46 (25%) completed it longer than 6 months but not more than 1 year after the pretest, and 22 (12%) completed it more than 1 year after the pretest. Table 8 presents coefficient estimates for the three groups for linear regression of posttest scores on group assignment controlling for pretest scores; the interval between pretest and posttest did not have a large effect on the BQ-13 outcome.

4. Discussion and Conclusion

4.1 Discussion

We are the first to examine the effects of a tailored multimedia education program versus usual care on barriers to pain management, CPI, which is a multidimensional pain outcome, and analgesic adherence rates of adult outpatients with SCD. Interaction with the PAINUCope® intervention was intended to provide adults with SCD evidence-based, pain-related behavioral choices and role model implementation of the behavioral choices to promote pain control [13]. This first RCT of a tailored multimedia education intervention in adult outpatients with SCD did not significantly reduce barriers to pain management, increase pain medication adherence, or decrease pain compared to usual SCD outpatient care. Reasons for lack of efficacy of the PAINUCope® intervention in the outpatients with SCD are not clear, but are likely related to insufficient intervention dose delivery (time on task) to allow learning.

Barriers to adherence to prescribed analgesics include concerns with side effects and fear of addiction [1, 3]. Although not significant compared to the control group, we did find a significant increase in analgesic adherence within the PAINUCope® group, which is an important finding of our study. Among patients with SCD, acute pain is the main symptom leading to hospitalization [4] and increased adherence rates can lead to reduced use of the acute care setting [33]. Therefore, improved adherence to prescribed analgesics is a preferred outcome.

Our study is also the first to evaluate the multidimensional nature of pain, by using the CPI as an intervention outcome for SCD pain. In prior research, the CPI predicted acute healthcare utilization among adults with SCD and as a pain phenotype [22]. In our study, however, the CPI values were not different between groups, indicating that the multidimensionality of the pain was not reduced by the intervention.

Patient Education—Interventions aimed at reducing patient barriers to pain management have been effective in patients with cancer [11, 15] and conceivably could be effective in patients with SCD. Web-based, multimedia, targeted, and interactive interventions were feasible in people with SCD [34]. In RCTs of web-based, multimedia, targeted, and interactive education interventions that included up to an average of 70 minutes of on-task engagement, investigators found increased knowledge scores in the intervention group that in one of the studies was sustained for 24 months [35] and for 3 months in another study [36]. Our non-significant findings may be due in part to a lack of reinforcement of patient intervention viewing behavior that was long enough to complete the education. Finding ways to engage adults with SCD in education about experiences they have had for years may take an approach that allows engagement that starts in the clinic and continues on-the-go or at home via mobile technology that is now pervasive and allows time-on-task at the patient's convenience. This issue is important since there are 14 components of the intervention. Although each component requires 40 seconds to 3 minutes, the complete set of intervention components required 18.55 minutes, which was more time than the patients engaged in the clinic setting. Improved health behavior and patient engagement resulting in weight reduction [37], and although not sustained at the 3-month follow up, increased stamina [38] and increased medication adherence [33] in studies of web-based and mobile platforms for delivering interventions.

Limitations of our study included setting and participant engagement. First, our study was conducted in one outpatient clinical setting in the Midwest U.S. and, therefore, cannot be generalized nationwide. Second, the participants did not fully engage with the tailored multimedia education program, which might be attributable to patient illness behavior, time constraints, or transportation.

4.2 Conclusion

We expected that tailored educational intervention where specific content was based on an individual's behaviors and attitudes would have been retained and resulted in better outcomes than usual care [32]. However, the findings in our study may be attributable, in part, to incomplete delivery of the intervention. Strategies are needed to improve intervention dose delivery and should be developed in collaboration with the adults with SCD and their providers. A consideration is to deliver the intervention in an online password protected format that the patient can access anywhere. Reinforcement of the intervention could come in the form of feedback on performance, personal messages and reminder prompts received via text smartphone technology or email, which have been found effective for patient engagement in their health care [39]. This approach would enable participants to view the intervention at their convenience as well as to view it multiple times, if needed to ensure complete learning of each intervention item.

4.3 Practice Implications

Our findings are consistent with a study that described the sensory pain characteristics, barriers, and analgesic use by adults with SCD and reported that nausea was the most troubling side effect of pain medication and addiction to pain medications was very concerning [1]. With identification of barriers to pain management, it then becomes necessary for the clinician to communicate and reinforce accurate information to SCD patients regarding specific barriers. Interventions are not an acceptable replacement for good patient-clinician communication, but serve as valuable tools in the delivery of appropriate patient education to SCD patients.

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Highlights

- Study of tailored multimedia education program versus usual-care
- Adherence rates increased within the intervention group but not between groups
- Intervention fidelity cannot be assumed with computer delivery

Figure 1.
CONSORT Flow Diagram: Sick Cell Study PAINUCope

Table 1.

Demographic and pain characteristics of participants (N=228).

Characteristics	Usual Care (n=118)	Intervention (n=110)	p Value
Age (in years)			.46
Range	18–63	18–74	
Mean (SD)	32.7 (11.1)	33.8 (11.2)	
Gender			.41
Male	41 (35%)	45 (41%)	
Female	77 (65%)	65 (59%)	
Race			.67
Black	116 (98%)	107 (97%)	
Others	2 (2%)	3 (3%)	
Ethnicity			.71
Hispanic	3 (3%)	4 (3%)	
Non-Hispanic	115 (97%)	106 (96%)	
Marital Status			.81
Single	85 (72%)	77 (70%)	
Married/Partnered	25 (21%)	23 (21%)	
Widowed	1 (1%)	3 (3%)	
Unknown	7 (6%)	7 (6%)	
Education			.74
Up to high school *	55 (47)	48 (44%)	
Some College	45 (38%)	39 (35%)	
College or above	9 (8%)	12 (11%)	
Unknown	9 (8%)	11 (10%)	
SC Type			.44
SS	87 (74%)	77 (70%)	
SC	22 (19%)	19 (17%)	
Other	9 (8%)	14 (13%)	
Current pain intensity (at pretest)			.58
Range	0–10	0–10	
Mean (SD)	4.3 (3.4)	4.1 (3.3)	
Worst pain intensity in past 24 hours (at pretest)			.60
Range	0–10	0–10	
Mean (SD)	5.8 (3.4)	5.5 (3.8)	

* Data shown are means $\pm$ standard deviations or frequencies with percentages in parentheses. P values were obtained using t tests for continuous variables and chi-square or Fisher's test for categorical variables.

Table 2.**Barriers to Pain Management and Example of Educational Content**

Barrier to Pain Management	Number of Screens	Educational Content for Each Barrier
1. Having pain means that the disease is getting worse	5	1. Explains that pain can be from sickle cell disease and other causes. 2. Provides information on the importance of recognizing pain early, and when it is important to call the physician.
2. I do not like having shots	5	1. Provides reassurances and validation of feelings about “shots”. 2. Discussion of different ways to give pain medicine that do not require repeated injections with needles. 3. Provides information on other ways to help relieve pain without using medicines.
3. Pain medicine cannot totally eliminate pain	9	1. Explains the importance of recognizing pain and telling the doctor and nurse about pain. 2. Provides information on different types of pain medicine that can be used to treat pain. 3. Provides instruction on what information about pain is important to tell the doctor and nurse.
4. It is important to be strong by not talking about pain	11	1. Provides reassurances and validation of feelings about talking about pain. 2. Describes health impact of unrelieved pain. 3. Discussion of different pain relief strategies to control sickle cell pain. 4. Explains the importance of recognizing pain and telling the doctor and nurse about pain. 5. Provides instruction on what information about pain is important to tell the doctor and nurse.
5. It is more important for the doctor to focus on curing illness than to put time into controlling pain	3	1. Describes health impact of unrelieved or untreated pain. 2. Provides instruction on what information about pain is important to tell the doctor and nurse.
6. It is easier to put up with pain than with the side effects that come from pain medicine.	4	1. Describes health impact of unrelieved pain. 2. Explains the importance of recognizing pain and seeking pain relief for improved quality of life. 3. Discussion of side effects of pain medicine and ways these side effects may be controlled.
7. Drowsiness from pain medicine is really a bother	5	1. Provides a discussion of drowsiness as a side effect of pain medicine and provides a description of how this side effect might be controlled. 2. Explains when sleepiness from pain medicine may resolve.
8. Confusion from pain medicine is really a bother.	4	1. Provides a discussion of confusion as a side effect of pain medicine and provides a description of how this side effect might be controlled. 2. Explains things that may help assist with mental confusion.
9. People get addicted to pain medicine easily.	12	1. Provides validation about the concern of becoming addicted to pain medicine. 2. Provides an explanation of the differences between addiction to pain and dependence on pain medicine for relief of sickle cell pain. 3. Provides information regarding likelihood of addiction to pain medicine for treatment of sickle cell pain. 4. Reassures that if changes to pain medicines or dose of pain medicines are necessary, this will be conducted safely and will be closely monitored by the doctor or nurse.
10. Nausea from pain medicine is really distressing.	6	1. Provides a discussion of nausea as a side effect of pain medicine and provides a description of how this side effect might be controlled. 2. Explains when nausea from pain medicine may resolve. 3. Explains steps that may be taken that may help assist with nausea.
11. Pain medicine can really make you say or do embarrassing things.	4	1. Explains that some people experience side effects with pain medicines, and inability to think clearly may be one of these side effects. 2. Explains steps that may be taken that may help assist with the inability to think clearly.
12. If you take pain medicine when you have some pain, then it might not work as well if the pain becomes worse.	7	1. Reassures that changes to pain medicines or dose of pain medicines are necessary, this will be conducted safely and will be closely monitored by the doctor or nurse. 2. Reassures that increasing the dose for most prescribed medicines increases their effectiveness against pain. 3. Discussion of the importance of taking pain medication as prescribed to prevent pain before it starts or gets worse. 4. Explains the importance of recognizing pain and telling the doctor and nurse about pain, especially if pain medication is not working as well as it once did.
13. Constipation from pain medicine is really upsetting.	5	1. Provides detailed information regarding constipation as a side effect of pain medicines and the need for prevention of constipation. 2. Provides the importance of management of constipation through hydration, eating certain foods, and getting adequate exercise. Also, using OTC laxatives with stool softeners as recommended by the doctors and nurses. 3. Provides information regarding use of bulk- forming laxatives.

Barrier to Pain Management	Number of Screens	Educational Content for Each Barrier
14. Pain	29	<ol style="list-style-type: none">1. Describes ways to discuss how pain feels and encourages person to partner with doctor and nurse in management of pain.2. Discussion of differences in meaning of pain to those experiencing versus the meaning to doctors and nurses.3. Discussion of the pain scale and the use of the pain scale with a description of the meaning of the numbers on the scale to doctors and nurses.4. Provides information regarding the importance of pain relief, the importance of telling doctors and nurses about the pain and that the person experiencing pain is the only person that knows how pain feels.5. Provides detailed information regarding the details to include when telling doctors and nurses about pain, including pattern, area, intensity, and nature.6. Illustrates a sample script for providing a detailed description (history) of pain to the doctor or nurse.

Table 3

Patient Outcomes by Group at Pretest and Posttest

Outcome	Occasion	Control		Intervention		p-value
		M	SD	M	SD	
BQ13	Pretest	2.39	0.92	2.15	0.87	.044
	Posttest	2.26	0.86	2.05	0.80	.069
CPI	Pretest	41.8	14.6	41.9	13.7	.937
	Posttest	41.2	13.7	43.0	13.6	.371
Adherence	Pretest	0.45	0.44	0.32	0.38	.032
	Posttest	0.52	0.68	0.45	.048	.469

P values were obtained using t tests for continuous variables and chi-square or Fisher's test for categorical variables.

Table 4.

Descriptive statistics: BQ-13 items by control (n=118) and intervention (n=110) groups and time

Item on BQ-13	Pretest		Posttest	
	Control Mean (SD)	Intervention Mean (SD)	Control Mean (SD)	Intervention Mean (SD)
1. Pain means disease getting worse	2.44 (2.02)	2.15 (1.91)	2.21 (1.90)	1.96 (1.73)
2. Not like shots	2.98 (1.88)	2.70 (1.87)	3.02 (1.76)	2.90 (1.92)
3. Pain medicine cannot control pain	1.87 (1.76)	1.64 (1.64)	1.80 (1.70)	1.42 (1.55)
4. People get addicted to pain medicine	2.75 (1.81)	2.84 (1.73)	2.60 (1.77)	2.51 (1.74)
5. Be strong by not talking about pain	1.91 (1.90)	1.77 (1.71)	1.83 (1.80)	1.68 (1.70)
6. Doctor to focus on curing illness than controlling pain	2.42 (1.96)	2.07 (1.89)	2.13 (1.86)	2.08 (1.73)
7. Take pain medicine, then it might not work if pain worse	2.72 (1.91)	2.35 (1.78)	2.47 (1.75)	2.12 (1.78)
8. Put up with pain than side effects from pain medicine	1.77 (1.75)	1.56 (1.59)	1.74 (1.71)	1.54 (1.62)
9. Drowsiness is a bother	2.50 (1.67)	1.85 (1.58)	2.34 (1.68)	1.67 (1.68)
10. Confusion is a bother	2.41 (1.94)	2.26 (1.80)	2.30 (1.79)	2.28 (1.78)
11. Nausea is distressing	3.30 (1.74)	2.97 (1.92)	2.97 (1.75)	2.65 (1.77)
12. Pain medicine makes you say embarrassing things	1.18 (1.60)	0.98 (1.38)	1.16 (1.61)	1.20 (1.57)
13. Constipation is upsetting	2.82 (1.73)	2.78 (1.80)	2.87 (1.82)	2.61 (1.80)

Table 5.

Summary of regression outcomes BQ-13, CPI, and adherence

Patient Outcome Posttest~Pretest + Group		Estimate	Std Error	t value	p value
BQ-13	Pretest BQ	0.493	0.058	8.515	<.001
	Group (ref=control)	−0.097	0.103	−0.942	.348
CPI	Pretest CPI	0.358	0.066	5.413	<.001
	Group (ref=control)	1.763	1.914	0.921	.358
Analgesic	Pretest Adherence	0.222	0.109	2.041	.043
Adherence	Group (ref=control)	−0.038	0.092	−0.416	.678

Table 6.

Delivery of a tailored multimedia education program

PAIN UCope Item	# needing intervention item	Seconds needed to view	% (with need) opened intervention	% opened and ran full length of time	% requested paper copy	% opened or requested
1. pain means disease worse	70	40	36%	27%	53%	74%
2. do not like shots	82	107	39%	15%	61%	74%
3. medicine cannot control pain	69	131	36%	19%	61%	75%
4. pain medicine addiction easy	92	180	40%	17%	55%	75%
5. be strong not talk about pain	76	50	41%	39%	54%	74%
6. MD focus on curing illness rather than controlling pain	67	50	34%	19%	58%	72%
7. take pain medicine now, not work when pain worse	80	76	38%	21%	61%	74%
8. easier to have pain than side effects from pain medicine	42	44	48%	26%	60%	81%
9. drowsiness from pain medicine a bother	80	162	9%	1%	51%	55%
10. confusion from pain medicine a bother	84	70	15%	1%	50%	60%
11. nausea from pain medicine distressing	91	57	12%	4%	53%	59%
12. pain medicine makes you say or do embarrassing things	56	88	14%	0%	50%	57%
13. constipation from pain medicine upsetting	86	58	12%	5%	50%	55%

Table 7.

Fatigue and Intervention Time on Task

	Selection Related to Fatigue			
	Neither	Tiring	Exhausting	Both
Items needed	8.0 (2.5)	8.0 (2.5)	9.4 (2.6)	9.8 (2.2)
Items fully viewed	1.2 (1.6)	1.0 (1.2)	1.4 (2.0)	1.4 (1.8)
% (out of needed) viewed	19% (26%)	17% (22%)	17% (24%)	14% (18%)

Table 8.

Time Effects Pretest to Posttest

		Estimate	SE	t value	p value
Up to 6 months	Pretest BQ	0.522	0.077	6.751	<.001
	Group (ref=control)	−0.077	0.131	−0.587	.558
6 months up to 1 year	Pretest BQ	0.774	0.107	7.265	<.001
	Group (ref=control)	−0.362	0.206	−1.753	.087
>= 1 year	Pretest BQ	0.479	0.204	2.347	.031
	Group (ref=control)	0.084	0.301	0.280	.783