CE Symptom Management Series
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Evaluation of a Low-Light Intervention—Starlight Therapy—for Agitation, Anxiety, Restlessness, Sleep Disturbances, Dyspnea, and Pain at End of Life

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Negative symptoms at the end of life are distressing for both the patient and family. Effective management of both physical and psychological symptoms improves quality of life and well-being, but intervention strategies are not always effective or feasible and often are exclusively pharmacologic. Developing treatment plans to meet symptom management needs is critical. A 2-site research study was conducted in southwest Ohio assessing effectiveness of Starlight Therapy in treating the negative symptoms associated with end of life. The study of 40 patients found the Starlight Therapy effective in treating the symptoms of anxiety, agitation, dyspnea, insomnia, and pain in 90% of the patients within a 30-minute period. The therapy was ineffective in only 4 patients. Physiological symptoms were measured upon initiating Starlight Therapy, 30 minutes after therapy, and 2 hours after therapy. Results found heart rate and respiratory rate significantly different from baseline to 30 minutes and from baseline to 2 hours ($P < .05$). Heart rate and respiratory rate were not significantly different from 30 minutes to 2 hours ($P > .05$). Further research is required to explore additional types of care, subjects, and sites, which could benefit from Starlight Therapy.

KEY WORDS

agitation, anxiety, color therapy, dyspnea, end-of-life negative symptoms, insomnia, pain, palliative care, Starlight Therapy

> …The object and color in the materials around us actually have a physical effect on us, on how we feel.[1]

Many patients at the end of life find themselves facing negative uncontrollable symptoms such as pain, agitation, anxiety, insomnia, and dyspnea, and in some cases, no amount of medication brings patient relief. This study researched a low-light intervention to reduce symptom burden at end of life.[2-6] The low-light intervention for this study is defined as Starlight Therapy. Starlight Therapy consists of a moving low-light image of green stars against a dark blue background with moving clouds projected via a laser light lamp on the ceiling in the patient's room.

PURPOSE

The aim of this study was to investigate the effects of low-lux Starlight Therapy for relieving the negative symptoms at end of life, which include anxiety, agitation, dyspnea, restlessness, insomnia, and/or pain.

EXISTING EVIDENCE

Complementary therapy and alternative medicine is defined by the National Centers for Complementary and Alternative Medicine as a group of diverse medical and health care systems practice and products that are not normally considered being conventional medicine.[7]

Starlight Therapy is a type of complementary therapy because it is not designed for cure but to promote comfort by management of symptoms and improve quality of life.

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Kravitis and Berenson[8] define the goals of complementary therapy as to promote relaxation, reduce stress and anxiety, relieve pain and other symptoms, reduce adverse effects of conventional therapy, and improve sleep.

The mechanisms responsible for favorable anecdotal patient outcomes with Starlight Therapy are unknown and may be related to modification of melatonin secretion or other neurotransmitters related to low-light conditions required for Starlight Therapy. Melatonin secretion by the pineal gland in the brain is a function of the duration of low light and darkness. Melatonin reinforces nocturnal decreases in central temperature, which facilitates restorative sleep.[9]

Favorable outcomes may also be a reflection of a Snoezelen stimulation therapy effect, which also uses low-level-light therapy. Snoezelen therapy uses the entire sensory buffet of auditory, visual, tactile, gustatory, olfactory, and kinetic modes to facilitate neuronal healing and relaxation to provide a sense of relief. Snoezelen therapy is reported as pleasurable and perceived as a humane approach for brain distress.[10,11]

Since the 1990s, the use of multisensory environments, also identified by the trade name Snoezelen, has grown. Developed in Holland in the 1970s, Snoezelen was used in the care of persons with learning disabilities, dementia, and other neurological issues to provide relaxation. In the therapeutic sensory environment, senses can be stimulated by light, smell, sound, and/or touch. Despite the weak evidence base for clinical effectiveness, methodological issues, and lack of standardization, multisensory environments are increasingly being used in day care, primary care, schools, and long-term and acute care. Core experiential elements include sensory adaptation of the environment to create calming effects. Music and/or visual effects are provided with technology, which can be watched, listened to, or interacted with. The intervention promotes stimulation or relaxation without reliance on verbal communication.[12,13]

Evidence from a small randomized controlled trial with semistructured interviews explored the use of a Snoezelen environment in a palliative day-care environment. A "quiet room" was compared with a Snoezelen room intervention. Results revealed a significant reduction in anxiety and that Snoezelen therapy was feasible for palliative care with recommendation for further research.[14]

Physiological effects of Snoezelen therapy were recently examined in control subjects and brain-injured patients. Results revealed that Snoezelen elicited changes in electroencephalographic activity by inducing slowing of oscillatory activity and reducing electroencephalographic complexity and irregularity, all of which was associated with higher levels of relaxation particularly in controls. In addition, primary changes were found in occipital and parietal brain areas.[15]

The disturbed sleep-wake cycle observed in patients with hospitalization is significantly correlated with decreased melatonin levels and constant high levels of light in patient care areas. Low melatonin levels are associated with depression, sadness, increased blood pressure, decreased immune function, accelerated cancer cell proliferation, and decreased free-radical scavenging. Low-light therapy may provide relief from constant lighting and resulting low melatonin levels.[16,17]

Limited evidence suggests that Starlight Therapy may also assist in maintaining or restoring natural circadian rhythms. Normally, rest-activity and sleep-wake cycles are controlled by an internal circadian clock monitored by the hypothalamus (an area of the brain), which takes its cue from the presence of light. Patients who experience circadian disturbances might be "reset" by low-light conditions needed for Starlight Therapy.[16,17]

As for the blue and green colors associated with Starlight Therapy, evidence suggests that the colors green and blue may further contribute to comfort as well. Green is associated with harmonizing effects and promotes relaxation and calmness. Green is also used to fight irritability and insomnia. Blue conveys to the mind a state of peace. Blue asserts restfulness and contentment. Blue has been shown to slow our metabolism and heart rate and does have a calming effect. White has protective qualities and can be quite powerful and represents wholeness, cleanliness, and purity. White may also help relieve negativity.[18-22]

Defining complementary therapy and alternative medicine is broad and constantly changing as patients explore options for relief of symptom burden. Starlight Therapy is a complementary therapy that requires ongoing research to provide future opportunities to management of end-of-life symptoms and promotion of quality of life.

SAMPLE AND SETTING

The study was conducted in a 53-bed freestanding hospice facility, which is a community-based, nonprofit care provider, and a freestanding Veterans Affairs Medical Hospice Center, both located in southwest Ohio. Inclusion criteria included any male or female patient at end of life defined as having a terminal diagnosis of 6 months or less and enrolled in a hospice program and currently residing in a hospice unit. Patients chosen for this study were experiencing at least 1 end-of-life symptom of anxiety, agitation, dyspnea, restlessness, insomnia, and/or pain. Both observation and/or self-report were obtained and used to assess distressing symptoms. A total of 40 patients (26 male and 14 female patients) participated in the study. The average age was 82.25 years. All patients receiving Starlight Therapy were in private rooms. Disease processes included various cancers, dementias, neurologic diseases, lung diseases, and heart diseases.

METHODS

Each patient and/or family member invited to participate in the study received an informed consent document that

described the study's purpose, procedures, and who to contact for questions. Of the 40 patients receiving the Starlight Therapy, 21 family members gave their permission. Because of the minimal risk nature of this study, patients and/or family members provided verbal consent to participate, which was documented in the consent records. Patients and families were instructed that they could withdraw from the study at any time without penalty. A lux meter was used to measure light exposure. Light dose was measured at baseline in the room and at 30 minutes and 2 hours to quantify the amount of light the patient was exposed to (Tondaj LX1010B 50,000 Lux Digital Light Meter, Shenzhen Handsome Technology Co, LTD, Guangdong, China).

Symptom assessment or observations were no different than everyday assessment of patients at end of life. The instruments used to record observations were chosen for their simplicity and ease of completion in the clinical setting by the nurse caring for the patient and providing Starlight Therapy. Therefore, the authors believe that the assessments by the nurses adequately reflect patient presentation before and during Starlight Therapy.

Observations included physiological, cognitive, and behavioral changes before and after application of Starlight Therapy. Symptoms measured for this study (agitation, anxiety, restlessness, sleep disturbances, dyspnea, and pain) are not exclusive to the end-of-life experience. However, these were the outcome variables chosen for this study at end of life. This study was approved by the local institutional review board, as well as the clinical sites' human research investigation committees. Data were analyzed using descriptive statistics, *t* test, repeated-measures analysis of variance, and χ^2 test for comparison of proportions expressed as percentages. Level of significance was set at ≤.05. The subjects' treatment plans were not altered during the study protocol. Seven of the 40 subjects received scheduled pain and/or sedation medications as prescribed during Starlight Therapy.

Tools and Instrument

Three measurement tools were used, taking into consideration symptom clusters, clinical utility, and barriers to measurement. Negative symptoms were measured using an adaptation of the Assessing Distressing Symptoms STAR Symptom Scale and Questionnaire.[23,24] Physiological symptoms were measured using an Outcome Measurement Tool. The tool was adapted from the research of both Head and Faul[23] and Jones et al.[24] This includes a 6-symptom assessment scale based on observation and/or patient self-report. Patient symptom reported interrater reliability in the range of 0.45 to 0.62. The tool had strong face reliability with the underlying factor structure and made sense to the clinicians working on the unit. Jones et al[24] reported that there is no criterion standard for validity, and consistency or reliability and usefulness in a clinical practice setting are the best measure of how well an instrument performs. The intent of the instrument is to help introduce a more objective element to management of end-of-life symptoms. Nurses completed the Assessing Distressing Symptoms STAR Symptom Scale and Questionnaire and the Outcome Measurement Tool after observation and assessment of the patient for any changes in physiological symptoms, behavior, and cognition. Data obtained and recorded on a paper form for this study were not significantly different from the data normally obtained during the provision of nursing care at end of life. A study protocol was prepared for the nurses and was included in a folder, which was given during the data-gather training. Training was not difficult because patient assessment of negative symptoms occurs as a daily routine. Starlight Therapy for data gathering was applied for 2 hours. Starlight Therapy was completed during the day, with the room completely darkened.

The following elements were observed and categorized by the nurse before application of Starlight Therapy: agitation, anxiety, restlessness, sleep, dyspnea, and pain. These were reevaluated after 30 minutes of therapy and again after 2 hours of therapy. For each observation, the evaluation was reported as zero (none at all) or 1 to 3 (a little), 4 to 6 (quite a lot), and 7 to 10 (a great deal). In addition, the nurse recorded vital signs (respiratory rate and heart rate), as well as any medication therapy before and during light therapy. The lux meter was placed on a stable bedside stand to prevent movement and turned on to the 2000 position. The lid was removed, and the nurse waited for numbers to stop fluctuating to document the lux or light value.

RESULTS

Light Dose

Starlight Therapy requires low light to visualize the moving light field. The patient experiences low light and sees moving stars and clouds as part of the Starlight Therapy intervention. Light dose for each patient was influenced by ambient sources of light from windows and hallways and was therefore variable. Therefore, it was necessary to demonstrate the actual low-lighting conditions necessary for Starlight Therapy.

Starlight Therapy was applied for 2 hours. We obtained assessment/observations at baseline, 30 minutes after beginning therapy, and 2 hours after beginning therapy. Patients receiving Starlight Therapy experienced significantly lower levels of light during therapy. Mean lux dose before Starlight Therapy was 65.85 and 22.78 during Starlight Therapy (t_{62} = 2.36, P = .02).

Vital Signs

Respiration and heart rate measures are described in Table 1. Respiratory rate significantly declined during Starlight Therapy. Mean respiratory rate decreased from a mean

TABLE 1 Respiratory Rate and Heart Rate Before and During Starlight Therapy

Time	Mean	SD	Variance	95% CI	*P*	No. of Subjects
Respiratory rate (in breaths/min)						
Baseline	23.91	6.30	39.79	21.81-26.01		36
Baseline to 30 min	18.63	3.98	15.89	17.33-19.93	<.01	36
Baseline to 2 h	17.88	12.33	12.33	13.87-21.88	<.01	36
Heart rate (in beats/min)						
Baseline	98.45	16.20	262.71	93.45-103.45		40
Baseline to 30 min	84.9	16.78	281.83	79.7-90.1	<.01	40
Baseline to 2 h	84.55	14.94	223.48	79.95-89.14	<.01	40

of 23.91 breaths/min to a mean of 18.63 breaths/min after 30 minutes. At 2 hours, mean respiratory rate decreased to a mean of 17.88 breaths/min. One-way analysis of variance for correlated samples revealed that respiratory rate was decreased significantly from baseline to the 2-hour measure after Starlight Therapy was started ($F = 26.38$, $P < .0001$). Respiratory rate was not significantly different when the 30-minute and 2-hour measures were compared.

Mean heart rate also significantly decreased during Starlight Therapy. Mean heart rate declined from 98.45 to 84.9 beats/min at 30 minutes and to a mean of 84.55 beats/min at 2 hours. One-way analysis of variance for correlated samples revealed that heart rate was significantly different from baseline compared with the 2-hour measure ($F = 17.04$, $P < .0001$). Again, Tukey post hoc testing revealed that from baseline to 30 minutes heart rate was significantly different ($P < .01$). Like respiratory rate, heart rate was also not significantly different when the 30-minute and 2-hour measures were compared. These findings for respiratory and heart rates suggest the effectiveness of Starlight Therapy may manifest in the first 30 minutes of therapy. This sample did experience additional reductions in respiratory rate and heart rate beyond 30 minutes. However, the initial benefit obtained by 30 minutes was sustained as evidenced by the vital signs measures at 2 hours.

End-of-Life Symptoms

Table 2 describes significant symptoms (agitation, anxiety, restlessness, impaired sleep, dyspnea, and pain) observed over the 2-hour period of Starlight Therapy and recorded on the Assessing Distressing Symptoms STAR Symptom Scale and Questionnaire. Symptom evaluation for each time period of therapy consisted of comparing percents of subjects experiencing distressing symptoms for 2 of the 4 categories over the 3 time periods; category—moderate symptom presence (rated by the nurse as a score of 4-7 or applies to the patient quite a lot, to a considerable degree or a good part of the time) or category—significant symptom presence (rated by the nurse as a score of 7-11 or assessed by the nurse as applies to the patient a great deal, very much, or most of the time) to determine if light therapy was associated with reduction in symptom distress.

Table 2 describes results for moderate and significant symptoms of distress (agitation, anxiety, restlessness, sleep issues, dyspnea, and pain) for the 2-hour protocol. Time 1 represents baseline to the 30-minute measure, and time 2 represents the period from baseline to the 2-hour measure. The χ^2 test for comparison of proportions expressed as percentages was used for analysis. This test is similar to Pearson χ^2 test and appropriate for sets of categorical data obtained from this instrument and provides observed differences if any between categories of data (baseline, 30 minutes, or 2 hours).[25,26]

Analysis revealed that in the first 30 minutes, as well as at 2 hours, light therapy was associated with significant reductions (as identified in percent difference in Table 2) of agitation, anxiety, restlessness, and sleep issues. Percent differences ranged from 32.5% to 73.9%, further described in the Figure. Greatest reductions in symptom distress occurred for anxiety (73.9% reduction from baseline at 2 hours, $P < .0001$) and restlessness (71.1% reduction from baseline at 2 hours, $P < .0001$).

Observed symptom distress of dyspnea and pain were not significantly different for each period of the light therapy protocol for this sample. However, this may be a function of the low number of patients with these symptoms at baseline. Only 4 patients had observed dyspnea at baseline. As for pain, 1 patient was observed having pain at baseline and 2 at the 30-minute measure. This may be a random finding or a finding for further research.

IMPLICATIONS

Starlight Therapy was effective for 36 of 40 patients in this sample (90%). Starlight Therapy significantly reduced the

TABLE 2 Observed Moderate and Significant Symptoms by Type and Time Period

Symptom	Time Period[a]	% Difference	95% CI	χ^2	*df*	*P*	No. of Subjects
Agitation	1	32.5	9.12-52.38	8.40	1	.003[a]	40
Agitation	2	51.9	30.70-68.27	23.69	1	<.0001[a]	36
Anxiety	1	50	27.41-67.24	20.2	1	<.0001[a]	40
Anxiety	2	73.9	53.67-85.97	43.48	1	<.0001[a]	35
Restless	1	49.4	25.59-66.81	19.4	1	<.001[a]	39
Restless	2	71.1	50.21-84.01	39.69	1	<.0001[a]	36
Sleep	1	34.3	11.54-53.85	9.51	1	.002[a]	36
Sleep	2	68.7	47.20-82.30	35.41	1	<.0001[a]	36
Dyspnea	1	7.5	−35.72	0.816	1	.3	40
Dyspnea	2	14.6	−33.32	3.5	1	.06	36
Pain	1	0	−33.08	0	1	1.0	40
Pain	1	12.5	−56.8	4.75	1	.02	36

Time period 1: baseline and 30-minute comparison; time period 2: baseline and 2-hour comparison.
[a]$P \leq .5$.

number and intensity of symptoms including agitation, anxiety, restlessness, and sleep disturbances for this sample. Starlight Therapy also provided significant physiological benefits as evidenced by reduction in heart rate and respiratory rate during therapy.

While integration of multisensory environments into care appears useful, evidence overall is inconclusive. Future practice guidelines for Snoezelen therapy need more evidence. It is important that nurses contribute to development of evidence for this therapy across the care continuum.[12]

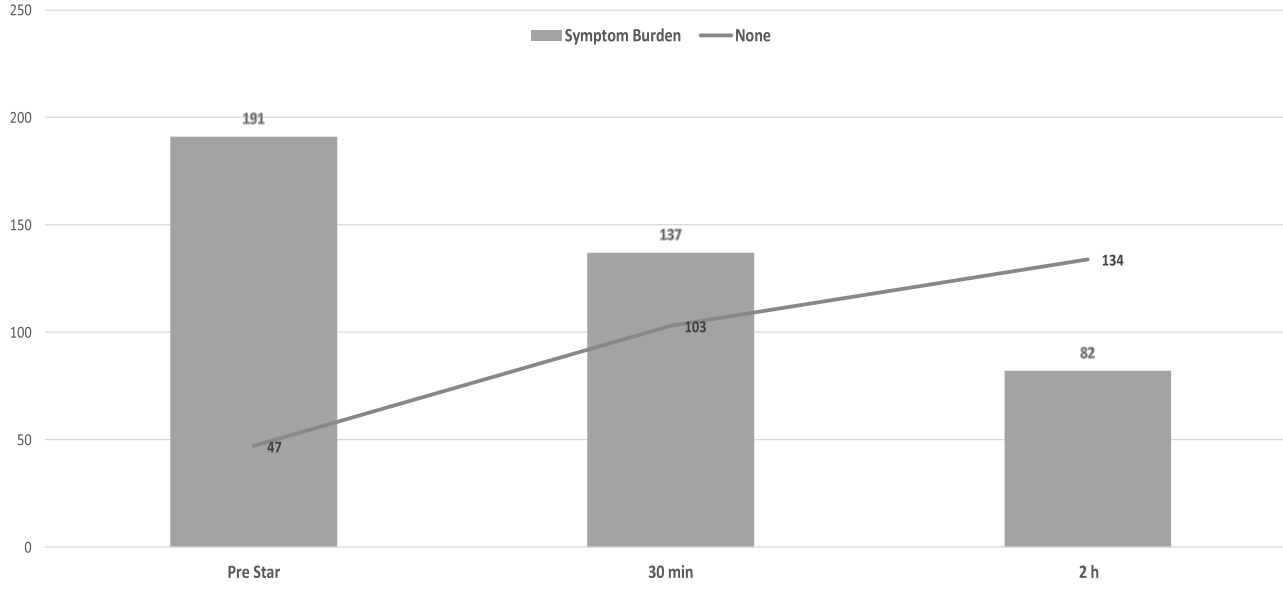

FIGURE. Symptom burden before and after Starlight Therapy.

Starlight Therapy may be effective for patients outside palliative care, particularly patients with brain injury, delirium, drug withdrawal, and other populations experiencing symptoms of illness. The source(s) of physiological and psychological responses to Starlight Therapy are unknown: Is it the low lighting conditions, the stars/clouds/colors, or a combination of all? These questions are the subjects for future research.[12,13,15]

For now, this study demonstrates that the low light (low lux) with Starlight Therapy resulted in significant reductions in end-of-life symptoms, as well as in vital signs.

CASE ILLUSTRATIONS

Case illustrations describe how Starlight Therapy can be used at end of life.

An 89-year-old woman presented with a diagnosis of sepsis and comorbidities of type 2 diabetes, advanced dementia, hypertension, hypoxia, encephalopathy, and renal failure. Patient symptoms that prompted Starlight Therapy were agitation, anxiety, restlessness, and sleep issues. The patient received morphine sulfate oral solution 10 mg and scheduled lorazepam 1 mg routinely with little or no effect on symptom burden. Prior to Starlight Therapy, the patient's heart rate was 120 beats/min and respiratory rate was 36 breaths/min. Lux dose in room was 0.003. No family was present, and music was playing softly.

Music and lights were turned off, and Starlight projector was turned on. At 30 minutes, the patient was sleeping; heart rate was 78 beats/min, and respiration rate was 18 breaths/min. Two hours later, the patient continued to sleep, and heart rate was 72 beats/min, and respiratory rate had dropped to 16 breaths/min.

Another case was an 86-year-old woman admitted for palliative care. As the nursing assistant bathed the patient, she shared her painful life story and began to weep, telling the story of having a child who had left home and that they had not spoken in years. Starlight Therapy was initiated, and the patient appeared to be in awe of the beauty of the stars in a darkened room. She cried and stated, "God is truly in this room. He has come to see me." The patient had significant reduction in observed anxiety and was able to sleep. The use of Starlight Therapy did not stop therapeutic presence of the nurse or the conversation. It was a way to provide rest and comfort. Contact was made with the daughter, and at a later date, the daughter visited her mother; all past issues were resolved, and the patient passed peacefully a few days later.

Study Limitations

This small study is a beginning to evaluate the use of Starlight Therapy to reduce symptom burden at end of life. Limitations are many and include a small nonrandomized convenience sample from 2 sites, likely errors in observations and measurement, and possible bias. In addition, there may have been other factors not measured or observed that influenced study outcomes. While the study results are not generalizable, the study does provide a beginning for future research. Furthermore, the study provides a glimpse into the possibilities for nursing to provide comfort at end of life by evidence-based modification of the care environment.

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