

Feasibility study of using blue-light blocking glasses to improve quality of life for cancer patients

Submission date 11/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/01/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/02/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Many cancer patients suffer from fatigue (extreme tiredness), insomnia, depression, and other symptoms and chemotherapy side effects that make it hard to function and reduce their quality of life. These symptoms may be related to changes in circadian rhythm (the everyday rhythm of sleep and waking). Melatonin, the sleep hormone produced by our brains after dark, organizes the activity of many organs and functions of the body. The brain produces melatonin when it is dark, leading to tiredness. Studies have shown that advanced cancer patients may have lower than normal levels of melatonin. This could result in disturbed circadian rhythms: as low melatonin levels may make it harder to get to sleep and coordinate body functions this leads to complications such as fatigue and insomnia. Studies have shown that blue light can stop melatonin from being produced. Blue light given off by electric lighting and computer screens can therefore be problematic for cancer patients with already low melatonin levels. To counteract the problem of evening blue light, special glasses have been made that block blue light from entering the eyes called blue-blocker glasses. These glasses are worn from local sunset time until bed-time. The purpose of this trial is to investigate if it is possible that blue-blocker glasses increase the production of melatonin in advanced cancer patients receiving cancer treatment therefore improving their quality of life.

Who can participate?

Adults with advanced receiving treated at the Block Center for Integrative Cancer Treatment (USA)

What does the study involve?

The study takes place over the course of three chemotherapy treatments, each of which is separated by two to three weeks. Firstly, for a week before the first chemotherapy treatment patients wear actigraphs (motion-sensing devices worn on the wrist). The actigraphs assess movement and sleep, and allows researchers to precisely determine circadian rhythms of sleep, waking and activity. The evening before coming for treatment, patients collect all their urine after sunset until the first time they urinate in the morning, to measure melatonin production. Finally, they fill out questionnaires on sleep quality, depression, fatigue and quality of life.

Actigraphs, urine samples and questionnaires are brought to the clinic at the chemotherapy visit. Patients then undergo two study periods in a random order. The first involves wearing blue-blocker glasses from sunset until it is time for bed, while repeating the same activities as last week. The second involves wearing sham (dummy) glasses that do nothing to block blue light in the evenings. Participants wear the actigraphs throughout each study period to monitor their sleep rhythms. Participants also complete a number of questionnaires in order to assess their mental wellbeing before and after each treatment period.

What are the possible benefits and risks of participating?

The only potential benefit is that the glasses might increase melatonin levels and temporarily improve circadian rhythms during the week they are worn. There are a few risks of wearing blue-blocker glasses. They should be not used while outside driving or walking in the dark. Some patients might find that the glasses change colours, though household activities and reading are not impaired by the glasses.

Where is the study run from?

Block Center for Integrative Cancer Treatment (USA)

When is the study starting and how long is it expected to run for?

November 2010 to May 2014

Who is funding the study?

1. Lighting Innovations, LLC (USA)
2. Institute for Integrative Cancer Research and Education (USA)

Who is the main contact?

Dr Charlotte Gyllenhaal
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Contact information

Type(s)

Public

Contact name

Dr Charlotte Gyllenhaal

Contact details

5230 Old Orchard Road
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Additional identifiers

Protocol serial number

2010-0372

Study information

Scientific Title

Pilot clinical trial of blue-light blocking glasses to improve cancer patient health-related quality of life

Study objectives

It is feasible to study the effects on circadian rhythms and quality of life of eyeglasses that block blue light in advanced cancer patients receiving chemotherapy. Blue-blocking glasses (blue-blockers) may increase melatonin production, which is inhibited by blue light emitted by home lighting and electronics. This may cause low melatonin levels, disrupting circadian rhythms. As cancer patients typically have abnormal circadian disruptions involving sleep problems, fatigue and other symptoms, the glasses may improve their circadian rhythms and thus their quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Illinois at Chicago Office for the Protection of Research Subjects, 14/08/2010, ref: 2010-0372

Study design

Single-centre single-blind randomized controlled cross over trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Advanced or metastatic cancer

Interventions

The study takes place over three study visits, separated by two to three weeks. All patients begin with a baseline observational period, and then participate in both blue-blocking eyeglasses and sham eyeglasses treatment periods. Randomization is determined by even or odd random numbers. All study periods occur in the 7 days before a planned treatment visit at the study clinic.

Baseline period: no study glasses are worn.

Blue-blocking eyeglasses: participants wear amber-colored plastic glasses that block blue light over 530 nm in wavelength from entering the eyes. Eyeglasses are worn beginning at local sunset time and taken off at bedtime (night-lights that do not emit blue light are supplied for safety during nocturnal activity).

Sham eyeglasses: participants wear placebo glasses which are yellow-colored plastic glasses that transmit all wavelengths equally. Eyeglasses are worn beginning at local sunset time and taken off at bedtime (night-lights that do not emit blue light are supplied for safety during nocturnal activity).

In each study period, patients wear wrist actigraphs (Motion-Logger, Ambulatory Monitoring, Inc, Ardsley, New York, USA) continuously to measure rest and activity. They also keep daily sleep logs. On the last night before the clinic visit, patients collect all urine after sundown through the time of the first morning urination, and bring it to the clinic. On the last day of the treatment period, patients fill out the study questionnaires: Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale, EORTC Quality of life, Powers and Ferrans Quality of life, and Piper Fatigue Scale.

Intervention Type

Device

Primary outcome(s)

1. Circadian organization of sleep and activity rhythms as measured by actigraphy. The 24-hour autocorrelation of motion levels at each time of day for all intervention days will be the main actigraphic variable is measured using the actigraphy during the baseline, blue-blocker and sham glasses study periods.
2. Level of urinary 6-sulfatoxymelatonin in overnight urine sample at the end of the baseline, blue-blocker and sham glasses study periods

Key secondary outcome(s)

1. Self-assessed nocturnal sleep using the Pittsburgh Sleep Quality Index (PSQI) and a sleep log at the end of the baseline, blue-blocker and sham glasses study periods
2. Cancer-associated self-assessed anxiety and depression using the Hospital Anxiety and Depression Scale at the end of the baseline, blue-blocker and sham glasses study periods
3. Self-assessed daytime fatigue as measured by Pittsburgh Sleep Quality Index at the end of the baseline, blue-blocker and sham glasses study periods
4. Self-assessed cancer-related quality of life using the EORTC and Powers and Ferrans Quality of Life scales at the end of the baseline, blue-blocker and sham glasses study periods
5. Self-assessed fatigue using the Piper Fatigue Scale at the end of the baseline, blue-blocker and sham glasses study periods

Completion date

31/05/2014

Eligibility

Key inclusion criteria

1. Histologically confirmed, advanced or metastatic cancer (solid tumors other than brain, esophageal or pancreatic cancer)
2. Patients with more than one malignancy or with a prior malignancy are eligible to participate, if that other cancer is currently under control
3. Life expectancy of 6 months or more in the judgment of the treating physician
4. Patient must be scheduled to receive at least 3 cycles of chemotherapy, other systemic anti-cancer therapy, or ongoing active palliative care
5. Patient may start this study at any cycle in their treatment, and any reasonable cycle length is acceptable as long as measurements can be taken before each treatment
6. Any number of previous treatments with chemotherapy and/or other systemic targeted therapies are permitted
7. Prior or concurrent treatment on another clinical trial is not exclusionary for participation
8. ECOG Performance Status of 0, 1, or 2

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Active concomitant malignancy not currently under control
2. Women who are pregnant, breast-feeding or planning to become pregnant during the study
3. Less than 30 days from major surgery
4. Less than 30 days from radiation therapy
5. Uncontrolled/Symptomatic brain or CNS metastases
6. Symptomatic spinal cord compression
7. Uncontrolled psychiatric disorders that would prevent participation in the study in the judgment of the treating physician
8. Serious co-morbidity that would interfere with the patient's capacity to participate in the study in the judgment of the treating physician
9. Blindness from any cause
10. Night shift workers
11. Melatonin supplementation

Date of first enrolment

01/11/2010

Date of final enrolment

31/05/2014

Locations**Countries of recruitment**

United States of America

Study participating centre**Block Center for Integrative Cancer Treatment**

5230 Old Orchard Road

Skokie

United States of America

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Sponsor information

Organisation

Block Center for Integrative Cancer Treatment

ROR

<https://ror.org/03vk8p158>

Funder(s)

Funder type

Not defined

Funder Name

Lighting Innovations, LLC

Funder Name

Institute for Integrative Cancer Research and Education

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/05/2022	21/02/2023	Yes	No