Protocol Title: Assessing environmental factors in healthcare facilities in order to improve the experience of patients, staff and the quality of imaging procedures

Protocol Project Number: RP0525

Protocol Date: November 20, 2017

Principal Investigators:

Michael V. Knopp, MD, PhD
Professor and Novartis Chair of Imaging Research,
Vice Chairman of Research
Department of Radiology
The Ohio State University Wexner Medical Center
395 West 12th Avenue, Room 430
Columbus, Ohio 43210
Phone: (614) 293-9998
Fax: (614) 293-9275
E-Mail: knopp.16@osu.edu

I. Overview

In this exploratory study, we want to investigate how environmental factors such as light, sound, temperature, smell and sensatory experiences such as vibration are being perceived by subjects in order to develop environmental strategies using those components to create a more relaxing, comforting experience for patients prior, during and after an imaging examination as well as for staff working in such environments.

We plan to include ***volunteer participants*** that complete survey tools and provide feedback on environmental experience, patients scheduled for imaging examinations, accompanying individuals of ***patients*** receiving care in the local environment, and ***staff*** working in healthcare environment.

In the subpopulation of patients that receive imaging examinations, we want to correlate observational findings and perception of environmental factors with image quality of the imaging examination performed with patient-based feedback on responses.

The goal of these exploratory efforts will be to serve as guidance to develop confirmatory clinical trials that eventually may facilitate and/or encourage refinements of facility environments and patient staff facility interactions to further improve the healthcare experience and quality of imaging examinations.

II. Objectives

Aim 1: To assess subjects' perceptions of environmental conditions and their preferences

Aim 2: To expose subjects to varied environmental conditions and to assess their perception and feedback

Aim 3: To explore potential patterns, factors of influence, points of reference in relation to the objectively assessed quality of an imaging examination and/or the perception of the patient

Aim 4: To explore the feasibility of innovative biofeedback, bio sensing and response capturing methodologies and technologies in order to guide the design of specific clinical investigations or trials

III. Background and Rationale

While extensive efforts are constantly undertaken to improve the capabilities of technology, such as imaging devices, to help detect, characterize and assess diseases, very limited efforts are undertaken to research systematically and analyze how environmental factors within healthcare facilities can influence and improve the experience of patients and staff. Patient motion, for example, is one of the sources of artifacts in imaging studies that may influence the quality, duration, and diagnostic certainty of imaging examinations. Patients are frequently confronted with recent unfavorable news about their health condition and are concerned about the outcome of imaging examinations and therefore may be especially receptive to positive or negative environmental factors and experiences.

The positive, calming, and relaxing impact of music has been well studied and recent questionnaire based assessments confirm that different light hues/colors lead to different experiences that can influence the overall feeling of person in a healthcare environment. A very important observation, however, is that those experiences are quite personal, and therefore, a wide variability of positive or negative perceptions to environmental stimuli are observed indicating that a personalization of those environmental stimuli might be the most effective approach.

Tremendous technological advances have occurred in recent years that enable readily controllable lights, sound, temperature, airflow as well as sensatory experiences such as smell or vibrations. These technologies are used in virtual amusement rides or enhanced cinematic experiences; however, their potential application within healthcare environments, especially imaging environments, remains without systematic analysis.

With the availability of consumer grade wearable devices, continuous capturing of physiologic parameters such as heart rate, motion, body perspiration and muscle tension has become readily feasible.

Short wave radar can be used to detect motion and will be explored to detect positional changes and potential other physiological characteristics that may inform about a subject's state of being relaxed or active.

Using electronic capture devices such as tablets or smart phones combined with easily manageable tactile feedback or response capture capabilities to questions, scenes or videos, data about a

person's experience and feedback can be readily obtained. Voice recognition and voice activation furthermore allow non-intrusive and effective ways to capture data on subjects' experiences.

In this study, we want to investigate environmental factors such as light, sound, temperature, smell and sensatory experiences such as vibration in patients scheduled for imaging examinations, accompanying individuals, staff working in healthcare environment and volunteers.

We plan to implement innovative methodologies to create different environmental experiences and use response assessment technologies ranging from verbal or tactile feedback to questionnaires.

In the subpopulation of patients that receive imaging examinations, we want to correlate observational findings with image quality of the imaging examination performed and with patient based feedback on responses.

The goal of these exploratory efforts will be to also serve as guidance to develop confirmatory clinical trials that eventually may facilitate and/or encourage refinements of facility environments and patient staff facility interactions to further improve the quality.

IV. Procedures

Research Design

A. Sample

We intend to include the following discreetly different populations in our assessment

Volunteer population

1. volunteers agreeing to complete an electronic survey tool to assess the perception and preference of environmental factors (virtual participation)
2. volunteers agreeing to complete the above survey and participate in environmental experiences and providing feedback about their experience (physical participation)

Staff population

3. staff working in imaging related healthcare environments completing survey tools regarding their perception and preference of environmental factors and participating in environmental experiences by providing feedback.

Patient population

4. patients that agree to complete a survey tool and either participate in specific environmental experience testing or may be exposed to an environment experience during the imaging examination. The imaging exam will be assessed in regard to quality factors such as motion artefacts as an indicator of being relaxed during the examination.

Inclusion Criteria

Volunteer population

- Male and female volunteers above the age of 18 who are able to give an informed consent or have a legal guardian able to give informed consent on their behalf

Staff population

- Male and female staff at the Ohio State University above the age of 18 who are able to give informed consent

Patient population

- Male and female patients greater than or equal to 18 years of age able to give informed consent or have a guardian able to give informed consent on their behalf
- Must have an imaging study such as an MRI, PET/CT, or CT scheduled to be performed at the Wright Center facility at Martha Morehouse

Exclusion Criteria

- Unable to communicate in English
- Subjects that are incapable of giving informed consent or that do not have a legal guardian to give informed consent.
- Prisoners
- Below age of 18.

A. Measurement / Instrumentation

All tools and devices will be operated according to the manufacturer instruction manual. If consumer grade devices do not have instruction manuals on how those are to be used or applied, the instruction manual for the exploratory testing will be put in place prior to such uses.

Survey tools

We will use survey tools that may either be in paper or electronic form such as SurveyMonkey or similar web app-based technologies. Surveys will by default be completed electronically that can be accessed with a link or will be available on tablets at the facility. As a default, participants will be expected to complete the service tools by themselves; however, participants that may not have the ability to fill out or complete the survey tools may be assisted by a person of their choice (family member, accompanying person) or member of the study team serving as a transcriptionist to only record the responses without biasing.

An open public participation survey will be released upon approval of this study that will allow us to get a general sense of how people would feel about the implementation of these environmental factors in a health care facility. This survey will be posted through online social media. This includes potential advertising on specific online university venues such as OSU onCampus today. This trial will also be posted on clinicaltrials.gov, Research Match, or other trial information databases.

Quality review of the imaging study to evaluate the presence of artifacts

Patients participating in this study who have given authorization for a blinded review of their imaging study will have their imaging study reviewed on a radiological image review workstation and assessed by an experienced reader of imaging studies in regard to the presence and severity of artifacts. Those findings will be recorded both in a structured and free text form using a survey tool. We anticipate that in this exploratory study observations will be made that will lead to the need to further detail and/or refine structured recording of the findings.

Facility, environmental and measurement instrumentation

Light perception

We will be using Wi-Fi/IP programmable LED lighting systems that will replace conventional lighting systems and may be in canned lights, spot lights, light chains or table lights. These lighting systems can be fully controlled by web based applications on smart phones tablets and computer systems and can be combined with input systems such as switches, motion detection or voice activated. Differences in lighting perception will be explored by varying lighting color and brightness.

Sound perception

We will be using Wi-Fi/Bluetooth addressable sound systems that will be linked with sound sources such as media players on smart devices or computer systems. Differences in sound perception will be explored by varying sound types (i.e. different music types, ambient noise, etc.).

Smell perception

We will explore the use of consumer grade ventilation systems that can be equipped to distribute packaged scents. Differences in smell perception will be explored by varying the types of scents.

Vibration perception

We will explore the use of chairs or blankets that enable subjects to perceive vibrations. An initial implementation will be the use of on relaxing/massage chair that enables the experience of vibration sensation in the back or leg area. We may use also potentially vibration blankets in the arm or neck area. Differences in vibration perception will be explored by varying the location, frequency, etc. of vibrations with the subject being placed in a chair on an imaging table/bed.

Voice activation

We will explore the use and linkage of voice activation system such as Amazon Echo, Google home or similar devices. Some participants may be asked to use voice activations to verbally select and/or change the environmental settings according to their preferences. We are evaluating the feasibility of voice activation with the imaging environment.

Temperature monitoring

We will use infrared detector camera technology to assess the skin temperature of subjects at different body regions and changes during the observational period. This will also be used to determine the temperature of the surroundings as well, for example, to determine the relative temperature of the chair and the imaging bed. Infrared cameras installed alongside the normal surveillance cameras to monitor patients during the imaging examination may also be used to monitor the temperature of the surroundings as well as the body to determine if that may be the reason for motion.

Short wave radar

We will use short wave radar to perform positional monitoring of subjects during the observational period. This short-wave radar will be used as a means to assess motion and detect subject movement in a room that we hope to correlate to their level of comfort and relaxation. Short wave radar is also technically able to detect very miniscule motion including blood flow and pulse rate,

which would allow us to move away from wearable devices to remote sensing devices further hoping to increase patient comfort. No short wave radar devices will be used during the imaging examination.

The levels of electro-magnetic field that are being used are at no risk and below the level of mobile phones. The radar sensors are of the technology that are found on self or assisted driving cars. Some studies have found that long-term, consistent exposure to short wave radiation over the course of several years may have negative effects on the central nervous system, cardiovascular system, and endocrine system. However, considering that in this study, exposure to short wave radar is limited to less than a few hours, this risk is insignificant.

Wearable devices

We will explore the use of wearable devices like Fitbit, Apple Watches, and Samsung Gear Fit devices, which allow the recording of motion and heart rate. Specifically, the following devices may be used during the study: Fitbit Flex 2, Fitbit Alta, Fitbit Alta HR, Fitbit Charge 2, Apple Watch Series 3, Samsung Gear S3, Samsung Gear S4, Samsung Wing, Samsung Gear Edge. Since this is an exploratory study, we will assess the feasibility of using these devices within the study's methodological parameters. This will allow us to determine which devices to use in the experimental trials.

These devices will be placed on the subject at their preferred wrist location and will be removed before leaving the facility. We hypothesize for example that tracking the pulse rate will be an indirect measure of the subjects' excitement level and may also be a ready measurement of the likelihood of motion during an examination. These wearable devices will not be used during the MRI imaging examination.

B. Detailed study procedures

Subject enrollment

As detailed already above, there will be three different populations enrolled in this study, volunteer, staff, and patients. All subjects will sign an informed consent form, and patients are additionally asked to sign a HIPAA waiver.

As part of the informed consent process, the subject identification document will be created that will identify the subject name and current contact information.

In case of patients, their medical record number, referring physician for the imaging procedure performed and contact information of a healthcare provider of their choice if they indicated that any incidental finding should be communicated directly to their healthcare provider, will be recorded.

This document will also record if the subject received a gift card and the amount.

The subjects participating in this research **may be enrolled at multiple times** and can also be involved in multiple subject categories. Multiple enrollment may occur for the purpose of longitudinal observations or assessment after healthcare treatments. The initial and follow up responses may be evaluated regarding changes over time.

Subject Recruitment

Virtual participation only

There will be a virtual participation only component of this research project where participants complete an online survey tool. This survey will be released via online social media postings about the ongoing survey as well as advertisements in specific online venues such as OSU onCampus today.

Physical, in person participation

We will use a brochure to inform potential interested participants about the ongoing research. This brochure will be available at clinics that frequently refer patients for imaging studies at the Wright Center and will also be posted on online social media. The trial will also be posted on clinicaltrials.gov, research match, or other trial information databases. We intend to place advertisements in specific online venues such as OSU onCampus today. The physical participation group can further be broken up into the three different categories of subjects: volunteers, staff, and patients.

Volunteer Population

Volunteers will be recruited using above identified processes, and word of mouth. Clinical trial registries will have the recruitment brochure as well as a recruitment video informing potential subjects about the trial. Additionally, volunteers may be recruited from people at the facility such as accompanying persons waiting for patients to complete their imaging study.

Staff Population

Staff in our environment as well as in other departments of the OSU Wexner Medical Center may be invited to participate. Staff will have access to the brochure and may be informed about opportunities to participate in internal communications.

Patient Population

Patients may be invited to participate if they are scheduled to get an imaging exam at the Wright Center facility. This means we would look at the schedule of patients expected for an imaging examination at the Wright Center of Innovation. When the imaging exam is scheduled or when they arrive at the facility patients may be asked if they are interested in participating in this research study. Very frequently we communicate prior to an imaging study with the patients, and we may make them aware that there is a possibility for them or also an accompanying person to participate in this research. We assume that we will also be informed from healthcare support staff of referring and collaborating healthcare providers that patients identified their interest to participate in the study. Frequently, patients also contact us as we are the communicated contact pathways identified on brochures and others posts and we will subsequently follow-up and discuss potential participation. Not every patient will be approached regarding this study, we will have to determine the feasibility in the schedule and determine if we have the staff on hand to complete the study, additionally, what imaging examination they get may also determine if at the time they can enroll in the study or not.

Administration of informed consent

Informed consent may be given at any time after the subject had appropriate time to read the informed consent form and ask and receive answers to any questions. As we anticipate that, for example, accompanying persons waiting for patients to complete their imaging study may be willing to participate in this study. Therefore, we may approach a subject immediately prior to the opportunity to participate especially as this is a minimal risk investigation. We have prepared a video that explains this trial to interested subjects. The video link may also be referenced in advertising material and brochures.

We prepared a training video for the trial staff to see how we would like to have the informed consent administered according to all aspects of GCP and applicable guidelines. There are different videos for each the patient, staff and volunteer populations.

The informed consent form may be given to subjects ahead of time. There will be online access to the informational video and the informed consent forms.

For participants on the online survey only (virtual participation), an online consent script will precede the survey. There will be no further consenting in this population.

RP0525 Audit Log and Training Log

This audit and training log provided will be used to keep track who has been trained to do the informed consent, complete the proper procedure for this study, as well as administer the wearable devices for this particular study and by whom. Additionally, this document keeps track of the subjects involved in the study and who administered the informed consent to them and when.

RP0525_Adjunctive_Data_Blank_Forms_V02.xlsx

Withdrawal from the study

A subject can withdraw at any time from the study. At the time of a potential withdrawal the subjects may be asked if he or she wants to do a complete withdrawal or just wants to stop further participation and allows the gathered data to be used. This option would only be applicable if the subject participates in the facility environmental experience.

Compensation for participation in the research

Volunteers and patients who participate in the physical environmental experience will receive a gift card of $20 - $50 gift card depending on their time commitment to the study.

Virtual participants who have only completed the online survey are only eligible to be entered from a raffle gift card.

Staff of the Department of Radiology and the Wright Center of Innovation will not be eligible for compensation for participation in this research, the time spent participating may be considered to be part of work time.

Subjects have the opportunity to decline the acceptance of the gift card or can designate that the value of the gift card would be donated to the Wright Center of Innovation in Biomedical Imaging development fund. A decline or designation to donate does not lead to any taxable events.

Gift card of $20 value

Completion of a survey tool and participation in environmental testing of less than 30 minutes.

Gift card of $30 value

Completion of a survey tool and participation in environmental testing of more than 30 minutes.

Gift card of $50 value

Completion of multiple survey tools and participation in extensive environmental testing exceeding an active participation time period of more than 60 minutes.

Raffle Gift Card

Participants who have completed the general online survey by a specific date will have the opportunity to submit their email address at the end of the survey to be entered into a raffle for a chance to win one of five $20 gift cards. This email will only be kept on record to determine the winners and will not be linked to their answers to the survey. These winners will be selected at random using a random number generator and will then be emailed to the winning participants after the date indicated on the survey.

Enrollment and participation choices

Online survey tool (virtual participation)

As this survey will be openly accessible, we will not place any restriction on the number of participants but plan to close the survey once we have reached 1000 responses. We would like to achieve a broad participation and would be delighted to have responses in the range of 100 – 1000. This survey is identified below and labeled as the general survey.

Environmental experience (physical participation)

We anticipate a 20% rate of incomplete data or dropouts, so we request an initial total enrollment approval of 500 subjects. Of the 500 subjects, we intend to enroll 125 staff members, 125 patients, and 250 volunteers. We intend to use survey tools to assess the perception and preference of different environmental components. Subjects may participate in multiple experiences within a single session.

Subject participation choices

Subjects will be classified according to their type of participation into the three categories of volunteer, OSU staff or patients. In order to be eligible for the study, all subjects must complete an informed consent form. Patients, additionally, may complete the imaging examination experience during their imaging procedure. The table below summarizes the options given to the subject and reflects those that are included in the informed consent form.

Dependent on the implementation and testing set up available, subjects will be given the choice to participate in up to six environmental experiences. While the research staff will identify to the subject which environmental experience will be available, subjects have the choice to only select those in which they are willing to participate.

In addition to the survey tools, we will be potentially using additional observational tools such as infrared camera, radar and or wearable devices.

Subject Type	Participation
Volunteer	
WCIBMI Staff	
Patient	
Choices	
Survey only	
Facility Experience	
Environmental Experience	
Lighting	
Sound	
Smell	
Vibration	
Temperature	
Voice activation	
Observational Tools	
Surveys	
Infrared Camera	
Radar	
Wearable device	

Location of performance of research

Due to the simplicity of the set up and straight forward design of this research it can be performed whenever subjects are available at the Wright Center facility; however, trained personnel will also have to be available.

While the patient related research efforts will be exclusively performed at the Martha Morehouse facility at The Ohio State University Wexner medical center, staff and volunteer environmental experience could be performed anywhere on the OSU campus or its affiliated facilities.

The online survey can be performed anywhere and the location will not be tracked.

Testing procedures and data recording

As we intend to develop research testing procedures tailored to the specific environmental experience or observational tools, we plan to refine the specific forms and assessment protocols in an iterative fashion during the initial phase that will include up to 25 subjects for each of the environmental experiences. The initial survey tools have been put in place and are available.

RP0525 Testing Procedure: Survey Tools

General Survey

The general survey that we intend to release via online social media for the public to take. This is the survey that will be openly accessible to the public and will be posted online for the virtual participation:

RP0525_EnvironmentalFactorsSurvey_SurveyMonkey.pdf

This can be accessed with the link: https://www.surveymonkey.com/r/environmental-perception

Study Survey

The survey tool that will be used to collect data from the subjects. Note that there is circular logic applied making sure all the data is combined into one database although no subject will actually complete every question.

RP0525_EnvironmentalFactorsStudy_SurveyMonkey.pdf

This can be accessed with the link:
https://www.surveymonkey.com/r/RP0525_EnvironmentalStudy

Imaging Assessment Survey

The survey completed by imaging assessors to determine the level of motion artefacts present in the images:

RP0525_ImagingAssessmentSurvey_SurveyMonkey.pdf

This can be accessed with the link:
https://www.surveymonkey.com/r/RP0525_ImagingAssessment

Incidental findings

Anytime there is an interaction with the patient population, there is the theoretical opportunity to observe an incidental finding. Any incidental finding observed by study staff will be reviewed by the study PI and further steps considered. There is a question on the informed consent form for subjects participating in environmental experience testing if they want to be notified in case of incidental findings. In addition, on patients' informed consent forms there is the question if they choose to be directly informed or if any incidental finding should be communicated to the health care provider of their choice.

Data analysis and analytics

As this is an exploratory trial, we have no prior data available to develop a detailed analysis plan. We will perform descriptive statistics and assess relationships between the preferences and observed data gathered from the survey tools and/or noninvasive measurement. We will consult statistical expertise at different phases of data gathering to review data capture and tabulation procedures as well as explore data analysis strategies.

Data sharing

Coded or de-identified data may be shared with other research projects as additional information or benchmarking observations. Data may be shared for further analysis with research teams at the Ohio State University or outside. The data sharing agreements would be documented and executed prior to sharing of data according to Ohio State University policies.

De-identified data may be placed on public databases especially if it is required by funding agencies such as National Institutes of Health, National Science Foundation and others.

C. Risk, Benefits, Safety, and Confidentiality

Risks

Volunteer and staff population

There are no apparent risks from the performance of participation in the survey tools and the environmental experience.

There is a theoretical risk that a data breach could occur; however, except for a separate coding identification sheet, all data will be kept in a coded form with no identifiable PHI information used in this research.

There is minimal risk that the utilization of wearable devices could lead to pinching of the skin, scratching of the skin and/or lead to the minor hematoma.

There is minimal risk that the use of vibration devices could lead to discomfort prior to deactivation/turning off of the vibration function.

Patient population

There are no apparent risks from the performance of participation in the survey tools and environmental experiences.

There is a theoretical risk that a data breach could occur; however, except for a separate coding identification sheet, all data will be kept in a coded form with no identifiable PHI information used in this research

There is a theoretical risk that the participation in this research may negatively impact the situational experience of a patient and could lead to deterioration of image quality of the imaging examination, even while highly unlikely.

There is minimal risk that the utilization of wearable devices could lead to pinching of the skin, scratching of the skin and/or lead to the minor hematoma.

There is minimal risk that the use of vibration devices could lead to discomfort prior to deactivation/turning off of the vibration function.

The generation of observational data may lead to incidental findings about a previously unknown health condition.

Benefits

Volunteer and staff population

There is no apparent personal benefit of participation in the survey tools and environmental experiences.

There is a benefit of contributing to the generation of knowledge to the benefit of society.

There may be a benefit of a personal experience increasing the awareness of environmental components on an individual's well-being.

There may be the benefit that facility environments will be adapted based on findings of this study that will lead to future preferable experiences.

Patient population

There is no apparent personal benefit of participation in the survey tools and the environmental experiences.

There is a benefit of contributing to the generation of knowledge to the benefit of society and future patient populations.

There may be a benefit of a personal experience that may improve the image quality of the examination, and that may help to reduce the level of uncomfortableness for the specific and future imaging procedure.

There may be the benefit that future imaging studies or imaging facilities will use environmental features based on findings of this study.

Safety Monitoring

There will be no specific safety monitoring.

Data security will be monitored according to institutional policies.

Confidentiality of Records

Volunteer and staff population

Only for the purpose of identifying a subject regarding participation and potential regulatory follow-up, a single coding identification sheet will be kept. All other data points will be generated in coded data structures.

Patient population

Only for the purpose of identifying a patient regarding participation and potential regulatory follow-up, a single coding identification sheet will be kept. All other data points will be generated in coded data structures. The patient's medical records will only be accessed by appropriately trained and authorized staff. All patient documents will be kept according to institutional policies. Outside of regulatory requirements, no patient identifiable information will be shared outside of the institution.

Internal Validity

Managing and verifying the internal validity is an important task in this exploratory research program in order to develop the appropriate methodology to be validated in prospective clinical trials.

As there is an opportunity that the staff member administering the facility experience can potentially bias the subject, we will perform training sessions with the staff prior to them administering the facility experience. We will also perform from time to time an observational assessment by a study member participating in the subject facility experience with the task to observe the team member administering the facility experience in order to ensure that no bias or systematic errors occur.

In this exploratory study where we use perception and observation-based assessments, we will have to constantly assess the potential sources of systematic errors or bias in order to ensure that we may derive conclusions that warrant generalization to other contexts.

We will assess the different factors impacting internal validity of the data sets we generate. For the specific factors we will address the following considerations. The following text uses material presented at https://en.wikipedia.org/wiki/Internal_validity and is hereby specifically acknowledged.

Temporal precedence

Potential lack of clarity how one experience may influence a subsequent experience as that might be a cause and effect relationship.

Confounding

A major threat to the validity of causal inferences is confounding. Observations in one variable may relate to another manipulated variable. Where spurious relationships cannot be ruled out, hypothesis would have to be appropriately developed.

Selection bias

Selection bias refers to the problem that, at pre-test, differences between groups exist that may interact with the independent variable and thus be 'responsible' for the observed outcome. Researchers and participants bring to the experiment a myriad of characteristics, some learned and others inherent. For example, sex, weight, hair, eye, and skin color, personality, mental capabilities, and physical abilities, but also attitudes like motivation or willingness to participate.

During the selection step of the research study, if an unequal number of test subjects have similar subject-related variables there is a threat to the internal validity. If subjects in two groups to be compared are not alike with regard to the independent variable, but similar in one or more of the subject-related variables, it may jeopardize the internal validity.

Self-selection to participate in this research can have a negative effect on the interpretive power of the dependent variable, this is especially known for online surveys where individuals of specific demographics opt into the test at higher rates than other demographics.

History

Events outside of the study/experiment or between repeated measures of the dependent variable may affect participants' responses to experimental experiences. Often, these are large scale events (natural disaster, political change, etc.) that affect participants' attitudes and behaviors such that it becomes impossible to determine whether any change on the dependent measures is due to the independent variable, or the historical event.

Maturation

Subjects may change during the course of the experiment or even between measurements. Both permanent changes, such as physical growth and temporary ones like fatigue, provide "natural" alternative explanations; thus, they may change the way a subject would react to the independent variable. So upon completion of the study, the researcher may not be able to determine if the cause of the discrepancy is due to time or the independent variable.

Repeated testing

Repeatedly measuring the participants may lead to bias. Participants may remember the answers or may be conditioned to know that they are being tested. Repeatedly taking (the same or similar) tests usually leads to score gains.

Instrument change

The instrument used during the testing process can change the experiment, an aspect that we will managed via device quality control to the largest extent possible. This also refers to observers being more concentrated or primed, or having unconsciously changed the criteria they use to make judgments. This can also be an issue with self-report measures such as facility perceptions given at different times. In this case the impact may be mitigated through the use of retrospective pretesting. If any instrumentation changes occur, the internal validity of the main conclusion is affected.

Differential attrition

This error occurs if inferences are made on the basis of only those participants that have participated from the start to the end. However, participants may have dropped out of the study before completion, and maybe even due to the study or experiment itself. If this attrition is systematically related to any feature of the study, the administration of the independent variable, the instrumentation, or if dropping out leads to relevant bias between groups, a whole class of alternative explanations may be possible that account for the observed differences.

Selection-maturation interaction

This occurs when the subject-related variables, color of hair, skin color, etc., and the time-related variables, age, physical size, etc., interact. If a discrepancy between the two groups occurs between the testing, the discrepancy may be due to the age differences in the age categories.

Experimenter bias

Experimenter bias occurs when the individuals who are conducting an experiment inadvertently affect the outcome by non-consciously behaving in different ways to members of control and experimental groups. It is possible to eliminate the possibility of experimenter bias through the use of double blind study designs, in which the experimenter is not aware of the condition to which a participant belongs.

D. Data Analysis

At this point we intend to only use descriptive statistics as all aspects of this research are exploratory. Upon further data analytics we will consult with the biostatistician when we explore more definitive statistical assessments

Funding support

This project is supported by the Ohio Third Frontier Wright-Center for Innovation in Biomedical Imaging project TECH and the Wright Center of Innovation development fund.

Bibliography

1. Bird Coloration: Mechanisms and Measurements. (2006). Vol. I. G. E. Hill & K. J. McGraw (Eds.),
2. Birren, F. (1978). Color and human respopnses. Aspect of light and color bearing on the reactions of living things and the welfare of human beings. Van ostran Reinhold Limited.
3. Elliot, A. J., & Maier, M. A. (2014). Color psychology: effects of perceiving color on psychological functioning in humans. Annu Rev Psychol, 65, 95-120. doi:10.1146/annurev-psych-010213-115035
4. Indow, T., & Kanazawa, K. (1960). Multidimensional Mapping of Munsell Colors Varying in Hue, Chroma and Value. Journal of Experimental Psychology, 59(5), 330 - 336.
5. Jafari, H., Zeydi, A. E., Khani, S., Esmaeili, R., & Soleimani, A. (2012). The effects of listening to preferred music on pain intensity after open heart surgery. Iranian Journal of Nursing and Midwifery Research, 17(Jan - Feb), 1-6.
6. Kwallek, N., Woodson, H., Lewis, C. M., & Sales, C. (1997). Impact of three interior color schemes on worker mood and performance relative to individual environmental sensitivity. Color Research & Application, 22(2), 121-132. doi:10.1002/(sici)1520-6378(199704)22:2<121::aid-col7>3.0.co;2-v
7. Landa, E. R., & Fairchild, M. D. (2005). Charting Color from the Eye of the Beholder. Sigma Xi, The Scientific Research Society, 93(September - October 2005), 436 - 443.
8. Luo, M. R. (2006). Applying colour science in colour design. Optics & Laser Technology, 38(4-6), 392-398. doi:10.1016/j.optlastec.2005.06.025
9. Mitchell, L. A., & MacDonald, R. A. R. (2006). An Experimental Investigation of the Effects of Preferred and Relaxing Music Listening on Pain Perception. Journal of Music Therapy, XLII(4), 295-316.
10. Page, T., Thorsteinsson, G., & Ha, J.-G. (2012). Using Colours to alter Consumer Behaviour and Product Success. International Journal of Contents, 8(1), 69-73. doi:10.5392/IJoC.2012.8.1.069
11. Walworth, D. D. (2003). The Effect of Preferred Music Genre Selection Versus Preferred Song Selection on Experimentally Induced Anxiety Levels. Journal of Music Therapy, XL(1), 2-14.
12. Wright, A. (2016). Color Psychology. Psychological Properties of Colours. Retrieved from http://www.colour-affects.co.uk/psychological-properties-of-colours
13. Wright, A. (2016). Color Psychology. How It Works. Retrieved from http://www.colour-affects.co.uk/how-it-works
14. Wright, A. (1995). The Wright Theory. Retrieved from http://www.colour-affects.co.uk/the-wright-theory
15. Wright, A. (2008). Colour Psychology. Retrieved from http://www.colour-affects.co.uk
16. Yu, C. & Peng, R. (2017). Biological effects and mechanisms of shortwave radiation: a review. Military Medical Research, 4(24). doi: 10.1186/s40779-017-0133-6