Effectiveness of External Vibration for Pain Relief During Intravenous Access in Adult Patients

NCT03619135

8/23/18

Effectiveness of External Vibration for Pain Relief During Peripheral Intravenous Cannulation in Adult Patients

PI: Kyle Stein
IRB ID #: 201601806

Project Details

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
Effectiveness of External Vibration for Pain Relief During Peripheral Intravenous Cannulation in Adult Patients

I.3 ***Short Title (optional):***

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

A large number of dentoalveolar (tooth extraction) procedures performed by Oral and Maxillofacial Surgeons utilize intravenous sedation. Procedures commonly performed may include surgical removal of teeth, bone grafting, surgical placement of dental implants, and removal of cysts or tumors from the jaws, among others. Obtaining peripheral intravevenous (IV) cannulation often proves to be a very stressful and anxious event for the patient. The anxiety and stress from the venipuncture alone affects not only the psychological stability of the patient, but also the patient's physiology. The Buzzy vibration external stimulation device has shown to be an effective tool in pediatric venipunture procedures. The aim of this study is to investigate the effects of the Buzzy stimulation device in pain and anxiety reduction during peripheral intravenous cannulation in an adult population.

Enrollees in this study will be patients who will undergo dental surgery with intravenous sedation. The patients who are enrolled will receive an IV either with or without the Buzzy. The Buzzy is a small vibration device which will be placed next to the IV placement site.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
- To investigate the efficacy of the Buzzy stimulation device in pain and anxiety reduction during peripheral intravenous cannulation in an adult population.
- Determine any benefit of the Buzzy system between men and women.
- Determine any benefit of the Buzzy system between different age ranges in adults.
- Is there a site benefit with the Buzzy system?

I.6 ***Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")***
The Buzzy is a reusable device that applies vibration to the skin surface to override the body's gate control pain pathway. It has been used effectively to reduce the discomfort of intravenous cannulation (IV placement) in pediatric patients. Also, it has been utilized to reduce the discomfort of injections in pediatric and adult patients. We are preforming this study to evaluate the effectiveness of the Buzzy in reducing the discomfort associated with intravenous cannluation (IV placement) in adults.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***
Canbulat N, Ayhan F, Inal S. Effectiveness of External Cold and Vibration for Procedural Pain Relief During Peripheral Intravenous Cannulation in Pediatric Patients. Pain Management Nursing, 2014 Jun 6 S1524-9042.N=176
Inal S, Kelleci M. Buzzy relieves pediatric venipuncture pain during blood specimen collection. MCN Am J Matern Child Nurs 2012 Sep;37(5):339-45.Buzzy alone no distraction: 6.56 -> 2.78, 58% reduction in pain.Fear 52% reduction N=120
Baxter AL, Cohen LL, Von Baeyer C. An Integration of Vibration and Cold Relieves Venipuncture Pain in a Pediatric Emergency Department. Pediatr Emerg Care, 2011 Dec;27(12): 1151-6. Pain reduced by child, parent, and nurse reports median 4 to median 2 = 50%. N=87

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Kyle Stein	kyle-stein@uiowa.edu	College of Dentistry

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Kyle Stein, DDS	kyle-stein@uiowa.edu	College of Dentistry	Yes	Yes	No		Yes	No
William Morio, DDS	william-morio@uiowa.edu	University Hospitals	No	No	No		Yes	No
Douglas Orzel, DDS	douglas-orzel@uiowa.edu	University Hospitals	No	No	No		Yes	No
Jordan Tortorich, DDS	jordan-tortorich@uiowa.edu	University Hospitals	No	No	No		Yes	No

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email

Nothing found to display.

II.3 ***The Principal Investigator of this study is:***
Faculty

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as "key personnel." For information about other team members who should be designated as "key personnel" please click on the help information.***

Name	Is Key Personnel
Kyle Stein, DDS	Yes
William Morio, DDS	No
Douglas Orzel, DDS	No
Jordan Tortorich, DDS	No

II.5 ***Select research team member who is the primary contact for study participants.***
Kyle Stein

III. Funding/Other Support

III.1 ***Funding Sources***

Type	Source Grant Title	Name of PI on Grant
Departmental		

* new source name

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Kyle Stein, DDS	No
William Morio, DDS	No
Douglas Orzel, DDS	No
Jordan Tortorich, DDS	No

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project.***
Upon IRB approval

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
No

V.22 ***Will this project use any resource/patients of the HCCC?***
No

V.25.a ***Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

No

V.26 ***The study involves nursing, nursing resources or evaluates nursing practices.***
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
100

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
40.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
0

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***
- ***Studies under IRB-03 enrolling non veterans as part of the subject population must present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.***

The study will be preformed on patients undergoing intravenous sedation for dental surgery.

This study is intended to be equally inclusive of male and female patients. An inclusion criterion is to be between ages 18 and 40. There are no medical conditions which would preclude participation in the study.

The control group (50% of total subjects) will have an IV started in the standard fashion.

The experimental group (50% of total subjects) will have an IV started in the standard fashion with use of the Buzzy.

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
The majority of the patient population treated by Oral and Maxillofacial Surgery is adults. All adults aged 18 to 40 who are receiving intravenous sedation for their dental surgery will be eligible for inclusion in the study. There are approximately forty patients per week at the college of dentistry who meet these criteria.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
The Oral and Maxillofacial Surgery department does approximately 2000 IV sedations at the UI College of Dentistry and Dental Clinics each year.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***

- Other UI campus site - College of Dentistry Oral and Maxillofacial Surgery Clinic

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***

No

VII.B. Project Description (B)

VII.B.1 ***Does this project involve any of the following (Check all that apply):***

- **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA)
- **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as "translational" or "basic science" aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
- **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
- **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)
- **Non-clinical** – any college/department that would regularly submit to IRB-02
- **Other – Describe:**
  Survey involving application of external vibration device while placing peripheral IV.

VII.B.1.b ***Provide the NCT (National ClinicalTrials.gov Identifier) number***

NCT03619135

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***

No

VII.B.6 ***Will any subjects receive a placebo in this study when, if they were not participating, they could be receiving an FDA-approved treatment for their condition?***

No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***

No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***

Yes

VII.B.19 ***Describe in detail procedures in place for maintaining device shipment and receipt records:***

The Buzzy units are reusable medical devices and as such, all device records will be maintained per standard departmental protocol by nursing at the College of Dentistry Department of Oral and Maxillofacial Surgery under supervision of the PI.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
N/A

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
All patients included in the study will have their record number noted on the study questionnaire should this be required for later use. The device is reusable and not implanted.

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
The study team/PI.

VII.B.23 ***Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)***
The device will be maintained in the dispensary at the College of Dentistry Department of Oral and Maxillofacial Surgery. The device is not dispensed and is available to the public for purchase and is not of concern for abuse.

VII.B.24 ***Is the device FDA-approved for the way it will be used in this study?***
Yes

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Brochures -
- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - This study will use subjects already planned for surgical removal of third molars with the use of intravenous sedation. The study will be explained (both verbally and with the written form) to the patients at the beginning of their surgical appointment. The patient will be given the opportunity to discuss participation with their escort (typically a family member or friend and always an adult) as needed.

VII.D.2 ***List the individual data elements you will need to access/use from the patient or clinic records to identify potential subjects for recruitment***
Age and planned sedation

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***
These two pieces (age and planned sedation) of information are our two inclusion criteria

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***
Age and whether the procedure are planned are two inclusion criteria which must be known in order to ask the patient to participate in the study

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***
There is no written information kept on potential subjects.

VII.D.6 ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research***
There is nothing to destroy since no written information has been stored.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject***

agreeing to participate?
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
The patient (subject) will be recruited and agree to (or deny) participate in this study in a surgical treatment room in the Oral and Maxillofacial Surgery Clinic at the University of Iowa College of Dentistry.

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
No

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Kyle Stein, DDS	Yes
William Morio, DDS	Yes
Douglas Orzel, DDS	Yes
Jordan Tortorich, DDS	Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
No

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
We will use subjects planned for third molar removal with IV sedation (previously informed of the IV process). The study will be explained (verbal and written) to the patient at the start of their visit. The patient will have the opportunity to discuss participation with their escort (always an adult family member/friend) as needed. They will need to decide within a few minutes if they wish to participate.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
After the patient agrees to participate.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

The potential subjects will be encountered in the oral surgery clinic. They will be seated in the procedure room. If the patient meets study criteria they will be asked if they would like to participate in the study. They will be able to review the recruitment brochure at that time in the clinic. The potential subject will then be approached a member of the research team who can further describe the study. A member of the research team will go over the consent document with the subject. It will be explained that there are no potential risks or complications involved with the use of the Buzzy. To minimize coercion we will inform that patient that there is no obligation to participate in the study and that participation is voluntary.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of***

the research.

- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
Yes

VII.E.1.a ***Will any subjects be blinded to which study arm they have been assigned?***
No

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***
The study will be made of two randomized groups with a 1:1 ratio. Those who use the Buzzy system (experimental group) and normal, routine IV start without Buzzy (control).

An equal number of forms noting Buzzy (experimental) and Standard (control) will be printed and placed in security envelopes. These will be randomly mixed and when an eligible and participating subject is identified, the top most envelope will be chosen and opened to assign the group.

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
A single questionnaire with before and after placement of intravenous catheter

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
No

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

The participants will be randomized into two groups, those who use the Buzzy system (experimental), and routine IV start (control). Prior to knowing their group, all patients will answer the "Before Intravenous Catheterization" portion of the form in order to eliminate bias. After this portion is complete, their group (experimental vs control) will be determined from opening a blinded envelope.

A tourniquet will be placed, followed by the Buzzy stimulation device (if in the experimental group). An alcohol swab will be used and then a 22 gauge IV catheter will be inserted, connected to fluids, and secured with tape. The antecubital fossa or the dorsal hand/wrist will be the only sites used in the study. All participants will fill out the post-insertion questions on the form and those patients that used the Buzzy system will then fill out the several specific questions related to the experimental group. This will conclude the patient's involvement in the study. The patient will then continue with treatment as planned. We will plan to exclude cases where the IV is not obtained on the first attempt, if a smaller or larger gauge IV catheter is required, or if an insertion site not listed above is required. The case will be excluded if adjunctive steps are taken to obtain IV access (i.e. Oral sedation, nitrous oxide, heat packs).

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - followup is not required in this study

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
No

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?
There may be risks associated with being in this study. You may experience pain and bruising at the insertion site of the IV line. There is also a low risk of infection at this site. These risks are associated with the surgical procedure and not the research.

There is the potential that your confidentiality could be breached and persons not on the research team could learn about your study participation, but we will safeguard your data as described in the confidentiality section. There may be unforeseen risks associated with participation in this research.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

There are no risks to this study. The intravenous catheter will be placed by an oral and maxillofacial surgery faculty or resident, so the patient will be monitored by that surgeon during intravenous placement (as are all patients).

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
No direct benefits

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
Decreased anxiety and fear in seeking treatment with IV sedation. Help decrease needle phobias and/or pain related to IV insertion, vaccinations, etc. This could help other oral and maxillofacial surgery clinics, and other organizations, such as blood banks, in seeking adult participants.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
The questionnaire form that will be collected will only contain the record number in order to track device usage as required by the IRB proposal. All forms will be kept secured in a locked file and stored by the PI. Only data which is related to the study will be collected. The minimum amount of private information needed to answer the research question will be collected.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - A file will be kept by the PI with the paper records as noted above. The files will be stored in a room that is locked when not in use. The patient's name will not appear on the record, instead only their record number will be used.
- Electronic records (computer files, electronic databases, etc.) - After collection of the paper records and sufficient data, the data will be put into an electronic format for data analysis. The data will be stored and accessed on University of Iowa Hospitals and Clinics and College of Dentistry computers. These computers are password protected with UIHC healthcare logon identification.
  - Name - Lee Carmen
  - Title - Associate Vice President, Healthcare Information Systems
  - University Job Classification - Staff

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
Yes

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***
No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
Simple descriptive statistics would be used to summarize the data. Normality of data will be assessed by Kolmigirov Smirnov test. Continuous outcomes would be assessed by t-tests, ANOVA, and multivariable linear regression models. Categorical variables would be assessed by Chi-square tests and multivariable logistic regression models. All tests will be two sided and a p-value of<0.05 would be set for statistical significance.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
Population mean = 3.42 points (std.dev of 3.10) [Wong-Baker FACES scale score]
Expected clinical difference to be detected = 2 point differences in Wong-Baker FACES scale score
Alpha = 0.05
Power = 80%
Sample size required is 38 patients in each of control and intervention groups (total sample size is 76 patients).

To allow for better statistical analysis and for patients excluded due to missed IV access attempts, etc. up to 100 patients may be enrolled.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
No

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
No