

AMELIORATION OF CLAUSTROPHOBIA AND DISRUPTIVE PATIENT MOTION
IN MRI

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Amelioration of Claustrophobia and Disruptive Patient Motion in MRI RESEARCH PROTOCOL

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Study Title: **Amelioration of Claustrophobia and Disruptive Patient Motion in MRI** (NIH SBIR Grant)

I. Aim and Hypotheses

Claustrophobia and disruptive patient motion are common impediments to MRI examination, but they may be prevented or ameliorated with a non-pharmacologic behavioral intervention administered by trained staff. The potential benefits of such an intervention are highly significant, considering that the alternatives are to cancel the study or administer sedation. Inability to complete their MRI scans adversely affects an estimated 700,000 patients every year in the US. These patients are either deprived of a diagnosis or exposed to risks of pharmacologic sedation which can have serious side effects, including death. The imaging facilities in turn, which typically cannot fill the suddenly vacated examination slots in time before the next scheduled patient, incur considerable lost revenue and efficiency.

The long term goals of this project are to:

1. Provide a validated clinically feasible means for non-pharmacologic amelioration of claustrophobia and disruptive patient motion in MRI practice achieved by training facility staff in assisting patients through advanced rapport and comforting language.
2. Assess the effect of team education and training in Comfort Talk® on global quality and economic parameters

The aim of this work is to demonstrate that staff in even different OSU MRI facilities (Main campus, Martha Morehouse, Stoneridge, OSU East, Carepoint East, Carepoint Lewis Center, and Carepoint Gahanna) can be straightforwardly trained to alter their verbal and body language while interacting with patients undergoing MRI studies in a manner that markedly decreases the proportion of such studies that are not completed due to patients' adverse reactions to the MRI environment. This has already been successfully demonstrated with the MRI staff at the main hospital, where training will continue. After training at the main site, cancellations due to patients' claustrophobia, inability to cooperate, refusal, as well as other patient-centric reasons declined from 8.1 – 1.6%. Furthermore, examinations that took longer than the allotted time decreased from an average of 203 per month to 14 per month, and Overall Assessment of Patient Satisfaction measured on the Press Ganey Surveys instruments and benchmarked against 907 other hospitals improved from the 3rd to 53rd percentile. We plan to extend the same training to MRI staff at the six additional OSU community based locations listed above. The staff of three sites will be trained during year one; the staff of the other three sites will be trained during year two.

The cost of incomplete examinations to patients in terms of diagnostic delay and to MRI facilities in terms of wasted slots and missed revenue is substantial enough to make such a program economically attractive. In fact, this is a small business grant submitted by a new company (Hypnalgessics, LLC), established to disseminate this training.

Specific Aim 1: Design and Expansion of the Live Component of the Comfort Talk™ Training Intervention

The Comfort Talk™ intervention has evolved into a proprietary and standardized R3 Process™ of Rapport, Relaxation and Reframing. Training sequences include training in advanced rapport skills, shaping of patient' expectations and basic comforting language and behavior for all facility staff (including receptionists, technologists, nurses, and physicians). A core of licensed healthcare professionals, trained in self-hypnotic relaxation techniques based on scripts found to be effective in prior trials (24, 33,46, 49) will be taught to guide patients in self-hypnotic relaxation techniques, using scripts found to be safe and effective in the radiology department. Techniques will be designed so that they can be integrated in the normal workflow of personnel without requiring extra staff time or longer examination slots.

Practice and certification will entail traditional testing and role-play in which the trainee interacts with an instructor-controlled virtual patient avatar and displays an appropriate Comfort Talk® strategy based on verbal and nonverbal “patient” cues. Live avatar patient interactions will increasingly be replaced by interactions with scripted online avatars programmed to display certain behaviors to which the trainee would need to quickly and appropriately respond. Observation of the trainer-trainee during at least two live teaching sessions with customers will be used to assess and certify the trainer's teaching ability. Feedback from trainees and customers will serve as measure of efficacy and acceptability of the train-the-trainer prototype.

Training will also include a hybrid live/online prototype for trainer-training and certification that contains standardized, timed Comfort Talk® content materials, background and education-centered topics, tools for support, community interaction with other trainers, interactive practice and tests, and follow-up.

Institution-based trainers will be developed as “Champions” who will support continuity of program usage, report effects and barriers to Hypnalgescics, update their local site on new information, and introduce new personnel to Comfort Talk®. The Champions will be knowledge generators for Hypnalgescics.

Training will be conducted at seven active OSU MRI sites. Acceptance, observation of staff behavior, qualitative feedback, and rates of non-completion will be used to assess efficacy of training, and further develop train-the-trainer materials. Using in-market piloting techniques, niche applications with their metrics will be explored to develop situation—specific supplemental materials.

Specific Aim 2: Design and Expansion of an Electronic Comfort Talk™ Platform,

The live Comfort Talk training intervention will be supplemented by an interactive electronic module and a live/online prototype as described above. All will enable the healthcare trainees to explore scenarios, practice the applications, tailor scripts for the best outcome for the patient, and track progress based on personal profile. The modules will support a guided dialogue which the participants will use to log the events for which input is sought. The platform will support traditional forms of web community interaction such as forums, and will be expanded to include a support area where live chat with Comfort Talk staff can occur for post-training support. It will contain functions to host online live interactive classes with bidirectional video linkage in conjunction with web-meeting systems. Support for Smartphones such as iPhone and Android will be included to take advantage of the portability and multimedia capabilities of these devices. The prototype of the electronic module will be beta-tested with 20 experts in hypnosis and participants of the hypnosis workshops of the Society of Clinical and Experimental Hypnosis and refined based on feedback from the users.

As the research has progressed, the need for site-specific individualization regarding the use of vocabulary and behavior patterns of staff and personalization for generic patient populations and

was recognized and integrated in platform design. As additional OSU sites are recruited, language for specific patient populations and situations will be integrated into subsequent trainer material. For example, one site may need wording suggestions for managing drunk patients at night in MRI; at another site, patients being examined while in head frames could be challenging. Wording suggestions for such patient groups without identification of individual patients is then integrated in Suggestions Cards the trainees can pull from the web-based Support platform. Each site has its own Training Support Portal with language suggestions that are specific to the make-up of their patient populations and their challenges.

Specific Aim 3: Prospectively Determine the Impact of Comfort Talk® Training on the Patient Experience and Return-on-Investment

The effect of Comfort Talk® training, including newly trained trainers and local Champions, will be assessed at six MRI satellites of the Ohio State University Medical Center. Three sites will be trained initially and three one year later. Analysis will include intra-site and across group comparisons of rates of: non-completion, scans exceeding allotted time slots, sedation rates, patient satisfaction scores, equipment and resource utilization, and economic at baseline and in 3-monthly intervals. Personnel behavior will be assessed in a modified Group Objective Structured Clinical Evaluation (GOSCE) at the same intervals. Data will be extrapolated to site-specific return-on-investment structures to be used for commercialization.

Milestones will be:

- A prototype version of the educational intervention including its electronic module with an expanded protocol for the Trainer Trainer module Evaluation of the intervention by users, both subjective and objective
 - Evaluation instrument selection and refinement User critique
 - A prototype Champion platform and research engine for feedback integration
 - Unequivocal randomized assessment of the benefits of Comfort Talk® training for the patients
 - Unequivocal randomized assessment of the economic benefits of Comfort Talk® training

II. Background and Rationale (Note: references refer to grant)

A. Background:

Magnetic resonance imaging is an essential modern diagnostic tool but fails patients who cannot remain still on the examination table because of claustrophobia, anxiety, preexisting pain, or intolerance to loud noise. An analysis of the literature from 1980 and 1993 indicated anxiety related reactions in 4-30% of patients undergoing MRI ranging from apprehension to inability to complete the test (1). Dewey et al. calculated from studies up to 2004 an average claustrophobia non-completion rate of 2.3% with a 95% confidence interval (CI) of 2.0 – 2.5% (2). In Dewey's own study with a conventional MRI scanner, the authors' non-completion rate was between 2.1% in a group of 42,998 patients and 2.3% in a group of 12,736 patients. Extrapolating this rate to the 30 million MRI-scans performed annually in the US, non-completion deprives about 700,000 patients of a timely diagnosis, further stresses and inconveniences them, while the imaging facility loses revenue because of its inability to refill the suddenly vacated examination slot in the time available. For the patients, the negative experience may even lead to refusal of future MRI examinations, excluding them altogether from the diagnostic accuracy of this non-invasive and radiation-free modality (3). Adverse events from the experience can have lasting effects: It has

even been reported that patients, who were not claustrophobic before scanning, developed phobias to enclosed spaces afterwards (4, 5).

Causes for Non-Completion of MRI Scans

Causes for non-completion of MRI scans are often grouped together under the term “claustrophobia,” but can have various origins. MRI has been shown to elicit high levels of anxiety in patients (6-11). Under standard care conditions, anxiety is not only abnormally high before the examination, but increases during the scan (11). Contributors to increasing distress are the closeness of the equipment to the patient, coil noise (likened to that of a jackhammer), duration of the examination (about 45 min), and elevated temperatures in the magnet bore (11, 12). 32% of MRIs performed in the US are examinations of the head (Marketing Data, GE Medical Systems, shared at the Radiological Society of North America Meeting in December 2009), for which a head coil is placed over the face as a further source of the feeling of enclosure. Strong predictors for stopping the MRI examination are baseline anxiety and baseline pain levels (5). Lying flat for extended time can be difficult for patients with cardiac and respiratory disease, and patients with obesity and sleep apnea may also be at higher risk of airway impairment (13). Patients who become distressed in the scanner may not necessarily ask for the scan to be halted but may move to such a degree that the acquisition of meaningful images is disrupted and the patients need be recalled for repeat examinations.

Effect of Provider Behavior on Patient Distress

Not knowing one’s diagnosis and learning about possible adverse effects can be great stressors and sources of anxiety (14, 15). Patients in this situation are vulnerable to a pessimistic interpretation of information they are soaking up (16). Words, tone, expressions, and context determine if the information received creates positive or negative expectations (17). Negative expectations bring about negative outcomes (18). Bayer et al. showed in experiments with sham stimulations that volunteers who expected pain reported pain, even when there were no painful stimuli (17). Dr. Lang’s research in the interventional radiology suite showed that negatively-valenced statements, as compared to none at all or to neutral ones, increase patients’ anxiety and pain when used to announce upcoming stimuli; also anxiety increased after stimuli when sympathy was expressed afterwards (19).

Perceiving others in distress produces an emotional reaction, which can trigger efforts to decrease distress to the observer as well as to the suffering person, and elicits a behavioral response, which may be targeted towards providing comfort and reassurance or withdrawal (20). This affective reaction, demonstrable on brain imaging, is the more pronounced the higher the observer scores on empathy scales (21). Higher scores on empathy scales, however, do not necessarily translate in appropriate clinical behavior. A study in the postoperative acute care setting reports that nurses who scored higher on such empathy scales, but did not have advanced education in patient interactions, did not provide better pain management for their patients (22). Particularly when personnel attempt to be extra nice, but do not do so in a fashion that helps patients help themselves, the risk of adverse events increase (14). Considering the power of verbiage and behavior of personnel on the patient’s experience and cooperation, it is not surprising that the Accreditation Council for Graduate Medical Education now demands training in Interpersonal and Communication Skills for resident physicians and that many medical schools followed suit (23). This realization, however, does not yet extend to technologists and nurses who are in the front line of the patient encounter at the MRI scanner and who are left to their own devices in keeping panicky, writhing, or moving patients still on the MRI table.

Technical and Pharmacological Approaches

Attempts to combat claustrophobia and anxiety range from providing mirrors that enable patients to see out of the magnet, earplugs for sound suppression, headphones for listening to music, blindfolds, accompaniment by an appropriately screened person, scanning prone, to use of “open magnet” designs or prototypes with extra short bore and 97% acoustic noise reduction (2, 6, 24, 25). Disadvantages to the use of open scanners are capital expenditure and an image quality still inferior to that of more closed designs. Furthermore, there is pressure to book an increasing number of obese patients on open magnets to accommodate their larger bodily circumferences, making these scanners less available for other patients, including claustrophobic ones.

Many centers use sedation to help patient’s complete MRI examinations. Murphy et al. report that 14.3% of 939 patients in their university-based facility received oral sedatives, IV conscious sedation, or general anesthesia. This did not include patients who may have used sedatives without knowledge of the physician (3). Eshed et al. provided IV sedation to 1.97% of 5,798 patients to treat claustrophobia, and with this adjunct reported an overall 1.22% non-completion (26). In a study comparing nasal midazolam spray with placebo in patients with comparable anxiety levels and characteristics, 4 of the 27 patients inhaling saline could not complete their scans as compared to none of 27 in the midazolam group (27). Moreover, the image quality in the sedated group ranged from good to excellent as compared to that in the placebo group where patient motion reduced image quality to ratings between very poor (not usable) to good only. This shows that the effects of untreated distress are not limited to non-completion but may also increase the risk of inaccurate interpretation and, thus, liability.

When medical sedation is used, serious side effects can occur even with relatively low doses (28). If all 700,000 patients who are estimated to be unable to complete their MRI scans were rescheduled with IV sedation, and if one were to extrapolate the risk of IV sedation as found in a large collaborative study with >21,000 endoscopies (29) to those, it is predicted that 4,000 patients would suffer serious cardiorespiratory complications and 220 patients would die each year. When patients under sedation or general anesthesia cannot hold their breath on demand during scanning, sudden deep excursions of the diaphragm can disrupt acquisition of interpretable images. Sedation takes time and can interrupt the normal scheduling of examinations: time requirements are 27 min in the hands of dedicated MRI sedation nurses and 47 min under care of inpatient nurses (30). Even with dedicated personnel present, sedation does not always work: IV midazolam failed to sedate 6% of patients during MR imaging (30). Because of the risks of IV sedation, patients should have no food for 6 hrs prior to presentation, require administration and observation by a medical professional credentialed in IV sedation, airway management, recovery monitored in dedicated space, and transport home in presence of a responsible adult. Many freestanding outpatient facilities cannot afford the complexity and cost of this additional care and do not qualify for sedation licenses. They typically refer claustrophobic patients to their referring physicians for sedative medications. These patients, however, will still need to arrange for a ride home and will not be permitted to perform attention-requiring activities for 24 hrs. A nonpharmacologic alternative would therefore be highly desirable for the sake of patients and facilities.

Non-pharmacological Alternatives

Quirk et al. found that many MRI patients combated anxiety on their own by using breathing and relaxation techniques, visualizing pleasant scenes, and performing mental exercises (10). Thus it would seem natural to help patients further their ability to use such techniques. Quirk et al. then also showed that a 12-min relaxation exercise reduced patient anxiety during MRI scanning (11). Medical hypnosis and systematic desensitization have also been used successfully to enable patients to complete MRI scans (31, 32) However, there were obstacles to implementing mind-body techniques more broadly in practice. A statement Klonoff et al. made in 1986, remains

valid: that behavioral techniques for use during radiological procedures, including MRI, have received surprisingly little attention even in the behavioral community (7). Main impediments were early beliefs that such techniques are best provided by mental health professionals, and that traditional hypnotic techniques and desensitization approaches just took too long for a busy practice. This has changed since it has become apparent, to considerable extent through Dr. Lang's clinical trials, that guidance in self-hypnotic relaxation on the examination table can be applied without interruption of workflow, that it saves time and money, and that personnel already involved can perform it quite expertly (33-35).

In three prior federally funded prospective randomized trials with >700 patients, Dr. Lang's group showed that guidance of patients in rapid self-hypnotic relaxation techniques during medical procedures in the catheterization and breast biopsy suites reduce pain, anxiety, medication requirements, complications, and cost (33-35). Lang's study methodology has since been used as a blue print by Montgomery et al who showed similar results in a prospective randomized study with women undergoing open lumpectomy (36). Efficacy of the use of adjunctive hypnosis in reducing pain and anxiety has also been demonstrated for burn care, plastic surgery, labor and delivery, and the removal of appendices, bone marrow, teeth, and tonsils, and first-trimester pregnancy termination (37-42). This evidence opened the path to promoting procedure hypnosis training for the healthcare professionals who are at the front line of treating patient distress.

Based on her published experience, Lang was asked to help a large private MRI practice, which already had a very low non-completion rate of 1.2%, to further reduce their rate. After team training in rapid rapport techniques and guidance in self-hypnotic relaxation, the non-completion rate of MRI's was reduced by 40% and resulted in annual savings of \$140,000 with maintained success at the time of a 1-year follow-up (24).

B. Rationale:

While other working groups have reproduced the findings of the Lang's trials and unequivocally shown that rapid hypnotic interventions provided to patients at the time of their medical tests and procedures significantly improved patient outcomes and saved cost (36, 43), the resulting evidence has not yet driven adoption in medical practices to a degree that drug trials of similar size and efficacy would have produced (44). This leaves a largely undeveloped market with considerable potential. The proof of concept has been driven by researchers in academia, but there was lack of a licensable product and/or delivery model with sufficient scaling potential to make it attractive to the usual venture community or to drive market penetration. Dr. Lang, who for most of her life pursued a successful academic career, realized that this important step could only be achieved through a full-fledged commercial effort and thus founded Hypnalgesics, LLC, dedicated to team training in the rapid rapport techniques and guidance in self-hypnotic relaxation techniques elaborated in her prior research. The company is built on the concept that medical personnel already involved in routine patient care are best suited to structure the patient treatment, resulting in maximal savings and a change in culture. The proposed work will not only help to establish the product line of procedure hypnosis in the MRI domain for Hypnalgesics, LLC, but can be a blueprint for expansion in other areas (for example an integrated breast care line, endoscopy/colonoscopy, or plastic surgery) by decreasing the amount of sedation needed.

The MRI product has compelling metrics. Depending on the arrangement with the patient's insurance carrier the facility may incur a revenue loss for every non-completed MRI between \$500--\$5,000. Assuming an average of \$2,000 per scan (including technical and professional fees), this translates into an annual burden of \$1.4 Billion to the health care industry. Since this unrealized revenue is absorbed in overhead, decreasing examination failures will decrease

overhead on all examinations and thus ultimately affect the cost of medical MR imaging overall. As medical imaging including MRI is a major driver of healthcare cost, measures that reduce overhead promise to have substantial impact on global healthcare expenditures.

Targeting a 40% reduction in MRI non-completion and assuming a willingness to pay ¼ - 1/3 of the expected annual savings for a product that achieves this, the opportunity represents an about \$160 Million market. For this extent of market penetration it will be necessary to develop a standardized and validated product with train-the-trainer and electronic teaching capability that can be upsized to meet the demand.

III. Research Plan

Overview

The goal of the proposed work is to assess the effect of team education and training in Comfort Talk™ on global quality and economic parameters of an entire MRI operation, NOT on individual trainees and NOT on individual patients. Based on our experience, personnel will assimilate the new behaviors and talking style they learn from Comfort Talk™ in their daily work as they see fit, resulting in a cultural change that improves patient outcomes in general and financial terms. The talking style and guidance in quick self-hypnotic relaxation techniques, which the licensed healthcare members of the team will learn, have all been rigorously tested in clinical trials, been shown to be safe and effective, and fall within established care practices.

For the project, staff employed at seven different MRI facilities of the Ohio State University Wexner Medical Center will be trained in the use of Comfort Talk™. The effect of training will be evaluated by use of questionnaires, a computer-based pre- and post test, and observation of behavior. (Training has already begun at will continue at the main hospital.) The individuals will complete the questionnaires and tests using self-selected ID codes, which they keep throughout the training, so that successive evaluations can be tied but not be associated with or traced to the identity of the individual who entered them. Observations of behavior before and post training will be based on an Objective Structured Clinical Examination for the group which rates the frequency by which certain behaviors are displayed throughout the day within the culture of the institution without identification of the individuals involved. For example, two observers will note whether there is infrequent or frequent use of negative suggestions, adaptation of the personnel's to the patients' level (e.g. bending over towards supine patients). The daily observations will then be averaged over several days across several scanner units of the facility so that potential identification of individuals becomes even less possible. Another outcome criterion, the overall rate of failed MRI scans and the associated loss of revenue, are fiscal data that are obtained in the normal course of business.

Hypnalgessics, LLC originally obtained an FWA and an IAA with Tufts Medical Center and obtained IRB approval from Tufts Medical Center in addition to the Boston University Medical Center. The Ohio State University Medical Center was added as a third site.

In April, 2013, this protocol will be open only for sites of The Ohio State University Wexner Medical Center that perform outpatient MRI exams and are specifically listed on page 1 of this protocol. No subsites will be involved. We will continue to pursue exempt status based on the following:

(1) *“Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”* Training in interpersonal and

communicative techniques is not only commonly accepted for medical professionals, but actually demanded for academic institutions, to the least for the physician trainee staff per ACGME demand. The individual teaching methods are all established, and the testing in a specific combination of them does not deviate from accepted teaching practice.

(2) *“Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.”*

(4) *“Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”* In the fiscal data that the researchers will obtain as to the rate of noncompletion of MRI scans and associated loss in revenue, it will not be possible to identify the individuals who were not able to complete their scans.

Baseline Site Information

The Ohio State University Wexner Medical Center has seven separate locations performing MR scans. This number doesn't include sites that are dedicated exclusively to mammography. Together, they perform between 19,000 -21,000 MRI scans per year. with projected noncompletion rates of approximately 5% per year. Annual losses due to non-completion total approximately \$977,000 per year. .

The investigators will meet with facility staff to identify site-specific medical and commercial drivers of the MRI operation, obtain accurate current metrics (total number of scans, reimbursement, resource use), potential niches of particular difficult or important subpopulations (we already learned about some such as breast interventional MRI, enteropathy patients with high vomiting rates upon contrast ingestion, Alzheimer patients), frequency and financial impact of non-completion and disruptive patient motion, as well as approaches and resources used in prevention and management of non-completion and disposition of patients. Discussion with the local researchers will define tracking of non-completion and motion metrics and identify which metrics can be mined retroactively and which metrics need be collected de novo for long-term effect analysis. At the same site visit, the investigators will observe staff behavior in their patient interactions with a modified Group Organized Structure Clinical Evaluation (OSCE) – see 4.5.2. They will also query where personnel see their greatest challenges so that training content can be adapted appropriately.

Comfort Talk™ Training Intervention

Comfort Talk™ training will be based on our prior research experience with techniques found to be safe and applicable in the radiology department. We outlined the intervention sequence in the book *“Patient Sedation Without Medication. Rapid rapport and quick hypnotic techniques. A Resource Guide for Doctors, Nurses, and Technologists”* (48) to which the PI has the copyright. It was beta-tested in the Basic Hypnosis Course of the 61st Annual Meeting of SCEH with excellent acceptance. The book won the Arthur Shapiro Award for Best Book on Hypnosis 2010. Teaching includes training in rapid advanced rapport, shaping of patients' expectations, and use of comforting language for all facility staff (including receptionists, technologists, nurses, and physicians). A core of licensed healthcare professionals receives, in addition, training in guidance

in self-hypnotic relaxation techniques based on scripts which found to be effective in prior trials (24, 33,46,49). Techniques will be designed so that they can be integrated in the normal workflow without requiring extra time.

A live module of 2x8 hrs will be taught in two waves separated by 3-6 weeks and be supplemented by a 4-hr electronic module. The 20-hr model was chosen because it is traditionally recommended by SCEH and ASCH as Basic Course requirement but may be reduced based on our outcomes. Teaching modes target interactive learning and will use a case-based approach with background analysis and opportunities to practice (47). Techniques will include lecture, large group discussion, live and video-based demonstration, small group discussion, extensive small group practice, and a microteaching exercise which the PI has adapted to interpersonal skill training and tested with radiology residents (47). Initially, teaching will be provided by Drs. Lang and by medical or mental healthcare professionals trained according to trainer standards. The teaching modes will be outlined in a Trainer Manual which will support Train-the-Trainer activities when upsizing of the trainer pool will become necessary.

Following each 8 hour live module, an Evaluation of Workshops form will be provided to all subjects for the evaluation of training effectiveness, satisfaction, and allow the opportunity to provide anonymous feedback. Input collected from the forms will be compiled and considered when implementing future training modules. More specifically, results will be used mainly for Hypnalgnesia LLC-internal quality control of trainer performance and general feedback of the educational offering. Results will also be used to fine tune the offerings according to specific desires and learning styles of the trainees at hand. Although the teaching approach always includes all 4 elements of the Kolb learning cycle and is based on experiential adult learning techniques, different teams have different preferences of emphasis and these will be respected when presenting the second session. In the comment sections, trainees sometimes indicate which scenarios in their institution are particularly challenging for them, and the second session will then address teaching points in this context. Feedback from the second session will mainly be of benefit for subsequent training at different institutions.

Electronic Comfort Talk™ Platform

The electronic module will provide trainees: 1) an extensible media library of example techniques and best practices in Comfort Talk™; 2) problem-solving and self-explanation prompts in response to patient scenarios; 3) skills assessment and self-reflection on progress; 4) contribution of narrative reports of cases of interest; and 4) links to specialized repositories of clinical data with targeted search engine capability for trainees and to allow instructors to access to demonstrations of interest; and 5) generate options for tailoring scripts. The module will allow trainees to maintain a personal profile, allow electronic grading of their exercises, and, via post-processing, offer appropriate materials based on their previous actions.

The module will remain available to trainees via the World Wide Web and will be easily updatable. The web-based system will also provide post-training support. It will function as an on-line community for exchange of experience and Comfort Talk Trainer input (including a live chat feature), support traditional forms of web community interaction such as forums, and include the ability to upload audio and video. Support for Smartphones such as iPhone and Android will be possible to take advantage of the portability and multimedia capabilities of these devices.

The basic 4-hr module will be gradually expanded to prepare for Phase II training where reductions in on-site training can be further explored. The resources of the web-based platform will enable web-meeting systems (such as WebEx) to host online live classes, where the participants see the screen presented by the instructor, and live interactions between instructor

and participants is possible. This feature will guide efforts in reducing the on-site live requirement of training and facilitate on-line commercialization opportunities.

Formative Evaluation of the Comfort Talk™ Training Intervention

Beta-Testing of the Electronic Module

The prototype 4-hr electronic module will be beta-tested with 10 experts in hypnosis and participants of the hypnosis workshops of SCEH, refined based on feedback, and submitted to additional 10 experts testers. The product will be integrated in Comfort Talk™ Training at additional sites. In a three-level evaluation based on the Kirkpatrick Model (50) users will provide: 1) positive or negative reaction to the module; 2) demonstrate learning through a pretest and posttest and 3) a behavioral reporting assessment. The first evaluation is of the effectiveness of the software to engage and support the learner. The second is to understand how practice impacts understanding of techniques and their appropriate application. The third is delivered to the user after they have tried techniques in their professional lives, enabling the assessment of transfer of knowledge and process from the training to the work environment.

Evaluation of the Entire Comfort Talk™ Sequence

A sustained reduction in non-completion will be the ultimate criterion documenting feasibility and efficacy of the Comfort Talk™ training intervention. Using published assessment methods for radical innovations, we will use in-market exploration with great emphasis on qualitative feedback, search for niches, metrics, and impact that may not be obvious upfront. This will include feedback from administrators, patient, and satisfactions surveys the institutions already utilize. In addition, acceptance testing, user critique, qualitative feedback from the trainees will be used and updated in 3-month post-training intervals.

Skill progression, acceptance or potential difficulties with learning or topics will become evident during the extensive small group practice in which mutual feedback between trainers and trainees occurs, and will be addressed. A pre and post test self-assessment modeled on an 18-item instrument the PI had developed for assessment of teaching efficacy in interpersonal and communication skills (47) will evaluate ease/unease in managing issues of rapport, dissonance, and distress in conversation partners. A 100 question post-test will assess mastery of content. Personnel behavior will be monitored in a modified OSCE for assessment of group behavior, which was adapted from the adherence check list used in the prior clinical trials of the PI to identify prescribed and proscribed behaviors for a self-hypnotic relaxation intervention which correlated with positive patient outcomes (24,33,49). The investigators will be trained to a kappa of 0.8 inter-rater reliability using tapes from Dr. Lang's extensive teaching video test library.

Trainer Development

All trainer-training programs will include live interactions and online components and will be highly standardized. To obtain the Hypnalgescics' certification as Comfort Talk® trainer, individuals will be expected to have completed at least one Comfort Talk® as students themselves; demonstrate successful use of the techniques in their professional practice; show familiarity with teaching content in a 100-question multiple-choice test with at least 80 correct answers; and practice and demonstrate ability to analyze provider-patient interactions and suggest appropriate Comfort Talk® skills online. Trainers will also need to submit at least 6 Suggestion Cards per cycle to the web platform, successfully complete 8 Neutralizer Exercises on a new platform element, and pass virtual patient interactions. Observation of the trainer by Hypnalgescics staff initially (and trained trainer-trainers later) during at least two live teaching sessions with customers will be used to assess and certify the trainer's teaching ability. Criteria will be correct content delivery in the time allotted, correct use of the hand-outs and materials from the trainer portal as prescribed, and professional trainee interaction. Feedback from trainers and customers

by questionnaire will serve as measure of efficacy and acceptability of the train-the-trainer prototype. Trainers will be recertified every two years based on training performance as evidenced by customer feedback; on-site, video-linked, or video recorded observation as well as successful interactions in the virtual environment.

Champion Development and Culturally Conscious Feedback for Continuous Quality Improvement

Institutional champions will be selected based on their interest, input by their superiors, and observed performance of Comfort Talk® skills during Comfort Talk® training. The Champions will support continuity of program usage, report back to Hypnalgessics of effects and barriers, update their local site on new information, and introduce new personnel to the basic ideas of Comfort Talk®.

Champions will undergo trainer-training and be engaged in training within and outside their team within the institution. Through their site-specific website they will provide feedback based on their observations, report on their experience with specific patient populations, need for their special considerations in the training design, support the entry of new Suggestion Cards, and enhance the repertoires of the Word Choices module.

Data mining tools will be used to look for patterns in the corpus of texts contributed in the Training Support Module within and across institutions. Text analysis has a three-fold benefit. First, demographic information can be mapped to the facility-specific and patient-type-specific text features to inform ongoing training site-personalization strategies. Second, a modified sentiment analysis tool will allow automatic feedback during user interaction with the Word Choices activity online. Third, novel language contributions can be flagged during analysis and evaluated as possible new Comfort Talk® techniques. This will enable culturally-conscious use of behaviors and wordings for integration into the overall Comfort Talk® skill repertoire, generation of video content, and programming of the avatar interactions.

Human Subject Involvement, Characteristics, and Design

Recruitment

We approached several medical centers about their interest in receiving Comfort Talk™ Training. Among several interested institutions, we initially chose three test sites; Tufts Medical Center, Boston Medical Center, and Ohio State University Medical Center. The centers expressed particular interest in having their MRI teams receive training in Comfort Talk™ in their facilities based on the feedback they received from their MRI teams and administrators.

Based on the excellent outcome data on reduction of cancellations in MRI and greatly improved patient satisfaction and feedback after Training of the MRI Campus at OSU, the Department of Radiology became interested in expanding training to the other MRI sites (which are now included in this protocol). As of April 2013, this protocol is open only to MRI facilities of The Ohio State University Wexner Medical Center. No subsites are involved.

Participation in the training will be in on a voluntary basis. The facilities will inform Hypnalgessics, LLC which team members wish to participate and were selected. The PI or his representative will then consent individuals who signed up for the training. Consent will be

obtained by using the standard complete institutional Informed Consent Form and will be documented in writing. Consenting individuals will obtain a copy of the signed form. Individuals will be informed that participation is their choice at all time points. They will be explained the nature of Comfort Talk™ and of the training, and that the effect of training will be evaluated by use of questionnaires, a computer-based pre- and post test, and observation of behavior, as well as noncompletion rates and economic parameters of the entire MRI unit.

Protection Against Risks

Measures that minimizes risk of identification of individual team members are as follows: Participants will complete the questionnaires and tests using self-selected ID codes, which they keep throughout the training, so that successive evaluations can be tied but not be associated with or traced to the identity of the individual who entered them. Observations of behavior before and post training will be based on a an Objective Structured Clinical Examination for the group (GOSCE) which rates the frequency by which certain behaviors are displayed throughout the day within the culture of the institution without identification of the individuals involved. For example, two observers will note whether there is infrequent or frequent use of negative suggestions, adaptation of the personnel's to the patients' level (e.g. bending over towards supine patients). The averaged daily observations will then be averaged over several days across several scanner units of the facility so that potential identification of individuals becomes even less possible. Another outcome criterion, the overall rate of failed MRI scans and the associated loss of revenue, are fiscal data that are obtained in the normal course of business.

During training, trainees will become familiar with self-hypnotic relaxation and are invited to experience self-hypnosis. An uninformed concern for trainees may be that patients become "stuck" in trance or don't want to return to their natural state of awareness in time to leave the facility. This is addressed by instructions of how to accelerate and assure full reorientation. The trainers are all very experienced and will assure that trainees are fully realerted at the end of the session.

Training materials and scripts the trainees will use with each other include instructions to incorporate only the suggestions that are helpful for them and to ignore unhelpful or unpleasant associations.

A very unlikely risk could conceivably be a scenario in which a person with active multiple personalities or active psychotic disease that may not have been obvious or known or treated prior to training becomes revealed. In this cased the individual would be referred for treatment. We note however that the likelihood of such reaction in such individuals is considerably less with Comfort Talk™ than if they were exposed by routine protocols to an MRI examination, which by itself sometimes elicits an panic reaction.

Confidentiality for possible revelation of personal issues of the trainees during the sessions will be sought in a training contract.

Prisoners and Children will not be among the trainees since we will be only working with employees who are all adults.

Potential Benefits

The trainees will learn skills that will enable them to handle stress better in themselves and in others. Their interpersonal and communication skills will improve and they will receive more

positive patient feedback. They will also be at greater ease to address conflict in a productive fashion. The trainees will be better equipped to express their empathy in a way that helps the patient. When their patients remain calm and still during their scans they will obtain better image quality reflecting well on the professional capabilities of the MRI technologists. They will be able to perform safer practice and reduce the need for medical sedation. When patients are calm they also tend to get through examinations faster and that may have positive effects on unwarranted overtime.

Potential benefits to the department will be a safer practice, higher quality images, greater patient satisfaction, and more revenue.

Considering the minimal risk of learning the new skills shifts the balance greatly towards the benefit and opportunity of being a better clinical practitioner.

Importance of the Knowledge to be Gained

The outcome of the study will provide the metrics of the Comfort Talk™ training intervention which can open the path to broader adoption and implementation in an effort to better address patient distress and improve quality, safety, and cost effectiveness of MRI imaging.

Data and Safety Monitoring Plan

This is not a clinical trial. There will be local PIs at the three institutions who will oversee the work of Hynalgesics, LLC in their institutions.

Subject Characteristics for Training Module Development and Testing

Subject criteria: The electronic module will first be tested by experts in hypnosis and/or participants of prior workshops for further development (not part of this IRB at OSU) before the electronic module will be integrated in the training at OSU and tested for acceptance by the OSU participants in the study.

- a) Inclusion criteria: ability to give consent
- b) Exclusion criteria: inability to operate a computer
- c) Withdrawal/Termination criteria:

Risk/benefit assessment: Individuals can learn new content and influence how it will be taught to upcoming generations

- a) Physical risk: Looking at computer screen may cause muscle tension
- b) Psychological risk: Content may remind viewers of distressing content
- c) Social risk: People who engage in learning how to achieve rapid rapport or hypnotic language may be conceived as wanting to exert undue influence on others
- d) Benefit of participating in the study: Individuals can learn new content and influence how it will be taught to upcoming generations

Specific methods and techniques used throughout the study: Interacting with computer

- a) Laboratory tests: none
- b) Study Procedures: following instructions on computer
- c) Subject Timeline: 4 hrs

Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

We will set up a Data and safety Monitoring Committee.

- a) Serious/Adverse event reporting: Adverse events will be reported to the IRB per The Ohio State University Medical Center's protocols

b) Accountability procedures as they relate to drugs, devices, and data: release of drugs and devices are not part of this study. The study files in the hand of the investigators will not contain identifiable individual information. The investigators will secure the study files in locked cabinets.

Subject Participation of the Individuals beta-testing the Module prior to testing at OSU (not part of this IRB application)

- a) Recruitment: From registrants at the local and national hypnosis societies (e.g. NESCH, SCEH) and prior Comfort Talk™ trainees
- b) Registration:
- c) Screening Interview/questionnaire: All participants at the workshops of NESCH and SCEH and affiliates are already prescreened by the event organizers to be in professional good standing and mentally stable
- d) Transportation: N/A
- e) Informed consent process and timing of obtaining of consent: before engaging in module
- f) Study performance location: Computer stations at the volunteer's choice on their own time and location

Personnel, who will conduct the study, include:

- a) Present during study procedure(s) and their proximity during the study: Drs Ajam and Lang will be available by phone since it is likely that many participants will do the module at home
- b) Primary responsibility for the following activities:
 - Obtaining informed consent: Dr. Ajam, or her representatives
 - Providing on-going information to the study sponsor and the IRB: Dr. Amna Ajam
 - Maintaining participant's research records: Drs. Ajam and Lang

Subject fees: none

Study results:

- a) Procedures to protect subject confidentiality: data files will be kept in locked cabinet. No individually identifiable data will be recorded during training or evaluation.

Confidentiality:

- a) Certificate of Confidentiality
- b) How data will be coded, recorded, and stored to protect confidentiality: For training module development, subjects will use a self assigned unique identifier which will not be known to or recorded to the investigators.
- c) Parties who will have access to the data, including the key to the identity code: We will not keep the identity code
- d) Parties who will have access to research records: Drs. Ajam and Dr. Elvira Lang

Subject Characteristics for Testing of Training and its Effects at The Ohio State University Wexner Medical Center

Subject criteria: The persons assessing the pilot (already beta-tested with experts) training program will be employees and staff of the MRI unit of The Ohio State University Wexner Medical Center and residents on rotation there

- a) Inclusion criteria: employment status and ability to give consent
- b) Exclusion criteria: inability to operate a computer
- c) Withdrawal/Termination criteria: upon request or termination of employment

Risk/benefit assessment: Individuals will be learning enhanced rapport techniques for managing patients undergoing MRI examination

- a) Physical risk: None beyond usual occupational exposures to computers and lectures
- b) Psychological risk: Minimal. Discussing adverse events may cause employees to recall prior distressing situations
- c) Social risk: People who engage in learning how to achieve rapid rapport or hypnotic language may be conceived as wanting to exert undue influence on others. Patients may want to be treated preferentially by trained individuals who may elicit expressions or perceptions of some jealousy by untrained individuals.
- d) Economic risk: None
- e) Benefit of participating in the study: Individuals can learn new content and how to improve patients' experiences during MRI examinations and by reducing patients' stress reduce their own stress.

Specific methods and techniques used throughout the study

- a) Interacting with computer, lectures, small group discussion, observation of interaction with patients
- b) Laboratory tests: None
- c) Study Procedures: Training and observation of behavior
- d) Subject Timeline: Approximately 20 hrs of training incl. computer interaction, 15-30 min evaluation of training

Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

We will set up a Data and safety Monitoring Committee. In addition, Dr. Amna Ajam and the Clinical MRI Supervisor will perform ongoing spot checks.

- a) Serious/Adverse event reporting: Adverse events will be reported to the IRB per The Ohio State University Medical Center's protocols
- b) Accountability procedures as they relate to drugs, devices, and data: release of drugs and devices are not part of this study. The study files in the hand of the investigators will not contain identifiable individual information. The investigators will secure the study files in locked cabinets.

Subject Participation

- a) Recruitment: From employees in MRI unit
- b) Registration:
- c) Screening Interview/questionnaire: Being employed and willing to participate
- d) Transportation: N/A
- e) Informed consent process and timing of obtaining of consent: before engaging in module and training
- f) Study performance location: Lectures and small groups: on-site; Computer stations at the volunteer's choice on their own time and location

Personnel, who will conduct the study, include:

- a) Present during study procedure(s) and their proximity during the study: Dr Lang will be available by phone since it is likely that many participants will do the module at home
- b) Primary responsibility for the following activities:
 - Obtaining informed consent: Dr. Amna or her representatives
 - Providing on-going information to the study sponsor and the IRB: Drs. Amna and Lang
 - Maintaining participant's research records: Drs. Amna and Lang

Subject fees: none

Study results:

- a) Procedures to protect subject confidentiality: Only aggregate data will be recorded; there will be not individually identifiable data

Confidentiality:

- a) Certificate of Confidentiality
- b) How data will be coded, recorded, and stored to protect confidentiality: No individually identifiable data will be recorded during training or evaluation
- c) Parties who will have access to the data, including the key to the identity code: We will not keep the identity code
- d) Parties who will have access to research records: Drs. Amna Ajam and Elvira Lang

Alternatives: Patient sedation which will be avoided by this training

How new information will be conveyed to the study subject and how it will be documented: Per e-mail or mail with log of date of information

Payment, including a prorated plan for payment: None

Payment for a research-related injury: None

Outcome: The outcomes will be success of the training program as determined by OSCE and the rates of non-completion of MRIs, scans exceeding allotted time slots, sedation rates, patient satisfaction scores, equipment and resource utilization, and economic at baseline before and after the training

Tissue banking considerations: N/A

VULNERABLE POPULATIONS: No prisoners or individuals unable to consent

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August 15, 2014

Protocol Number: 2011H0205
Protocol Title: AMELIORATION OF CLAUSTROPHOBIA AND DISRUPTIVE PATIENT MOTION IN MRI, Amna Ajam, Radiology
Type of Review: Continuing Review with Amendment - Expedited
IRB Staff Contact: Matthew Carter - Biomedical IRB Analyst
614.247.1557
Carter.1005@osu.edu

Dear Dr. Ajam,

The Biomedical Sciences IRB **APPROVED** the Continuing Review of the above referenced research.

Date of IRB Approval: August 13, 2014
Date of IRB Approval Expiration: August 13, 2015
Expedited Review Category: 9

In addition, the IRB **APPROVED** the amendment request to amend the research dated May 22, 2014 (remove Nichole Storey from the study team) on August 13, 2014.

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for **one year** from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378. All forms and procedures can be found on the ORRP website – www.orrp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zadnik, OD, PhD, Chair
Biomedical Sciences Institutional Review Board





Biomedical Institutional Review Board

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August 13, 2015

Protocol Number: **2011H0205**
Protocol Title: **AMELIORATION OF CLAUSTROPHOBIA AND DISRUPTIVE PATIENT MOTION IN MRI, Amna Ajam, Radiology**
Type of Review: Continuing Review – expedited
IRB Staff Contact: Erin Odor Phone: 614-688-1332 Email: odor.3@osu.edu

Dear Dr. Ajam,

The Biomedical IRB **APPROVED BY EXPEDITED REVIEW** the above referenced research. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research meets the applicability criteria and one or more categories of research eligible for expedited review, as indicated below.

Date of IRB Approval: August 11, 2015
Date of IRB Approval Expiration: August 11, 2016
Expedited Review Category: 9

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

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Karla Zadnik, OD, PhD, Chair
Biomedical Sciences Institutional Review Board

