TRAINING IN COGNITIVE BEHAVIORAL THERAPY FOR VAGINISMUS: PHASE I

Vaginismus involves "recurrent or persistent involuntary contractions of the perineal muscles surrounding the outer third of the vagina when vaginal penetration by a penis, finger, or other object is attempted."[1-2] This problem is commonly reported by women[3-6] and can negatively impact their psychosocial and psychosexual functioning and broader quality of life.[1-2] Efficacious, effective and cost efficient non-pharmacologic treatments, i.e., cognitive behavioral therapy for vaginismus (CBT-V),[7-9] are available, and in widespread use outside of the U.S. However, these treatments are not widely used in the U.S., largely due to lack of medical education and training opportunities and appropriate supervisory resources (i.e., a cadre of senior clinicians trained in this protocol).

To address this gap, we have designed a ***collaborative, interdisciplinary, cost effective and sustainable*** simulation training protocol for CBT-V, which can then be piloted with standardized patients (SPs). We seek funding from the Stanford Teaching and Learning Academy to ***collaborate*** with Dr. Moniek ter Kuile of Leiden University Medical Center (LUMC) in the Netherlands (who created CBT-V and has evaluated its efficacy in a series of clinical trials in Europe[7-9]) and the Stanford Center for Immersive and Simulation Based Learning (CISL).

SPECIFIC AIMS

1) Create a CBT-V simulation training protocol.
2) Create at CBT-V script/patient story and train a standardized patient (SP) to use it.
3) Implement an iterative pilot of the simulation protocol/script incorporating stakeholder (clinician, patient, supervisor and simulation center staff) feedback into protocol revisions.

BACKGROUND AND RATIONALE

Vaginismus is currently categorized as a Genito-Pelvic Pain/Penetration Disorder (GPPPD)[10] and is presumed to be the result of an involuntary muscle spasm involving the musculature of the outer third of the vagina,[1-2] which makes any kind of vaginal penetration painful or impossible. Population based studies suggest variable prevalence of vaginismus by culture, age and geographic location, with most credible prevalence estimates hovering around 6%.

Cognitive Models of Vaginismus. Ter Kuile, Both, and van Lankveld (2010)[11] proposed a circular fear-avoidance model of penetration disorder (i.e., vaginismus) (**Figure 1**), which outlines both the initiation and maintenance of vaginal pain related to penetration and includes cognitive, behavioral, and psychophysiological components. Specifically, it demonstrates that negative penetration experiences (e.g., painful penetration) can lead to the development of maladaptive, catastrophic thoughts about penetration/pain (e.g., "Penetration will be unbearable"), which may, in turn heighten anticipatory anxiety and fear about penetration. Heightened emotional reactivity to attempted penetration can lead either to avoidance of penetrative sexual encounters all together, or to hypervigilance- -i.e., intensely selective attention to pain sensations or stimuli associated with penetration- -which may compound difficulty and pain associated with penetration (**Figure 1**).

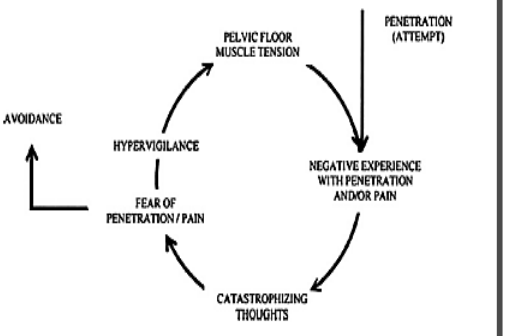

Figure 1:
Cognitive Antecedents of Vaginismus

Cognitive behavioral interventions, such as CBT-V, which target maladaptive beliefs about sexual penetration are highly effective in treating vaginismus.[7-9] Typically a CBT-V protocol is implemented in an OB-GYN examination room by an interdisciplinary clinical team consisting of: 1) an OB-GYN provider who offers the patient education about female genital anatomy, the musculature associated with the vaginismus response, and safe self-insertion of dilators used for therapeutic exposure; and 2) a skilled psychotherapist who helps the patient to

identify and address catastrophic fear of/over attention to pain with penetration, and who supports and maintains the patients' emotional engagement during dilator based exposure.

U.S. based physicians and mental health providers receive little to no training in the assessment and treatment of vaginismus and none are trained to use CBT-V. This gap warrants attention as it translates into diminished treatment options for women. *Given the greater array of evidence based treatment options currently available to male patients with sexual problems, this work addresses an important gender based disparity in U.S. health care*.

APPROACH

We will achieve our specific aims through a series of interlocking steps designed to train our team to master the implementation of CBT-V. **First**, selected members of the Stanford team will "embed" themselves in ter Kuile's LUMC clinic and observe her implement CBT-V with English speaking patients. **Second**, the team will work with the CISL staff to create a simulation training protocol and the development of a patient "back story" (i.e., how this "patient" developed vaginismus) and scripts to be used for the SP undergoing CBT-V. **Third** we will pilot the CBT-V simulation protocol with this SP in an iterative "user centered design" process during which feedback from all stakeholders (simulation center staff, CBT-V clinicians, "patient", and "supervisor"- - ter Kuile) is continuously elicited, processed, and subsequently incorporated into a revised version of the simulation protocol. This is a perfect first step in training U.S. clinicians in CBT-V and will yield a highly refined and re-usable simulation protocol.

Evaluation will also be an iterative process designed to produce a constant stream of constructive feedback to the protocol designers, therapists, and supervisor regarding the quality and credibility of the simulation protocol and SP script, treatment fidelity (i.e., therapist's correct implementation of CBT-V techniques in accordance with the treatment manual), and therapist comfort and effectiveness with the protocol. Evaluation efforts will include: a) formal, written evaluative feedback from the "patient" regarding the quality/credibility of the simulation protocol, perceptions of therapist comfort and effectiveness with the protocol, and "patient" comfort with the CBT-V treatment throughout the entire simulation implementation period; b) therapist self-assessment regarding comfort with and self-efficacy for correct implementation of the protocol (gathered at the beginning and conclusion of each simulation); and c) formal, written evaluative feedback from Dr. ter Kuile to each therapist regarding correct and appropriate implementation of the CBT-V protocol. Formal evaluation of treatment fidelity on the finalized protocol is delineated in a Phase II proposal.

Timeline. Sept- Dec, 2016, draft simulation protocol and patient script; **January, 2017**, immersion in LUMC clinic; **Jan-Feb, 2017**, refinement of simulation protocol and script; **Jan – Aug**, 2017, iterative piloting of simulation protocol.

OUTCOMES

Anticipated Work Products include: 1) a trained team of CBT-V therapists at Stanford; 2) high quality "how we did it" presentations for professional conferences; and 3) a published article delineating the development of a CBT-V simulation protocol.

Dissemination efforts will include the scholarly presentations and products delineated above. In addition, it is our long term goal to secure additional funding for this newly trained team to ultimately develop a Stanford based training on CBT-V for future generations of clinicians. Further, it is our hope to tailor this treatment for sexual violence related posttraumatic stress disorder. Drawing upon the trauma expertise of the Stanford Psychiatry team, we hope to further collaborate with ter Kuile's team to develop a trauma centered CBT-V protocol.

CONCLUSIONS

Our proposal, which centers on simulation based training for a core group of master clinicians, aptly addresses this problem in an ***effective and cost-efficient manner***. Simulation based learning is a novel means of safely pursuing a first stage of training in the CBT-V protocol. As the simulation protocol will be highly refined (and thus re-usable) at the conclusion of this project, the ***sustainability*** of this training program is ensured.

Anticipated Questions about the Timeline, Budget and its Justification:

Q. **Why is travel to the Netherlands required, for how long and how did you derive your travel costs?** A: It is imperative that we see the treatment implemented with real patients by a master clinician in order to derive a realistic simulation protocol and patient script. For obvious reasons, video recording of this treatment with real patients is inappropriate. Travel costs were based upon the most economical airfare and lodging accommodations identified, and are based on one traveler. We are investigating other sources of funds for travel for other team members, including our post-doctoral fellow, who has access to travel funds restricted for trainee use.

Q. **Why can't you begin consultation until January 2017?** A: It takes months for the Dutch team to arrange English speaking patients for observation. If funded, we will use the months of August -December, 2016 to review the treatment manual, extant literature on this treatment and work with the Dutch team led by ter Kuile to develop the initial draft of a simulation protocol and patient script, which can then be refined upon visiting the LUMC clinic.

Q. **Why must ter Kuile travel to the U for the development the simulation protocol?** A: Several reasons. We need her to help us train the simulation patient and to provide real time coaching of the therapists as they learn to implement this treatment. While it is technically possible to do this without travel, i.e., she could coach via skype, the 9 hour difference between California and the Netherlands makes this very difficult indeed. Moreover, the appropriateness of transmitting this treatment, even via simulation and SPs, over the internet is questionable and raises significant ethical questions.

Appendix A

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