Introduction

Background

Intimate partner violence (IPV) is a prevalent problem that has serious effects on human health. According to the National Violence Against Women Survey (NVAVS) funded by the Center for Disease Control (CDC) and the National Institute of Justice, about 5.3 million intimate partner victimizations occur among women in the United States each year (Black et al., 2010). The consequences of violence on victims' well-being include acute physical injuries, as well as long term consequences regarding mental and physical health (Campbell, 2002; CDC, 2003). Physical injuries due to violence range from mild to severe and can even be lethal (Greenfield et al., 1998). Furthermore, women who are victimized are significantly more likely than non abused women to have a variety of disabilities, sicknesses, gynecological problems, disturbed sleep, and pain (Morbidity and Mortality Weekly Report, 2008). Victims may also adopt coping strategies that involve harmful health behaviors, including smoking, drinking, taking drugs, or engaging in risky sexual activities (Greenfield et al., 1998). The chronic stress that many victims experience also takes a toll on cognitive and emotional functioning and is often a precursor to other mental health issues (Campbell 2002). Indeed, violence is significantly related to depression, anxiety, substance abuse, and traumatic stress reactions (Archer, 2000).

Types of Intimate Partner Violence

There are two commonly recognized types of intimate partner violence: *characterlogical violence* and *situational couple violence* (Babcock, Canady, Graham & Schart, 2007; Johnson, 1995). The focus of this study is on situational couple violence.

Characterlogical violence (or "patriarchal terrorism") refers to systemic male violence. It includes violence, economic subordination, threats, isolation, and any other control tactics. In families who experience patriarchal terrorism, violence occurs on average more than once a week and also escalate in seriousness over time. According to the literature, the motivation behind this type of violence is a man's desire to have general control over woman (Johnson, 1995).

Situational couple violence is a form of IPV where there is mutual violence between partners. An individual may not intend to hurt his/her partner, but nevertheless "loses control" and becomes aggressive (Archer, 2000). Both men and women can be victims of this type of relationship abuse, and it appears that females have higher rates of perpetration than previously thought (Archer, 2000; Johnson, 1995).

A comparison of the two forms of violence is provided in the following table:

Characterlogical violence	**Situational couple violence**
Male uses physical and emotional abuse to dominate and control his female partner. (Johnson, 2008)	The partners may be assaulting each other rather than one being a clear aggressor and the other being a clear victim (Dutton & Corvo, 2006)
The victim (female partner) experiences continuous fear and control (Johnson, 2008).	Violence erupts between partners over efforts to control a specific situation (Rosen, Stith, Few, Daly & Tritt, 2005).

	There may be areas of strength in the relationship (Stith, McCollum, Rosen, Locke & Goldberg, 2005).
The victim (female partner) may stay in the relationship for pathological needs (Johnson, 2008).	The partners may prefer to remain in the relationship with a desire to end the violence, enhance the quality of their marital relationship and successfully parent their children (Stith, McCollum, Rosen, Locke & Goldberg, 2005).

As a result, the two forms of couple violence differ by their mode, frequency, severity, and intent. To this end, situational couple violence is not just a "milder form" of violence; it is rather a separate form.

Couple Therapy for Situational Couple Violence

According to Johnson and Leone's (2005) study using data from a large national survey, about 65% of violence in relationships exhibit the characteristics of situational couple violence. Importantly, the partners who are experiencing situational couple violence may prefer to remain in the relationship with a desire to end the violence, enhance the quality of their marital relationship, and successfully parent their children (Stith, McCollum, Rosen, Locke & Goldberg, 2005). Based on these observations, McCollum & Stith (2007) argue that carefully conducted conjoint treatment may be a preferable treatment for situational violence.

The Aim of the Proposed Research

This study aims to diminish situational couple violence and its consequences by investigating the effectiveness of couples' therapy in preventing situational violence. While couples therapy has been applied in working with situational couple violence before, empirical data on its effectiveness is limited. The main contribution of the proposed study is that it will use psycho-physiological markers to investigate the effectiveness of the couple therapy in preventing and diminishing situational couple violence.

Attachment, Affect Regulation, and Intimate Partner Violence

A well-documented explanation for relationship violence comes from attachment theory. According to attachment theory, early experiences of insecure attachment relationships are associated with dysregulation of affect, or emotions, later in life (Keiley, 2002). Studies investigating the association between attachment and relationship violence have found that individuals who are violent report significantly higher levels of relationship anxiety (Holtzworth et al., 1997). Many studies have also demonstrated the link between attachment security and constructive communication skills that might lessen the use of violence in arguments (Rholes & Simpson, 2004). During problem solving, secure individuals are able to regulate their emotions more effectively and are in turn less rejecting, more supportive, and more inclined to rely on and trust a partner, as compared to insecure individuals (Mikulincer & Shaver, 2007).

Attachment theory has been widely used by violence researchers. Earlier research has concentrated mostly on individual perspectives in understanding the interactions in which violent behaviors emerge. However, increasingly researchers began to improve their understanding in dyadic aspects of intimate partner violence since violent behaviors occur within the couple

system (Mikulincer & Shaver, 2007). The relationship between attachment and affect regulation is also well established (Mikulincer, Shaver, & Pereg, 2003).

The objective of the current study is to provide quantitative evidence that attachment based couple therapy will be effective in preventing violence through regulation of affect. Attachment based couple therapy models deal with many relationship problems by intervening in the "interactional cycle", i.e., rigid patterns of negative interactions that couples develop over time (Johnson, 1996). To change these patterns, therapists teach communication strategies and the healthy expression of emotions to promote change in emotional, cognitive, and behavioral pathways (Johnson, 1996). Through the expression of emotions in response to a partner's negative responses, such as unavailability, detachment, or rejection, individuals can better regulate their emotions and develop more functional coping skills.

For many relationship problems, including communication (Johnson, & Whiffen, 1999) and sexual problems (Johnson et al., 1999; Johnson, 1996), attachment based couple therapy has been shown to improve relationships by helping partners regulate their emotions more effectively. Since dysregulation of affect is also known to be an important predictor in the escalation of violence (Penney & Moretti, 2010), this project bridges these links to hypothesize that attachment based couple's therapy will be effective in preventing situational couple violence through regulation of affect. For this purpose, psycho-physiological markers of emotion regulation will be used to monitor the relationship between affect regulation and the change in the interactions between the couple.

Psycho-Physiological Markers of Emotion Regulation

Indicators of stress reactivity, including cortisol level and vagal tone, have been effectively used to assess the effectiveness of psychotherapy for various mental health problems, e.g., depression (Huber et al., 2006) and posttraumatic stress disorder (Olff et al., 2007). Such psychophysiological variables are also commonly used as indicators of affect regulation (Krakowski, 2003). This project will build on these results and use stress related physiological measurements to investigate the effectiveness of conjoint therapy. This will be achieved by longitudinal monitoring of the stress regulatory endocrine system before, during, and after conjoint therapy with violent couples.

Significance

Many programs designed to prevent intimate partner violence solely target male offenders (Babcock, & La Taillade, 2000). While, domestic violence shelters and other facilities traditionally support only female victims by offering therapy and educational programs. However, recent findings on separate batterer intervention programs indicate that these programs do not work as well as expected (Dobash et al., 1996). Although batterer's intervention programs for male offenders seem to be effective in reducing physical violence for some men, there is lack of support that they are effective for all men under all circumstances. Many of the program evaluations will not take into account the high dropout rate. In some studies, the dropout rate is almost as high as 62% (Dobash et al., 1996). These observations suggest that current intervention programs that treat batterers and victims separately may have limited effectiveness for many couples. Furthermore, in contrast to widespread expectations, couples who experience situational

couple violence may still want to remain together. Therefore, for some couples it is important to be able to improve the relationships and end the violence within the dyad.

Literature on the Effectiveness of Couple Therapy

Previous research has examined couples' therapy based treatment for domestic violence across several studies. In these studies, researchers have conducted couple's therapy when working with couples experiencing domestic violence and reported differing, but promising results. In 1984, Taylor used Cognitive Behavioral Therapy in an 8 stage couple's treatment program and, after a 6 month follow up, 65% of the 50 couples treated were "violence-free". In 1985, Riza, Stacey, and Shupe conducted couples therapy, and one year after counseling, 78% reported a reduction or cessation of violence with 79% remaining together. In 2002, Stith, McCollum, Rosen, and Locke conducted couple's therapy with 20 couples with a 43% recidivism rate, and a follow up at 6 months measured by the woman's report of any violence. In 2006, LaTaillade, Epstein, Werlinich implemented the Couples Abuse Prevention Program (CAPP) based on cognitive behavioral couple treatment with 17 couples. They found significant decline in partner hostile withdrawal (withholding emotional contact in a hostile fashion) for men and women, trends toward less humiliating behaviors by their partner in men and women, and a significant decrease in negative communication by males and females. In 2012, Gottman and Bradley implemented the Creating Healthy Relationships Program (CHRP), which is a conjoint couple and relationship education program designed to reduce IPV in low income situationally violent couples. In this study, Gottman and Bradley conducted therapy with 115 couples. Results showed that participation in CHRP prompted an increase in attitudes that reflected healthy relationship skills, predicting a reduction in IPV for the follow up.

In 2012, Linville, Shamblin, and Ball interviewed 48 client participants and 5 staff members to get a better understanding of couples' experiences when participating in a conjoint treatment program for intimate partner violence. Participants reported benefits and changes in their lives from participating in the conjoint groups for intimate partner violence feeling they felt the experience increased safety, that they benefited from being in a group that supported one another working toward a common goal, an increased awareness of the role their behavior plays on their relationship, behavior changes such as being calmer, listening better, and taking better care of themselves, and finally learning tools for how to better communicate with their partners and handle relational stress.

The Contribution of the Current Study

While the literature on the effectiveness of couples therapy suggests that couples therapy can be effective in preventing and diminishing situational couple violence, these results are mostly based on self-report data. Therefore, they do not provide quantitative grounds for the link between couples therapy and decline in situational couple violence. The aim of this study is to investigate this link by monitoring psycho-physiological markers of emotion regulation along with self-report data. If successful, the results of this study will provide quantitative and objective evidence on the effectiveness of couple therapy. Furthermore, these results will provide preliminary data in uncovering the psycho-physiological mechanisms through which couple therapy reduces violent behavior.

Overall, this study has significance not only for the scientific community, as research on the effectiveness of conjoint therapy can pave the way for more comprehensive and large scale effectiveness studies, but for the individual participants, as they will be receiving quality treatment for a severe and potentially debilitating problem: violence within their intimate relationships.

Study Design & Objectives

Purpose

The purpose of this study is to understand whether the couple therapy that is used in practice is effective in preventing situational couple violence. More specifically, we will focus on couples with mild to moderate forms of situational couple violence to investigate how couple therapy can be effective in preventing the escalation and recurrence of situational couple violence. For this purpose, the response of partners to therapy will be investigated by integrating self-report questionnaires and psycho-physiological markers of emotion. All couples who exhibit characteristics of characterlogical violence will be excluded from the study.

The change in partners' emotion regulation over the course of therapy will be measured using psycho-physiological markers of stress response. Using these measurements, the interplay between changes in violence and the emotion regulation of partners in relation to each other will be investigated in a dyadic (couple) context. More specifically, the following aims will be pursued to understand the relationship between couple therapy, emotion regulation, and violence:

Aim 1: Examine the associations between IPV and each partner's psychophysiological regulation in terms of Hypothalamic Pituitary Adrenal (HPA) activity and Parasympathetic Nervous System (PNS) activity. This aim will investigate whether dysregulation of HPA and PNS activity in each partner is correlated with the existence and intensity of IPV for the couple. Existence and intensity of IPV will be assessed using self and partner report questionnaires. HPA activity will be measured using salivary cortisol, and PNS activity will be measured using vagal tone and vagal regulation by using an eMotion Heart Rate Variability (HRV) sensor.

Aim 2: Examine the longitudinal effects of conjoint therapy on IPV and each partner's psychophysiological regulation in terms of HPA and PNS activity. This aim will investigate whether the reported intensity of IPV for couples decreases after couples start therapy and whether this change is correlated with regulation of HPA and PNS activity for each partner. This aim will examine the effect of couple therapy on each individual partner separately.

Aim 3: Examine the longitudinal effects of partners' psychophysiological regulation on each other's psychophysiological regulation and on IPV. This aim will explore patterns of change in each partner's psychophysiological regulation as a function of their partner's psychophysiological regulation. More specifically, this aim will investigate whether couple therapy facilitates change by restructuring the relationship in such a way that the change in one partner's behavior helps the other partner regulate their emotions in a functional way.

Study Design
This study has a longitudinal design that requires therapy sessions over 8 weeks, with data collected at every visit. Couple therapy will be conducted using an attachment and affect regulation based therapy approach described below under "Couple Therapy". Data will be collected in the form of self-report and partner-report measures, as well as physiological screening of the neuroendocrine system. These measures are described below under "Data Collection". The flowchart for the design of the study is shown below.

After careful screening, eight couples will be enrolled in the study. The couples will be divided into two groups, each consisting of four couples. Distribution of participants to the two groups will be randomized. Group 1 will immediately begin 8 weeks of couple therapy and Group 2 will complete8 weeks of couple therapy after an 8 week (+ or – 10 days) waiting period is completed.

The pre-test, post-test, and follow-up physiological data collection will be completed at the following times for couples beginning the 8 weeks of couple therapy:

- Baseline Pre-test: Before starting the therapy sessions.
- Post-test: One week (+ or – 5days) after the end of the therapy session.
- Follow-up: Three months (+ or – 10 days) after the post-test.

The participants that are assigned to Group 2 will also complete the physiological data collection before starting the 8 week waiting period. When participating in the 8 week couple therapy Group, participants will complete a small number of assessments at each therapy session.

The participants that are assigned to Group 2 will have one additional assessment session at baseline. In order to help those in Group 2 who will not be receiving therapy for the first 8 weeks, individuals in this group will be taught safety planning, given information on local resources to help victims of violence, and will be instructed in stress and anger management strategies. Following this 8 week waiting period, they will receive 8 weeks of couple therapy unless they choose not to. All the physiological and behavioral data collection will be repeated once Group 2 starts therapy.

If a couple discontinues after the baseline and before the end of the study (EOS), the EOS assessments should be obtained.

For couples in Group 1, involvement in the study will last throughout a period of five months with approximately 14 hours of active participation. For couples in Group 2, involvement in the study will last throughout a period of seven months with approximately 16 hours of active participation.

Couple Therapy
Each couple will receive couples therapy for 8 weekly sessions. Each therapy session will last approximately an hour. The therapy sessions will take place in UH Mood Disorders Program, room #12-126, on the 12th floor of the W.O. Walker Center. An attachment and affect regulation based therapy approach will be used in couple therapy.

The participants will receive standard couples therapy that they would have access to outside of the study. The therapy itself is not experimental, but rather it is the data collection, physical measures, and timing which are the experimental portions of the study.

All therapies will be conducted by the PI, Dr. Gunnur Karakurt. Dr. Karakurt is a Licensed Marriage and Family Therapist and AAMFT (American Association of Marriage and Family Therapy) approved clinical supervisor.

Hypotheses

The main hypothesis of the proposed study is that conjoint therapy will gradually promote affect regulation of both partners in orchestration; i.e., improvement in one partners' ability to regulate emotions will have a positive effect in the other partner's ability to regulate emotions. If the outcome of this project supports this hypothesis, these results will provide biologically interpretable and quantitative grounds for the effectiveness of conjoint therapy and pave the way for more comprehensive and large scale effectiveness studies, which, in turn, may establish conjoint therapy as a strategy that will complement "parallel track" treatment in preventing and diminishing IPV.

The physiological processes that were found to link attachment and affect regulation include parasympathetic regulation of heart rate and Hypothalamic Pituitary Adrenal (HPA) axis activity (Beauchaine, 2001; Böhnke, Bertsch, Kruk, & Naumann, 2010; Porges, 2001). There is increasing evidence for the role of HPA axis in the development and enhancement of aggressive behavior in youth as well as adults. Furthermore, cardiac vagal tone, a common physiological marker of the regulation of the Parasympathetic Nervous System (PNS), is correlated with both anxious and disruptive behaviors (Böhnke, Bertsch, Kruk, & Naumann, 2010; Porges, 2001). Putting these observations together, the proposed research further hypothesizes that, through promotion of affect regulation, attachment based couple therapy will enhance regulation of PNS and HPA activity in couples, which in turn will have a diminishing effect on IPV.

In summary, the proposed research integrates research findings on the links between couple therapy, affect regulation, physiological markers of emotion regulation, and IPV to hypothesize and test a novel psychophysiological model for the mechanisms of change induced by couple therapy in the context of IPV.

Target Subject Population

Subject population:

Inclusion criteria:

1) This study is open to married, dating, and cohabiting couples.
2) Couples will have to be involved in an intimate relationship for at least one year with the current partner.
3) Both partners have to be older than 18 years of age at the time they signed the consent form.
4) Couples must have mild to moderate forms of situational couple violence.

5) Both partners must want couples therapy and both partners must desire to maintain the relationship.
6) Both individuals from the couple must participate concurrently, although they will sometimes be separated when asked questions of a sensitive nature.
7) Only heterosexual couples will be included in the study.
8) Both partners can be on psychotropic medication, if they are on medication and stable for past 12 month prior to enrollment, and no psychiatric hospitalization for past 2 years.

Exclusion Criteria:

1) Couples will be excluded from the study if there are indicators of severe intimate partner violence and/or characterlogical violence as this study targets couples with mild to moderate levels of violence. In order to distinguish between these two different types of violence, we will use specific items in the Conflict Tactic Scale (CTS) completed by both parties (Johnson, & Leone, 2005).
   Severe and/or characterlogical violence in this study is defined as follows:
   - If participants answer yes to both of the following items: "I punched or hit my partner with something that could hurt", "I kicked my partner".
   - If participants answer yes to any of the following items: "I choked my partner," "I slammed my partner against a wall," "I beat up my partner" "I burned or scalded my partner on purpose," and "I used a knife or gun on my partner".
   - One of the partners reports that a violent behavior was repeated at least six times in a year by their partner or themselves.

   If one of the partners indicates that any of these behaviors was exhibited by their partner or by themselves, the couple will be excluded from the study. In other words, these behaviors will not be scored, the scale will be used to detect the existence of any of these behaviors and exclude the couple in the case any of these behaviors exist.
   This conceptually based classification has been supported by factor analyses and by a growing recognition that the etiology and treatment of occasional minor violence (situational couple violence) may be quite different than the etiology of repeated severe assaults (characterlogical violence) (Gelles 1991; Hollzworth-Munroe and Stuart 1994: Johnson and Ferraro 2000: Straus and Gelles 1990).
2) Participants will also be excluded from the study if they answer yes to the following questions: "Do you have any firearm at home?", "In your previous relationships, did your partners ever tell you that you were physically abusive?"
3) Participants will be excluded from the study if they are not stable on psychiatric medication for more than 12 months.
4) Couples will be excluded from the study if there is a discrepancy between partners' reports of violence (received or perpetrated) in the CTS, defined as the difference between the partners' reports of the frequency of a particular act by the same partner. If the difference of the average score of the partners, or for any of the acts in the scale in the CTS is greater than 2, the couple will be excluded from the study. For example, if the female partner reports that the male partner pushed her three times but the male partner reports that he never pushed his partner, the couple will be excluded from the study since the couple will receive a difference score of three for the act of pushing.

5) Participants will be excluded from the study if undiagnosed, untreated serious mental illness is suspected during pre-screening. In order to screen participants with severe mental health problems, SCL90 will be used. We will use the cut off 0.885 with the area under the ROC curve with lower and upper bounds of the 95% confidence interval.
6) Participants will be excluded from the study if there are indicators of substance misuse. We will use the 16 item SSISA to screen participants' substance use. We'll score only 14 items out of the 16 items, which were selected by the TIP 11 consensus panelists from existing alcohol and drug abuse screening tools. A score of 4 or greater has become the established cutoff point.
7) Participants will be excluded if they reported any history of violent legal offences in the past 2 years.
8) Participants will be excluded if participants are currently suicidal and/or psychotic and/or patients who is moderately ill (e.g. equivalent of CGI score 3 or greater) at the pre-screening.
9) Participants who are not literate or cannot speak English will be excluded. The questionnaires require a 6th grade reading level.

Vulnerable populations:
Since this study targets couples with mild to moderate levels of situational couple violence, couples will be excluded from the study if there are indicators of severe intimate partner violence, including discrepancy between partners' reports of violence (received or perpetrated), untreated serious mental illness, or substance abuse. Participants must be literate and English speaking to participate in the study, as some forms must be filled out independently online.

Inclusion of Subjects with Major Psychiatric Illness:
This protocol allows for the inclusion of participants with major psychiatric illness as long as patients are on the same medication and stable for at least 12 months prior to enrollment. Patients with unstable mental health conditions (e.g. suicidal, psychotic, and/or SCL90 cut off score 0.885 with the area under the ROC curve with lower and upper bounds of the 95% confidence interval.) will be excluded at the screening period. All of the staff who will interact with participants will be trained to triage patients needing immediate attention and if necessary, they will be able to refer to community mental health agencies or research psychiatrists within the department for evaluation (see IRB protocol #01-07-05) to ensure they can answer questions about mood and anxiety disorders, and the medications in question (if applicable).

Employees of UHCMC or Case Western Reserve University (CWRU):
Employees of UHCMC or CWRU are allowed to enroll in to this study provided they meet the inclusion/exclusion criteria. However, we are not actively seeking out employees of UHHS or Case for enrollment.

Study Specific Procedures

Recruitment:
Couples will be recruited through mental health agencies and organizations, including Bowell Family Medicine Clinic, The Free Clinic, The Centers for Families and Children, Health &

Wellness Division, Rape Crisis Center, Domestic Violence & Child Advocacy Center, Bellefaire JCB, Beech Brooke, Insight Learning and Wellness Center and the UH Mood Disorders Program. These mental health agencies will be provided with the inclusion and exclusion criteria and they will refer potential couples to the PI. The availability of the inclusion and exclusion criteria to the referring individuals and organizations will enable these individuals and organizations to automatically exclude couples who do not meet these criteria. In addition to seeking referrals, IRB approved recruitment fliers will also be posted to places including local mental health and community agencies, faith organizations, and university counseling services. These fliers will indicate that a study on the feasibility of couple therapy is in the process of recruiting participants. The fliers will provide information on inclusion criteria, study procedures, confidentiality, and cost to participants. The fliers will also provide tear away stub with the PI's contact information. Once potential participants contact the PI, an initial interview will be scheduled. These potential participants will be further screened by the PI in the initial interview to determine whether they meet the inclusion and exclusion criteria.

For the initial interview, the setting will be a private and secure room at the UH Mood Disorders Program, at the Department of Psychiatry. Participants will be interviewed separately. At this first interview, participants will be informed about the study. The participants will also receive information on resources for people experiencing violence in their community, stress, and anger management techniques. If the participants are willing to participate, they will be asked to sign consent forms and HIPAA forms at this time. After the participants sign the forms, they will be given the prescreening questionnaire. If the PI determines that the couple is eligible based on their answers to the prescreening questionnaire, the couple will be scheduled for the first assessment session. If the participants are not eligible, they will be provided with the list of referrals (please see attached) and will be informed that all the information they have provided will be destroyed.

Study site
The site will be at the Mood Disorders Program in the Department of Psychiatry at University Hospitals. The PI's office will be used as the private area to conduct the couple therapy and to collect physiological data, located in room #12-126 on the 12th floor of the W.O. Walker Center (10524 Euclid Avenue, Cleveland, OH 44106). It is a large, comfortable room equipped with task chairs, and will be suitable for couple therapy. The Mood Disorders Program also has a waiting area and a receptionist to guide participants through to the therapy room, along with security. For safety measures, the PI's office is equipped with a panic button in case of emergency, and doors in the clinical area are locked with UH access only. The Dahms Clinical Research Unit (DCRU) may be used for physiological data collection.

Obtaining Informed Consent
If potential participants are willing to participate, they will be asked to sign paper copies of the consent form at the initial clinical interview. Informed consent will take place in the PI's office at the Mood Disorders Program .The consent form for participation in this project will include detailed information on the project, study procedures, risks, benefits, alternatives to participation, financial information, confidentiality information, and privacy information. The consent form will also explain how anonymity will be maintained for the questionnaires. Information about

anonymity will also be conveyed verbally, and questions about the anonymity procedures and confidentiality will be answered.

After explaining the study, the researcher will leave the room so that the couple can privately discuss the decision to participate or not, thus minimizing the possibility of coercion or undue influence. The consent form will be written in simple, nonscientific language to assure comprehension, and participants will have the opportunity to ask questions. The details about limits to confidentiality due to mandatory reporting procedures will be carefully discussed both verbally and in the consent form with the participants. These limits to confidentiality include: a) if in the course of the sessions it is suspected or revealed that children are being abused, this will be reported by the PI to Child Protective Services, b) if the life of any participant is in danger, this will also be reported. Participants will be given a copy of the consent form.

In order to provide additional confidentiality protection for this information, we will obtain a Certificate of Confidentiality from the National Institutes of Health.

Interventions
This week-to-week treatment manual was developed by the PI and Dr. Margaret Keiley, Professor of Marriage and Family Therapy at Auburn University, and a consultant for this study.

The treatment manual describes the phases *of therapy*. There is some overlap between the steps described in the treatment manual. For couple therapy, the relationship is the main focus. Sometimes, each individual in the couple may be at different stages of progress, or one partner may have difficulty expressing their needs, or hearing their partners' needs. Therefore, the couple therapist may need repetitions and incorporate overlaps in some steps.

All therapy sessions will be videotaped. These records will not include any identifying information. Video recorders will be placed in such a way that the faces of the participants will not be visible in the recording. These records will help the PI understand the dynamics of the couples and identify potential adverse events. Audio records will not be sufficient for this purpose, since the participants' body language (their posture, the way they sit, their distance from each other) provides important information in this regard. Recorders will be located behind the participants, and only the back of their head will be visible. We will also make every effort to keep the videos in a safe and secure location. Recordings will be kept in a locked cabinet at the PI's office at the W.O. Walker Center, room 12-126 in the Mood Disorders Program on the 12th floor. The PI's office is locked and access is limited to only those individuals permitted access on the Walker ID badge. The video tapes will be destroyed after 2 years upon completion of the study. The building has a private security firm available 24 hours.

All therapies will be conducted as a couple. Training on stress management and safety planning will be performed as individuals. There will not be any group sessions. The goal of couple therapy is to help and improve couples' capacity to regulate emotions, solve problems, and communicate through therapy with the couple together. The specific steps that will be followed in conjoint/couple therapy are the following:

Week 1: Engagement
Goals:
The overall goal at the beginning of therapy is to create an alliance with both partners; that is, to create a relationship with each individual in which the therapist is warm, supportive, understanding, genuine, and empathic. In other words, both partners in the room will feel that the therapist understands their experience and is someone with whom they will be able to explore new behaviors and new ways of interacting with each other.

Interventions & Mechanisms:
Creation of alliance. The creation of alliance occurs through joining with each partner, then exploring each partner's experience of the problem.

Engagement. Engagement is an ongoing process throughout therapy that should be actively monitored. This process is characterized by the therapist being empathically and authentically attuned to and connected to each individual on a personal level and being genuine in his/her interactions with the clients.

Assessment. At this stage, the therapist assesses the goals of both partners. The therapist also assesses what the focus of therapy will be and shares that plan with the participants.

End State:
At the end of session one and all of the rest of the sessions, both partners feel safe and accepted by the therapist, have some hope that the therapist will be able to help, and agree to return to therapy. In addition, the therapist has an initial idea about the major conflicts and interactional cycles, as well as the attachment positions of each individual.

Week 2: Assessment and Diagnosis
Goals:
The overall goal of assessment and diagnosis is to identify the negative interactional attachment cycles that occur and the feelings (overt and vulnerable) that everyone experiences during these cycles.

Interventions & Mechanisms:
Focusing on the interactional cycle. Focusing on the interactions is the key mechanism of this stage. Here the therapist aims to intervene the interactional cycle, that is, rigid patterns of negative interactions couples find difficult to change. To change these patterns, therapists utilize communication and expression of emotions to promote change in emotional, cognitive, and behavioral pathways. This is part of the process of making sure that the therapist has an understanding of the clients' experiences.

End State:
At the end of session two, the therapist has an initial idea about the major conflicts and interactional cycles as well as the attachment positions of each individual.

Week 3: Accessing Unacknowledged Emotions
Goals:
The goal of the third session is to identify the unacknowledged emotions (overt and vulnerable) that everyone experiences during interactional cycles.

Intervention & Mechanisms:
Tracking and reflecting the cycles. In this stage, the therapist tracks and reflects the cycles by identifying the process and structure of the interactions in terms of affect, attachment positions, and attachment behaviors (distance-withdrawer, pursuer), piecing them together from both partners' descriptions and direct observations, and then reflecting the process of these interactions back to the partners. While doing so, the therapist interrupts and redirects the conversation when any partner talks about things other than the interactional cycle of focus.

End State:
Both partners have an expanded view of the problem and acknowledge to a certain extent how their interactions contribute to the problem. Both partners feel safer, more comfortable, and more accepted by the therapist.

Week 4: Reframing Interactional Cycles
Goals:
The goal of reframing is to access the unacknowledged vulnerable feelings of both partners in therapy in the context of their defensive emotional experiences that hold their interactional cycle in place (distance-fear/pursuer-anger). Most people are usually unaware of these vulnerable emotions (fear, sadness, anger, shame) and do not explicitly express them in their interactions.

The purpose of reframing is to access and unearth these vulnerable feelings that are hidden by the overt and defensive, angry or stonewalling ones, making them an explicit part of the therapeutic dialogue.

Interventions & Mechanisms:
Vulnerable feelings are accessed by focusing on the actual emotional experiences of the partners that occur during the therapy sessions. The therapist actively invites all in the room to engage in and focus on these emotional experiences, then expands and reprocesses these experiences by using the following techniques.

Validation. Validation of each person's responses and emotions as legitimate and understandable is crucial during this stage of therapy. Validation helps the partners to stay in contact with their emotional experiences and removes one major block to their engagement with their emotional states – self-blame.

Heightening of emotions. Heightening of emotions is a way of helping individuals fully experience and resonate with their vulnerable emotions. The therapist highlights and intensifies key vulnerable emotions that arise in the session and are related to the attachment positions of each partner. This heightening of vulnerable feelings helps people to engage with their emotional experience more intensely and create a new way of interacting with their partner.

Heightening can be achieved by:

1. Maintaining a consistent and persistent focus on key vulnerable emotional responses. The therapist blocks exits or changes in the flow of experience that are likely to lessen the emotional intensity of the vulnerable feeling in that moment. This should not be confused with "venting" of emotion.
2. Repeating a phrase to heighten its impact, usually this is a catch phrase used by the person.
3. Using clear, poignant images or metaphors that crystallize experience, for example, heart sinking, the floor dropping out from under you, it burns you to see him do that. The therapist should use each person's own language.
4. Directing individuals to enact their vulnerable emotional responses again.
5. Referring to bodily/physical reactions (e.g., I shake when I hear this. There is a catch in your voice as if it hurts to even put it in words.)

Evocative responding. This intervention focuses on the tentative, unclear, or emerging aspects of individuals' experiences. The therapist may focus on the most poignant elements of an emotional/bodily response, the conflicting elements within that response, the action tendency inherent in the emotional experience, or how cues are perceived or processed by others in the room. The therapist may simply repeat certain phrases, offer an image or metaphor, or ask exploratory questions. These reflections and questions are offered tentatively, for the clients to accept, correct, or reject.

Emphatic stipulation. The therapist makes inferences about an individual's current state and experience from nonverbal, interactional, and contextual cues, from the therapist's empathic immersion in the client's experience, and from knowledge of the interactional positions and patterns of the couple. Based on such inferences, the therapist offers a formulation of each partner's experience that adds a new element, or puts elements together in a new way, thus helping everyone to crystallize his/her experience and process this experience one step further. Inferences are typically around defensive strategies and core catastrophic attachment fears. The goal of this mechanism is not to offer insight or labeling, but to facilitate more intense experiencing through the new understandings about emotions, thoughts, and behaviors that will arise.

End State

Each partner's attachment longings emerge and begin to be clarified during reframing. The partners feel relief in being able to process and understand their own emotions and their relationship patterns; that is, they feel a sense of efficacy when they begin to realize that each person unwillingly has helped to create the relationship cycle (e.g., If I created it, maybe I can make it different). This is also the time when attachment wounds (past incidents that have damaged the attachment, and actively influence the way the relationship is defined in the present) are explored and clarified.

Week 5: Choreographing Change

Goals:
The therapist is involved in choreographing a series of change events in which individuals who typically withdraw from interaction are able to express their own emotional experiences and attachment desires, while staying engaged in the interactions. At the same time, the individuals who are typically critical or blaming are able to hear these expressions without shutting down their own vulnerable feelings and attachment desires. They, too, are able to remain fully engaged in the interactional cycles, expressing their own vulnerable feelings. In so doing, each partner is explicitly taking a new position with their partner and this new position elicits a reorganization of the interactional cycles.

Interventions & Mechanisms:
During the process of choreographing change, the therapist focuses on the attempts that individuals make to express their vulnerability directly to their partner and help them to do so. For example, when individuals are unable to express their own desires, the therapist helps them to identify these and encourages the direct expression of them to their partner. In addition, if individuals express what they want to the therapist, the therapist redirects them to share these feelings with the others in the room. At the same time, the therapist facilitates the listening and responding process of other individuals in the therapy room.

As more positive interactions emerge, the therapist tracks and reflects the changes to the original negative interactional cycles that have resulted in this more positive cycle. For example, as withdrawers experience their real fears of contact, process them, access more specific hurts, and directly express these to their partner, the therapist validates and reflects this new behavior. The partner may respond with some disbelief and detachment as they hear such a direct expression of the typically withdrawn members' feelings and what they will and won't do in the relationship. If this is the case, the therapist helps those withdrawers to stay focused on their own reactions and continue the dialogue with their partner.

At the same time, the therapist helps the partner who tends to be blaming to hear and deal with their anxiety about this new behavior from the withdrawer. The therapist helps the partner who has been critical and blaming in the past, to focus on themselves rather than on the withdrawer, accessing their own attachment fears and experiences, and processing them. The therapist helps the pursuer to access both their longing for connection and real fear of the dangers of connecting. The therapist helps this partner to share these experiences with the withdrawer.

Restructuring interactions. For both the withdrawing and critical partners, the therapist reframes their difficulties in stating desires or accepting new expressions as their own vulnerabilities and fears arising from past experience of negative cycles. The therapist choreographs enactments of present positions that are now more explicitly, consciously, and actively taken and shapes those interactions to include new elements from the newly synthesized experiences arising from engagement, thus turning new emotional experience into new interactions.

End State:
Each partner sees the other partner differently and interacts with them in a new way. Withdrawn partners are fully engaged in interactions, experiencing their own vulnerable feelings, and sharing them with their partner.

Week 6: Emotional Engagement
Goals:
In this stage, the therapist helps clients facilitate expression of needs and wants by restructuring interactions. The objective is to enable both partners state their own desires in the relationship context by staying engaged with their own emotional experience. By being open to their partner's emotional experiences, they will be able to state these desires in ways that increases the likelihood that these desires will be met by their partner. For example, instead of a wife demanding that her husband do something, she will be able to ask him. In turn, he will be able to respond honestly about whether or not he is able to comply at this time to this request. In this way, each person will be able to present his/her specific requests in a manner that pulls the other person toward him/her and maximizes the possibility that the others will be able to respond. Attachment positions will become flexible and attachment signals and emotions become clear.

Interventions & Mechanisms:
Enactments: In this stage, the therapist focuses on the partners' attachment needs, and helping them to express and own those needs and their corresponding emotions. The therapist directs one partner to the other partner in a particular way to enact the present interactional position, encourage the new emotional experience to the other, and enact new behaviors. The therapist supports each stated need and attempts to directly choreograph specific change events. The main function of restructuring is to alter the crystallized present position, challenge old patterns of relating, and heighten new or rarely occurring responses.

The therapist monitors the acceptance by others in the room of the person who is expressing his/her new or vulnerable emotional experiences and trying to engage in new interactional patterns. The therapist facilitates everyone's hearing of, processing of, and response to these new experiences. De-escalate the old, destructive interactional cycles and restructure a new and intimate interaction.

End State: The more critical partner is fully softened and acknowledges and shares their own attachment desires and vulnerable feelings. Contact between the partners becomes intense and authentic.

Week 7: Emphasizing Creative Problem Solving
Goals:
The primary goal of this step is to highlight the emergence of new solutions to relationship problems. By this time, a new way of interacting with one another based has been developed on reconnecting events during previous sessions. With this session, the therapist becomes less directive and is a guide to keep interactions on the new level of experiencing one another.

Interventions & Mechanisms:
Encouragement and support. The therapist provides encouragement and support when highlighting the changes that have occurred. The therapist validates each person's movement toward change with specifics regarding what they have changed and what they should continue to strive to change. The therapist particularly supports individuals when they proactively own their part in the interactional cycle by helping their partner to be open and responsive to these new actions. In addition, continued observation of new attachment experiences and questioning about the feelings that are evoked by the new interactions is required. The therapist invites the more hesitant partner to respond or the more vocal partner to be open to other partner's perceptions.

Redirection. At this point, the therapist teaches the partners to begin interrupting their own negative interactional cycles as well as practicing re-attachment strategies and self-softening/ soothing techniques. The therapist requests that everyone begin doing this independently so that by practicing new interactions, they become natural.

End State:
Both partners feel able to carry out new tasks in their interactions with one another. They feel connected to one another in new ways. An atmosphere of trust and safety becomes evident as vulnerable feelings are exposed more readily and problem-solving becomes easier because conflict is at the level of differences in opinion rather than insecure attachment interactions.

Week 8: Termination/Consolidation
Goals:
The goal of termination is to consolidate changes that have been made and look toward the future. All participants will be able to reflect on the changes they have witnessed and made as well as the feelings these changes have evoked. A discussion of the process of therapy is useful at this time as it pertains to memories of pivotal events that occurred for each of them.

Interventions and Mechanisms:
Encouragement and support. The therapist highlights each person's contribution to the changes in the relationship. The therapist encourages participants to continue to validate each other's feelings, desires, and wants.

Aftercare teaching. The therapist discusses a plan with all clients for relapse management and prevention. The plan should be in the context of how they can expect feelings of disconnection again at times, but what ways can they reconnect with one another.

End State:
All participants in therapy appear more flexible in their relationship positions to one another. Responses are empathetic and emotionally receptive. Both partners monitor and regulate negative affect in an emotionally engaged manner. A sense of connectedness exists between both partners, as well as a decrease in negative cycles.

Data Collection

For each couple, data will be collected at each visit. Data will be collected in two forms:

1. Self-report and partner-report questionnaires will be collected using several measures, all of which have adequate reliability and validity.
2. Physiological data will be collected by monitoring heart rate variability and cortisol level at the DCRU.

Screening Measures

In order to examine eligibility, demographics and some clinical data will be collected.

- CAGE questionnaire. CAGE is a brief alcoholism screening test (Mayfield D, McLeod G, Hall P.1974)
- Simple Screening Instrument for Substance (SSI-SA). Abuse (SSI-SA)The SSI-SA was intended as a brief screen of substance abuse symptoms. It was designed utilizing a binary (yes/no) response format to facilitate scoring and to minimize subjective interpretation of scores Center for Substance Abuse Treatment. (1994).
- Conflict Tactics Scale 2 (CTS2;Straus, Hamby, BoneyMcCoy, & Sugarman, 1996) assesses intimate partner violence based on partners' rating of their own and their spouse's conflict strategies, measuring the intensity and frequency of psychological/verbal and physical conflict. This scale has been shown to have good reliability and validity (Straus, Hamby, BoneyMcCoy, & Sugarman, 1996). This is also be used throughout the study to monitor couple's relationship change.
- Symptom Checklist (SCL90-R) (Derogatis, 1994) will be used to assess acute psychopathology. This measure will also be used throughout the study to monitor participants' mental health change.

Outcome Measures

Both behavioral and physiological measurements will be used to evaluate the effectiveness of conjoint therapy. No medical records will be reviewed at any time.

Physiological Measures: The change in emotion regulation of participants will be assessed by monitoring the HPA axis and PNS activity. The HPA axis is a major part of the endocrine system that controls reactions to stress. PNS is responsible for simulating the activities when the body is at rest. Therefore, monitoring the HPA axis and PNS activity together will enable assessment of emotion regulation (Porges, 2001). The HPA axis will be monitored using cortisol reactivity, which measures short term changes in the concentration of cortisol, a steroid hormone that is released in response to stress (Böhnke, Bertsch, Kruk, & Naumann, 2010). PNS activity will be monitored accessing vagal regulation (tone, reactivity); that is, the effects produced on the heart when only the parasympathetic nerve fibers are controlling the heart rate. Part of vagal regulation is heart rate variability monitoring, which will be done via eMotion HRV sensor (Please see attached information about the HRV sensor).

Couples will be separated upon arrival and will wait for 15 minutes to reach their resting period, in order for cortisol levels and heart rate to establish a more accurate baseline. The participants will relax by reading previously selected magazines or listening to calming music. They will be

measured for baseline levels of cortisol (via saliva samples) and heart rate variability (via eMotion HRV sensor). The participants will then wait for another 15 minutes.

Then, the couple will be reunited and cortisol and vagal reactivity of both partners will be measured following a discussion of a relationship conflict, in line with the Rapid Marital Interaction Coding System (RMICS) (Heyman & Vivian, 1993). Heart rate will be measured throughout this process. Saliva samples will be collected 15, 30, and 45 minutes following the task.

Mouth swipes will be used to measure saliva cortisol. Participants will be asked to place the oral swab into their mouth (under tongue), keep in place for 1 minute, and put the oral swab into the collection kit tube. eMotion HRV will be used to measure heart rate variability. eMotion HRV Sensor is an internally powered heart rate variability measurement device. During measurement, the sensor will be connected to the patient via two electrodes. The electrodes will be placed approximately along the electrical axis of the heart. The negative electrode (yellow) will be placed in the right infraclavicular fossa (just below the right clavicle). The positive electrode (red) will be placed on the left side of the chest, below the pectoral muscle in the left anterior auxiliary line. The research personnel will start the measurement by pushing the sensor power button down for one second. The green indicator light will light up and start blinking synchronously with the heart rate. At the end of the measurement, the research personnel will push the power button continuously for five seconds to end the measurement. The sensor will power down and the green indicator light will turn off.

Finally, each partner will complete questionnaires composed of the measures described below. It is expected that the lab session will last two hours. Participants will also complete measures on variables that may influence cortisol, such as conflict, unusual events, caffeine consumption, or exercise patterns (Kudielka, & Kirschbaum, 2003). After they finish completing all of the questionnaires, the therapist will instruct them in relaxation techniques and interventions to help deal with any negative emotions before they leave the assessment session.

The same procedure will be followed for each assessment phase (pre-test, post-test, and follow-up) and will take place during the hours of 4 pm to 8 pm because that is when the body's Circadian rhythm causes cortisol levels to normalize.

CTSC Dahms clinical unit will process and analyze the cortisol levels. The PI is in contact with Paul Hartman, Megan Miller, and Valori Corrigan for utilizing the Dahms Clinical Unit. For interpretation of the data, the PI is receiving consultation from Prof. Douglas Delahanty from Kent State University Department of Psychology. Please see the attached letter of commitment from Prof. Delahanty.

Behavioral Measures: At each visit, participants will complete questionnaires measuring attachment patterns, affect regulation, dyadic adjustment, emotional abuse, and IPV. Both partners will fill out the questionnaires separately, in different rooms. The participants will fill out the questionnaires after the collection of physiological data.

Questionnaires include various measures about intimate relationships, all of which have been widely used in previous studies. These measures were chosen based on their conceptual and psychometric qualities. Statistical procedures (e.g., confirmatory factor analyses) will aid aggregation of these measures and the precise definition of latent variables. The measures that will be used are the following:

- Emotional Abuse Questionnaire (EAQ) (Babcock, Jacobson, Gottman, & Yerington, 2000; Jacobson & Gottman, 1998).
- Relationship Satisfaction Scale (Burns, & Sayers, 1992).
- Personal Assessment of Intimacy in Relationships (PAIR) (Schaefer, & Olson, 1981).
- Dyadic Adjustment Scale (DAS) (Spanier, 1976).
- Revised Dyadic Adjustment Scale (RDAS) (Busby, et. al 1995).
- Conflicts & Problem Solving Scale (CPS) (Kerig, 1996).
- Managing Affect and Differences Scale (MADS) (Arellano & Markman, 1995).
- Difficulties in Emotional Regulation Scale (DERS) (Gratz, & Roemer, 2004) will be used to assess affect regulation.
- Experiences in Close Relationships Scale (ECR) (Brennan, Clark, & Shaver, 1998) will be used to assess the attachment in relationships.
- Coping Inventory for Stressful Situations (CISS) (Endler & Parker, 1990) will be used to assess affect regulation.
- Family Daily Hassles Index (FDHI) (Rollins, Garrison, & Pierce, 2002) will be used to measure family stress/hassles and health status.
- Interpersonal Reactivity Index (Davis, 1983) will be used to measure empathy and perspective taking.
- Perceived Stress Scale (PSS10) (Cohen, et al 1983).

Participants can quit the study anytime they would like and there will be no penalty for dropping out of the study. If a participant drops out of the study, the PI will make at least 3 attempts to contact the participant, consisting of phone calls and a certified letter. The participants will be encouraged to perform a final follow-up visit.

Digital Data Collection of Patient Assessments: At the beginning of the study, the data management team (DMSAU) will obtain an email address for each research participant enrolled into the study. Throughout the study, this email address will be used to send a link to access the participants-rated survey. This email address will allow the participants to access the participants-rated survey from within the REDCAP server. Through this email address, the participants will be emailed a link to access self-report study assessments. This link will be created through the REDCap "management participant list" tool. This link does not carry any PHI or de-identified data. This link does not expose any information about the participants' identity or other information. All participants' responses will be recorded in a secured environment within the REDCAP server. As an additional security measure, the link will expire after the participants completes the participants-rated survey.

If any technical problems emerge that prevent the digital collection of data (accessing the REDCAP server, connectivity, computer technical issue, etc.), the participants can still complete

the paper version of the participant-rated survey. While participants will be encouraged to enter their responses digitally, they will continue to have the option of responding on paper if they so choose.

Participants will receive via email a 128-bit hash value (e.g. 3425eee5999025d4847fd3ca1b2a362c) that will uniquely identify them as the appropriate subject, essentially serving as a username and password in one. Participants will click on the link to go to the Self Report Survey in RedCap. All transmissions between the client and RedCap will take place over a 128 encrypted line. Answers will be stored in a MySQL database that is housed in the same HIPAA class data center as the above mentioned Oracle server. The Self Report Survey can still be completed on paper if that is the participant's preference or there are technological difficulties. In that instance, the data will be entered by study staff and will be double checked by second study staff.

Fig 1. Project Flow Chart

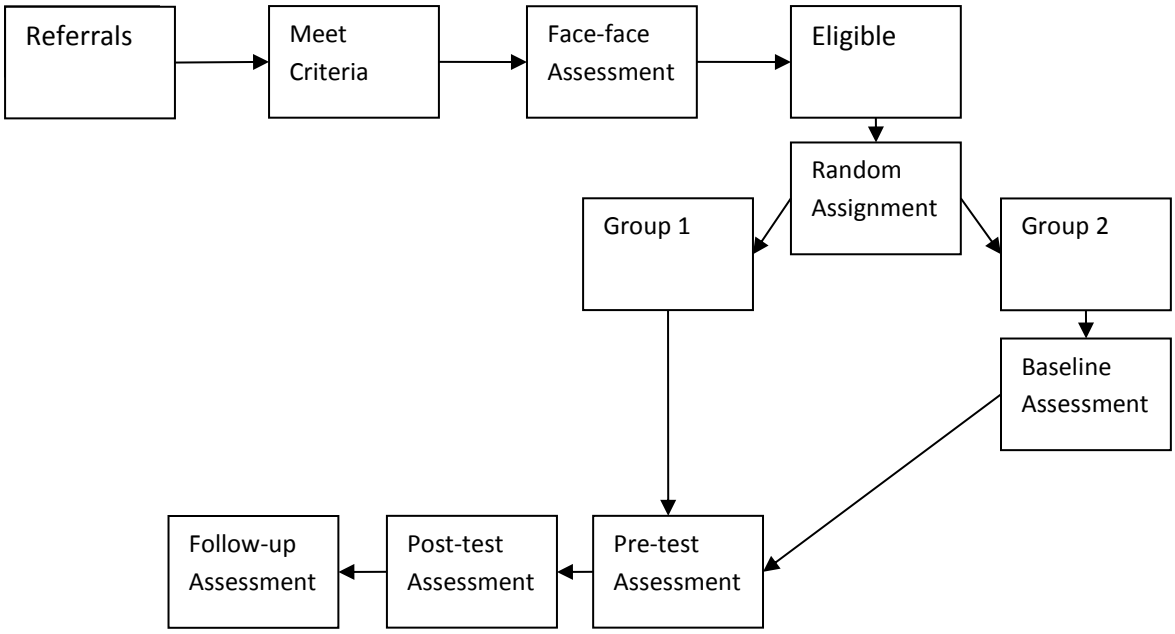

Table 2. Assessment schedule

Group 1		Screening	Baseline /Tx 1*	Tx2	Tx3	Tx4	Tx5	Tx6	Tx7	Tx8	Post-test*	Follow up /EOS*									
Group 1	(Tx) week	-x	0	1	2	3	4	5	6	7	8	20/EOS										
Group 2				waiting period									Baseline 2/Tx 1	Tx2	Tx3	Tx4	Tx5	Tx6	Tx7	Tx8	Post-test	Follow up /EOS
Group 2	(Wt) week	-x	0	1	2	3	4	5	6	7	(n/a)	(n/a)	8	9	10	11	12	13	14	15	16	28/EOS
ICF		x																				
Screening measures																						
	Demographics	x	x	(x)*	(x)*	(x)*	(x)*	(x)*	(x)*	(x)*	(x)*	x*	x^a	(x^a)	(x^a)	(x^a)	(x^a)	(x^a)	(x^a)	(x^a)	(x^a)	(x^a)	x^a
	CAGE	x																				
	SSI-SA	x																				
	CTS	x	x	x*	x*	x*	x*	x*	x*	x*	x*	x*	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a
	SCL-90	x	x								x*	x*	x^a								x^a	x^a
Behavioral measures																						
	ECR		x								x*	x*	x^a								x^a	x^a
	CISS		x								x*	x*	x^a								x^a	x^a
	FDHI		x								x*	x*	x^a								x^a	x^a
	EAQ		x								x*	x*	x^a								x^a	x^a
	DAS		x								x*	x*	x^a								x^a	x^a
	RSS		x								x*	x*	x^a								x^a	x^a
	DERS		x								x*	x*	x^a								x^a	x^a
	PAIR		x								x*	x*	x^a								x^a	x^a
	MADS		x								x*	x*	x^a								x^a	x^a
	CPSS		x								x*	x*	x^a								x^a	x^a
	IRI		x								x*	x*	x^a								x^a	x^a
	RDAS	x		x*	x*	x*	x*	x*	x*	x*				x^a	x^a	x^a	x^a	x^a	x^a	x^a		
	PSS-10	x	x	x*	x*	x*	x*	x*	x*	x*	x*	x*	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a	x^a
Physiological measures																						
	heart rate variability (eMotion HRV sensor)		x								x*	x*	x^a								x^a	x^a
	saliva cortisol (3x)		x								x*	x*	x^a								x^a	x^a
	* indicates Group 1 only procedure																					
	x^a indicates Group 2 only procedure																					

Efficacy & Data Analysis

Data analysis plan

This study is designed to be an initial feasibility study to collect pilot data in pursuit of the following aims:

Aim 1: After the first wave of data collection (pretest), the cross sectional relations among the basic constructs of interest will be examined. These basic constructs are psychophysiological markers of emotion regulation and IPV. In order to understand how these markers are related to violence, t-tests will be used to understand this effect. Each partner's HPA and PNS activity is expected to be directly linked to the violence perpetrated by their partner.

Aim 2: The objective of this aim is to understand whether violence decreases over time following therapy and whether this decrease is accompanied by respective change in physiological markers of emotion regulation. For this purpose, series of chi-square-test will be used as well as qualitative analysis.

Aim 3: In order to represent the interaction between the emotion regulation of partners, links from emotion regulation of each partner to the emotion regulation of the other partner at the next time point are included. Qualitative analysis with a grounded theory approach will be used.

The proposed sample size (8 couples) is chosen as a tradeoff between data collection time and statistical power. Since this is a feasibility study, we chose to start with a small sample size. GPower was used to estimate statistical power for the primary hypotheses. Assuming 8 couples (16 participants), with 4 couples in each group and two waves of data each, the statistical significance can be detected. Specifically, with power = .40, this study can detect an effect size of f =.80 (Using t-test statistics). Also chi-square test will be used to test the effectiveness of the intervention with power = .40. With this level of power, this study can detect an effect size of f =.60 (Using chi-square statistics).

The PI will continually monitor the study design to determine if there is a need to make modifications or discontinue the study due to lack of efficacy from therapeutic intervention.

Safety

Compensation for research related injury

In the event that a participant sustains physical injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, UH may not pay for the costs of treatment for injuries that result from noncompliance with study procedures.**Safety Information**

There are a number of interventions cited in the literature for clinicians concerned about violence occurring between partners in between therapy sessions. The below violence prevention strategies and safety interventions from the literature will be used in this project to deal with situations that may arise. In the following, the general strategy is highlighted in italics, followed by a description of how the strategy will be applied in this study.

1. *Identify the conflict issues between the couple and discuss situations in which violence may be prompted along with what can be done to avoid or work against such situations.* This violence prevention strategy will be widely discussed during the couple therapy sessions as part of the proposed intervention. Please see the treatment manual.
2. *Identify the risk factors for further violence, including substance abuse, severe mental health problems, having previously violent relationships, access to firearms, and comfort with severe violence.* Participants with high risk of severe intimate partner violence will be identified and these participants will be excluded from the study. Please see details about the exclusion criteria.
3. *Identify the techniques that participants can use at home when they feel that a situation may be escalating out of control and teach these techniques to the participants.* The following techniques will be taught the participants in this study:
   a) Timeout procedures: The participants will be taught of ways of identifying a situation that is getting hostile by recognizing cues that lead to high conflict and walking away when they identify such a situation.
   b) Stress management techniques: Participants will be taught of breathing exercises, guided imagery, and safe place techniques to deal with stressful situations. Handouts will be provided (Please see appendix for the handouts).
   c) Anger control and problem solving techniques will be taught as part of the couple therapy.
4. *Specify safety planning for worst case scenarios*. Participants will be taught of safety planning and handouts will be provided (Please see appendix for the handouts).
5. *Provide a referral sheet for the participants with numbers and locations of various emergency services as well as 24 hour hotline numbers*. A referral sheet will be provided to the participants. The referral sheet will also include numbers and locations of area mental health providers as well as the fee associated with their services. (Please see appendix for the referral sheet).
6. *Monitor possible buildup tension between the partners.* The therapists will see the participants in weekly scheduled sessions and will call the participants at least once in between sessions to monitor the buildup of tension.
7. *Meet each partner individually for safety assessment.* The therapists will meet clients individually after each session to make sure that they feel safe going home with their partners. If not, the therapist will encourage the two to separate to avoid any violent situations. Each partner will also be provided by a phone number at which they can reach the therapist and arrange for individual time with the therapist if they wish to.
8. *Provide an emergency contact number for the participants.* The participants will be provided a phone number of an experienced therapist to contact in case of emergencies. This phone number will be associated with a voice mail that is remotely accessible. Participants will also be advised to call 911 in case of emergencies that needs prompt response.

Risk Management

Plans for subjects at the end of the protocol:
After completion of the project and follow-up data collection, participants will be briefed about the study and some preliminary findings will be shared. Participants will also be provided with

referral information in case of future need. After data is analyzed and the results are published, the data will be destroyed.

The therapy that participants are receiving is not experimental, rather the data collection procedures comprise the research. After 8 weeks of sessions, if participants request additional therapy, the PI will be continue to be their therapist until their issue is resolved or they secure another therapist. The PI will also provide referral information in case participants would like to continue with another therapist.

Data and Safety Monitoring

Data Monitoring. The proposed research will include data from approximately 8 couples. The final dataset will include self-reported demographic and behavioral data, along with cortisol levels and heart rate information. All identifiers will be removed from the final dataset prior to release for sharing.

Data will be reviewed after every assessment session. The PI will analyze the data from the first cohort before proceeding with the next to determine if the research should proceed as planned, if PI needs to modify the protocol or discontinue the research (e.g., if Group 2 is doing better than Group 1).

Safety Monitoring. The PI will be responsible for monitoring the safety of the participants. In this study, the welfare of the participants will be of primary concern during treatment. There are a number of interventions cited in the literature for clinicians concerned about violence occurring between partners in between therapy sessions. Several prevention strategies and safety interventions from the literature will be used to prevent and deal with situations that may arise. These strategies and interventions are described in the attached Safety Chart.

Careful assessment will be conducted to understand the dynamics of situational couple violence and potential safety issues that couples are experiencing. The PI will ask questions about whether participants feel they are in danger. If participants are afraid that their partner will retaliate after disclosing sensitive information, these couples will be excluded from the study. Withdrawal from the study will be honored without any coercion.

Treatment will not begin until both partners have been informed about the possible disruption and emotional upheaval that might arise during the 8 therapeutic sessions. As a safeguard, all participants will be taught stress and anger management strategies, such as: calm place, the light stream technique, spiral technique, breathing shift, and diaphragmatic breathing. (Please see attached information about these techniques). These techniques are frequently used in eye movement desensitization and reprocessing (EMDR) therapies as one of the evidence based treatments for Post-Traumatic Stress Disorder (PTSD), including treatment of veterans by the Department of Defense (American Psychiatric Association, 2004). A referral information sheet will also be provided to each participant. The same clinical precautions/procedures will be used if a participant expresses self harm.

Prior to leaving the therapy session, participants will be asked about their anger level. If they report being angry, they will be asked to remain at the research site until they have calmed down. Participants will also be asked about how safe they are feeling before leaving the session. For fearful participants, safety planning will be offered along with referrals and shelter information. The PI will call the local police at any time if a participant becomes aggressive or s/he feels threatened. In their 10 years of experience conducting the couple's treatment program with violent couples, McCollum and Stith (2008) reported that no involvement of local police was needed.

In order to help those in the control group who will not be receiving therapy for the first 8 weeks, individuals in this group will be taught safety planning, given information on local resources to help victims of violence, and will be instructed on stress and anger management strategies.

Subject Privacy
Consents will be received after the prescreening interview. For any interaction with the participants and the PI, the setting will be a private and secure room at the UH Mood Disorders Program. The room will be equipped with noisemakers to make the conversations private and not understandable by outside listening.

Data Sample Confidentiality
Participation in the study is confidential. Only the PI will know the participants' identity. Data will be de-identified. Traditionally used identifying information about participants, such as name, address, telephone number, or social security number, will not be put into either the public or controlled access databases for this project. Participants will have individual personalized login numbers to ensure that assessments at each data collection time connect to the correct participant. Participants will be contacted via email and telephone to remind them of the 3-month follow up assessment. None of the data will be entered into the participants' medical records and no study information will be shared with participants' physicians.

Confidentiality of the data will be maintained within legal limits. Access to participants' records will be limited to the PI. However, the study records must be available for review. The institutional Review Board (IRB) at University Hospitals of Cleveland, and other regulatory agencies may need to review study records.

The PI will receive a Certificate of Confidentiality from the government. This certificate protects against the involuntary release of information about participants collected during the course of this research. Since IRB approval is required to apply for a Certificate of Confidentiality, the PI will apply for the Certificate of Confidentiality after IRB approval is obtained. Nobody will be enrolled in the study before Certificate of Confidentiality is obtained.

The PI has been trained and certified in human subjects research. Information will be disclosed only with the participant's permission or as required by U.S. or Ohio law. Research personnel involved in this study cannot be forced to disclose any information collected in this study in legal proceedings. However, the PI is not prevented from taking the necessary steps, including reporting to authorities, to prevent serious harm to the subject or others, specifically children. In

this case, an appropriate Department of Children Services in the participant's community will be notified if anyone on the research team suspects a child is experiencing abuse.

All data and participant contact information will be destroyed at the end of the study period, following publication. If any results of the research are published, no information that could identify the participants will be released.

Data/Sample Security
Data collection and data security will be performed using RedCap. Paper versions for the technical problems will be entered to the redcap system as soon as technical problems were solved. These paper versions will be de-identified and will not include any identifying information. Data collected via RedCap will be password-protected. Participant assessment data will be confidentially downloaded into the CWRU secure computer server. Staff at the Office of Information and Technology at UH and CWRU will ensure downloaded data continues to remain secure, and they will create computer password links so that only the PI can have access to participant data. De-identified data located on the secure UH computer server will be translated into a readable Excel database at the completion of all study assessments. The data will be stored on the Case Western Reserve University network. Data transfers between computers will be protected by SSL encryption. If researchers need to transfer data outside of the network, an ironpad will be used to ensure security of the data.

The status of all participant data will be monitored by the PI on a weekly basis (e.g., assessments completed, drop outs). The data downloaded to Excel will be kept in a password protected program folder on a password protected local hard drive that will be physically located in a locked environment. Although the computer is a part of Case/UHCMC network, the database will not be accessible via the Case/UHCMC network. Only the PI will have the access to the data.

We recognize the sensitive nature of our research and the need to maintain strict confidentiality. We will take the following necessary steps to do so:

1. No record of participation in the study will be entered into the medical records of the participant.
2. We will implement the following schema for managing the linking of the data:
    a) Prior to participant enrollment, we will generate sets of unique barcode labels, referred to as the ID.
    b) Informed consent will be obtained and the participant will be enrolled in the study.
    c) Study staff will use one set of barcodes for each participant, placing bar a code on each data sample. The unused labels will be retained in a study folder until the end of the study and then destroyed.
    d) The code linking the ID with the participant's information will be kept in a password protected database separate from the primary database.

Financial Considerations

Payments to Subjects
Participants will receive $20 ($40 per couple) for each assessment session. In order to receive this amount, individuals must participate as a couple. The study has three assessment sessions. Participants will be paid for their initial visit and then $20 for all three assessment sessions. Participants who complete the study will receive a total of $80 ($160 per couple). Additionally, the participants will be provided $5 dollars per couple to cover the parking expenses, totaling $60.

Due to their longer involvement in the study and one additional assessment sessions, participants in the Group 2 will receive additional monetary compensation. Group 2 participants who complete the study will receive a total of $100 ($200 per couple). Group 2 participants will also receive $5 parking reimbursement, totaling $65.

Costs to Subjects
Costs to the participant include transportation to the research site. Participants will be reimbursed for parking, but they will not be reimbursed for gas or public transportation.

Risks and Benefits

Risks
There is a chance that some participants, either due to the intervention or due to completing the questionnaires, will be encouraged to think about aspects of themselves or their relationships that they had not considered previously. If so, these thoughts could be stressful and upsetting. Participants may become distressed due to the sensitivity of the particular topic. There is also a risk of unanticipated change in the participants' relationship. One of the risks of couple's therapy is the end of the relationship or divorce as a possible outcome of the partners gaining insight in to the relationship. In clinical trials, attachment based therapies have been shown to be effective in treating couples with negative affect cycles and conflicts (Johnson & Whiffen,1999), however, there may be a risk of escalation of conflict during the study. Several prevention strategies and safety interventions from the literature will be used to prevent and deal with such situations. Please see Section 16.1 (Data and Safety Monitoring for a detailed plan for maintaining the safety of the participants).

Benefits
The participants may benefit from this study in terms of improved handling of conflict in their relationship.

Alternatives to participation
Alternative treatment options are available in the community to treat IPV. These options include anger management groups for the offenders and self-esteem groups for the survivors of IPV. Also, participants can seek individual and couple therapy as alternative treatment options. Participants will be provided with a list of alternative treatment options during the informed consent procedure so as to avoid undue influence or coercion. Please see the appendices for the list of care providers and local resources.

Withdrawal from Study Participation

Voluntary participation. Participation is completely voluntary, and participants will be encouraged to terminate their participation in the proposed study if they express discomfort. If the couple chooses to withdraw from the study, they will be referred to other therapy and the referral list will be provided.

Both partners need to be willing to attend the therapy. If one partner decides to quit the study, we will stop and referrals will be provided. If one or more of the participants are willing to continue therapy individually, the PI will continue to see them individually until each of them secures a therapist. In that case, data collection with the couple will be discontinued.

Participants will be considered for withdrawal from the study if they do not consistently attend sessions (if they miss two or more sessions) or if they are aggressive and uncooperative during sessions.

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Appendix: Safety Chart

Prevention

- Exclude high risk couples from the study
- *Identify the risk factors for further violence, including substance abuse, severe mental health problems, having previously violent relationships, access to firearms, and comfort with severe violence. (Please see details for exclusion criteria).*
- *Teach techniques that participants can use at home*
- Timeout procedures, stress management techniques, anger control & problem solving techniques. (Please see handouts for these techniques)
- Provide a referral sheet for the participants with numbers and location of various emergency services as well as 24 hour hotline numbers

During intervention

- *Identify the conflict issues between the couple and discuss situations in which violence may be prompted along with what can be done to avoid or work against such situations.*
- The therapists will meet clients individually after each session to make sure that they feel safe going home with their partners.
- *Monitor possible buildup tension between the partners.* The therapists will see the participants in weekly scheduled sessions and will call the participants at least once in between sessions to monitor the buildup of tension.
- Each partner will also be provided by a phone number at which they can reach the therapist and arrange for individual time with the therapist if they wish to.

Worst Case Screnio

- Follow the emergency protocol
- Therapist will separete the couple and continue to see them as individual clients.
- Make appointment for the next session.
- Participants will be taught of safety planning and handouts will be provided (Please see appendix for the handouts).
- *Provide an emergency contact number for the participants.* The participants will be provided a phone number of an experienced therapist to contact in case of emergencies. This phone number will be associated with a voice mail that is remotely accessible. Participants will also be advised to call 911 in case of emergencies that needs prompt response.
- A referral sheet will be provided to the participants with the information about shelters. The referral sheet will also include numbers and locations of area mental health providers as well as the fee associated with their services. (Please see appendix for the referral sheet).