The effect of adding biofeedback on heart rate variability to the treatment of intimate partner violence perpetrators with cognitive behavioral therapy.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49595

Source
ToetsingOnline

Brief title
Treatment of intimate partner violence with biofeedback.

Condition

- Other condition

Synonym
Intimate partner violence

Health condition

Het gaat niet om een aandoening, maar om het gebruik van geweld, waarbij wel sprake kan zijn van comorbide stoornissen, die echter geen focus zijn van het onderzoek.

Research involving
Human

Sponsors and support

Primary sponsor: De Waag
Source(s) of monetary or material Support: KFZ (via Divisie ForZo/JJI) en Stichting Koningsheide verstrekken subsidie.

Intervention

Keyword: Biofeedback, CBT, HRV, Intimate partner violence (IPV)

Outcome measures

Primary outcome

The main study parameter is the combined amount of reduction in the occurence of physical and psychological violence as measured with the equally named subscales of the Conflict Tactics Scale-2 (CTS-2).

Secondary outcome

Secondary measures are the Anger Bodily Sensations Questionnaire (ASBQ) and HRV-values pre- and posttreatment. We will also analyze the effect of motivation on treatment outcome.

Study description

Background summary

Meta-analyses of current treatments of intimate partner violence (IPV) perpetrators show little to no effect in reducing violent behavior in intimate relationships. Current practice in Europe is to treat risk factors with cognitive behavioral therapy (CBT). An important therapy goal is to learn self-control, which requires an early recognition of increasing arousal in order to prevent escalation. However, the scientific literature on IPV shows that perpetrators have difficulties in self-observing bodily signals that accompany the build-up of arousal preceding IPV. A high level of emotional arousal further hampers the ability to self-observe and subsequently to

self-control behavior. Because of this, we presume that IPV perpetrators can not fully profit from *top down* CBT interventions aimed at developing self-control.

With our newly developed smartphone application, GRIP-app, we aim to contribute to the awareness of bodily signals that are associated with increased arousal and subsequently contribute to the facilitation of reaching treatment goals of IPV perpetrators. GRIP-app works in concordance with a wearable heart rate sensor. It offers biofeedback on stress level (derived from heart rate variability, a general marker of physiological arousal) and voice volume to help perpetrators recognize increasing arousal. The smartphone will signal a notification when a preset threshold is surpassed. We presume that by providing biofeedback and supporting self-observation, perpetrators can practise self-control before arousal becomes too high, thus preventing violence. This presumption is built on prior research in other fields that shows that using wearable technology contributes to achieving health-related goals by increasing self-regulative abilities as well as increasing commitment to achieving these goals.

Study objective

The first objective is to investigate whether biofeedback on HRV and voice volume will lead to a larger decrease of IPV compared to treatment as usual (CBT only). Second, to test the premise that IPV perpetrators have trouble self-observing bodily signals related to arousal, and whether adding biofeedback to treatment increases awareness of bodily arousal signals. Third, to explore whether HRV-values improve from pretest to posttest after using biofeedback. Fourth, to gain an impression of the feasibility and practical implications of using biofeedback with the newly developed GRIP-app and to establish future research directions.

Study design

Randomized Controlled Trial (RCT) comparing treatment as usual (TAU) with CBT to an experimental condition where biofeedback is added to CBT (EXP). After obtaining informed consent, subjects will be randomly assigned to one of the two treatment conditions, both with a 9-week duration. The primary outcome measure will be administrated at T0 (before intervention period) and T1 (after intervention period).

Intervention

TAU consists of the CBT-based safety for partners treatment module, developed by De Waag, which focuses on motivation, psycho-education and self-control. Five out of eight weeks are aimed at self-control interventions. During this time, subjects in the experimental condition (EXP) will be instructed to wear a

chest strap and use GRIP-app as often as possible and comfortable.

Study burden and risks

Regarding the burden, participants in the treatment as usual condition (TAU) will receive regular treatment, and in addition fill out the outcome questionnaires, and undergo a 5-minute baseline and posttreatment measurement of HRV by wearing a heart rate sensor (see below).

Participants in the experimental biofeedback condition (EXP) will undergo these same procedures and additionally wear a Polar H7 heart rate sensor during weeks 4-8, used in conjunction with GRIP-app on their smartphone. As for comfort, participants might experience some physical discomfort by wearing the Polar H7, because the device is worn on a soft chest strap which has to be made wet before use. The chest strap also might feel tight or slightly painful to the skin after prolonged wear. However, the strap is adjustable in size, addressing tightness, and participants are free to limit their wearing time to the minimum requirement or to leave the study and continue with regular treatment. We have not found any risks or serious negative effects associated with wearing the chest strap in literature. We will provide wearing instructions and therapists will continually inquire into reasons that preclude wearing the strap, being medical or otherwise.

As for data privacy, because Bluetooth is required, participants are exposed to possible malevolent hacking attempts. However, we believe that the hardware and software will primarily be used in the (relatively) safe home environment, and that the Bluetooth requirement does not deviate from most people*s standard usage of their smartphone. All data on physiological measures is handled exclusively through secure network connections, accessing a server through a cryptographic network protocol, where a therapist dashboard protected by hashed passwords is coupled to GRIP-app with a unique code. No safety credentials are hard-coded into the source code. Users have control over the data they share with their therapist.

Participants referred by a probation officer might feel watched or controlled. Data collection is limited to surpassings of the thresholds, only viewed before the start of a therapy session and then discussed in-session with their therapist. Participants are free to quit the study if they do feel watched, without naming a reason. When quitting, we will ask whether their data might still be used for data analysis or if they want to have it permanently removed.

Weighed against each other, we believe that the possible benefits of the experimental condition * reduction of IPV - outweigh the possible burdens and risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Recent perpetration of IPV (in the year prior to referral);
- Age: 18 or above.
- Subject is in possession of a smartphone running iOS 11.2.5 or higher, or Android 6.0 or higher;
- Sex: Male;
- The relationship in which violence occurred is still on-going. Partners do not necessarily need to be living together, but will need to be visiting each other at least three times a week to be included. Because of the short duration of the study, we want to be sure that there is enough time for the intervention to be practised. Therapist will monitor whether the relationship goes on during the study;
- Lack of self-control, as assessed during the intake procedure, is a risk

factor that is targeted in treatment.

Exclusion criteria

- Treatment is mandatory / referral by a probation officer;
Sensitivity to crisis, liability to act out dangerously towards oneself or others, requiring immediate intervention, e.g. suicidality, serious self-harm, psychosis;
- Substance abuse of a severity that requires clinical treatment or which therapists deem to need treatment before any other interventions take place;
- Referral is part of conditions imposed by a judge or a probation officer.
- Aggressive behavior occurring only outside of an intimate relationship;,
Additional exclusion criteria for participation in this study:
- Stalking behaviour as primary reason as referral for treatment;
- A restraining order issued by the mayor during the intervention period (this prevents contact between partners);
- Any reason that leads to a subject not willing or not being able to wear a chest strap, i.e. medical reasons, psychological conditions such as panic disorder, or any reason of relevance to the subject;
- Having or entering a new relationship where IPV does not occur.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2020
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Polar H7 heart rate monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25289
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69507.018.19
OMON	NL-OMON25289