The Effect of Biofeedback on Intimate Partner Violence: A Randomized Controlled Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25289

Source
NTR

Brief title
GRIP2019

Health condition

Not applicable

Sponsors and support

Primary sponsor: No commercial sponsoring. See funding bodies.
Source(s) of monetary or material Support: Kwaliteit Forensische Zorg (KFZ) grand number 2019-104
Stichting Koningsheide P2019-532

Intervention

Outcome measures

Primary outcome

Conflict Tactics Scale (CTS-2) as a measure of frequency of intimate partner violence

(measured at the start and end of the study period)

Secondary outcome

Bodily signals indicative of arousal, as measured with the Anger Bodily Signals Questionnaire (ABSQ) questionnaire (measured weekly)

Study description

Background summary

Studies on cognitive behavioral therapy (CBT) for IPV offenders show small or no effects on recidivism. Offenders may not fully benefit from CBT, because their awareness of arousal is low, leading to high arousal overtaking them and making it difficult to control their behavior. Biofeedback can support awareness of arousal. With this purpose, we developed a smartphone application, Good Reaction Is Prevention (GRIP), that when used in conjunction with a heart rate monitor, measures heart rate variability and notifies users when a personal stress threshold is surpassed. In a randomized controlled trial (N=40) we compare a 9-week CBT-based program aimed at developing self-control where IPV offenders are treated either with GRIP-app or receive treatment as usual (TAU) without biofeedback. Primary outcome measure is the Conflict Tactics Scale-2, measuring the frequency of different types of IPV. Secondary outcome measure is the Anger Bodily Sensations Questionnaire, measuring awareness of bodily signals that occur when feeling angry. We hypothesize that the GRIP-condition leads to a greater reduction in IPV frequency as measured by the CTS-2 and to a greater awareness of bodily sensations that accompany anger, when compared with the TAU-condition.

Study objective

Primarily, we expect that the use of biofeedback will have beneficial effects on transfer to real-life situations, resulting in a decrease of intimate partner violence from pretest to posttest. Secondly, we hypothesized that biofeedback will increase awareness of bodily signals indicative of arousal. Exploratively, we aim to investigate the differences in HRV-values from pretest to posttest.

Study design

The study period is 9 weeks
Week 1: ABSQ, CTS-2, HRV
Week 2: ABSQ
Week 3: ABSQ
Week 4: ABSQ
Week 5: ABSQ
Week 6: ABSQ

Week 7: ABSQ
Week 8: ABSQ
Week 9: ABSQ, CTS-2, HRV

Intervention

TAU (n = 20) = Patients in the TAU-condition receive a standard IPV treatment protocol which all IPV offenders at the Waag receive (i.e. the Safety for Partners treatment protocol). Duration: 9 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Male, 18+, in treatment for intimate partner violence at the Waag (an outpatient forensic treatment center), lack of self-control as a risk factor and treatment target, being in a romantic relationship and living together or seeing each other at least three times a week, being in possession of a smartphone with iOS 11.2.5 or higher, or Android 6.0 or higher

Exclusion criteria

stalking is main reason for treatment, medical or other reasons that preclude wearing a chest strap with heart rate sensor, a restraining order that prevents contact with the romantic partner, any reason that supersedes TAU, such as the need for immediate care with regard to suicidality, psychosis or imminent danger for others.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
A paper will be written, describing the data and results of this study, and offered for publishment to a
scientific journal. It is our intention to share our data file with other researchers that wish to follow up on or check up on our data set. Research results will be made available publicly regardless of outcome. The study has been registered at ToetsingOnline, a platform for public disclosure of scientific studies with human subjects. The results of the study will also be presented at symposia and congresses, and when possible included in Dutch psychology journals/magazines and education.

Ethics review

Positive opinion

Date:	09-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49595
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8886
CCMO	NL69507.018.19
OMON	NL-OMON49595

Study results