Researching synchrony of heart rate in the therapeutic relationship in the treatment of early childhood trauma, en de possibility of improved emotion regulation through feedback of heart rate.

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The current research is focussing on a potentially new instrument to monitor the tension of patients, which is feedback of heart rate. Monitoring heart rate during therapy sessions could make it easier to detect tension early. Early detection of a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON48633

Source
ToetsingOnline

Brief title
Synchrony en feedback of heart rate

Condition

- Anxiety disorders and symptoms

Synonym
(complex)PTSD, trauma

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Het onderzoek is onderdeel van de opleiding tot Klinisch Psycholoog van de hoofdonderzoeker. Financiering voor de arbeidskosten van het onderzoek en voor de benodigde hulpmiddelen is binnen de opleiding geregeld. Hoofdonderzoeker is in loondienst bij de Parnassia Groep

Intervention

Keyword: (interpersonal) synchrony, biofeedback, Heart rate, Psychophysiology

Outcome measures

Primary outcome

Primary study parameter: feedback versus no feedback of heart rate.

Primary outcome measures: heart rate, average heart rate, standard deviation of

heart rat, HRV.

Secondary outcome

Secondary study parameter: quality of the therapeutic relationship.

Study description

Background summary

The heart rate of patients with (early childhood) trauma changes when they relive their trauma's (heart rate goes up) and when they dissociate (heart rate goes down) (Perry & Szalavitz, 2017; LeDoux, 2002; Ogden, Minton & Pain, 2006; Porges, 2003; Van der Kolk, 1996a, 1996b). In these instances the patient can go outside his window of tolerance, and when that happens continuing the usual therapy session is not useful because the patient can't think, learn of process as well as usual (Ogden et al., 2006; Ogden & Fischer, 2014, Siegel, 1999/2015). The therapist will have to switch to emotion regulation, in order to get the patient back into his window of tolerance. Only then the usual therapy can continue.

Another phenomenon is that the therapist 'resonates' with the patient through

his mirror neurons and his mentalizing abilities (Schippers, Roebroeck, Renken, Nanetti & Keysers, 2010). This way, there is a synchrony between patient and therapist. Research (see for an overview Koole & Tschacher, 2016) shows there is more synchrony when there is a better relationship between patient and therapist. Patient and therapist will, for example, move the same way more often, speak at the same tone more often, and use the same vocabulary more often, when they get along better.

Hypothetically, there is also a synchrony between patient and therapist in terms of heart rate. When we apply this hypothesis to the treatment of early childhood trauma, we expect that the heart rate of the therapist rises when the patient is reliving his trauma, and the therapists heart rate drops when the patient dissociates. This hypothesis would fit the clinical observation that therapists sometimes get anxious when their patients relive their trauma's, en get sleepy of emotionally absent when their patients dissociates (see for example McWilliams, 2011).

Heart rate variability (HRV) can ben used as a measure for stress (Porges, 2011). Given the above, we expect to also find synchrony between the HRV of the patient and the HRV of the therapist.

Synchrony in heart rate has previously been found in romantic relationships (Helm, Sbarra en Ferrer, 2012; Ferrer en Helm, 2013; Hubler, 2013; en McAssey,Helm, Hsieh, Sbarra en Ferrer, 2013; Weissman-Fogel en Shamay-Tsoory, 2017). Also, synchrony in HRV was found in romantic couples (Helm, Sbarra en Ferrer, 2014). Synchrony of heart rate was also found in mother-infant relationships (Field, 2012).

In the therapeutic relationship, no such research has been done. We expect to find synchrony of heart rate and HRV here because both the patient and the therapist want to form and maintain a working relationship, and the task of the therapist is explicitly to facilitate this relationship, and to tune into the patient. The skill to make contact with the patient, and to fix ruptures in the relationship, is very central to the work of a therapist. One could argue that the therapeutic relationship both has features of a romantic relationship and of a mother-infant relationship. It has been established before that the better someone is in empathizing with the other, and tuning in in the other (which is the task of a therapist), the more there is synchrony (Goldstein, Weissman-Fogel & Shamay-Tsoory, 2017; Levenson en Ruef, 1992). This brings us to the hypothesis that there is also synchrony of heart rate and HRV in the therapeutic relationship.

Therapists who treat patients with early childhood trauma try to keep their patient within their window of tolerance (Ogden et. al. 2006; Siegel, 1999/2015). They have several instruments for this, like their mentalizing abilities, their observations during the session (looking for signs of stress), analysing the content of what their patients say, and their

counter-transference (e.g. the tension they feel as a result of working with the patient). Oftentimes we see that patients with early childhood trauma have difficulty registering their tension: they don't realize they are tensed, or realize it too late, perhaps because they have limited contact with their bodily sensations (Ogden & Fischer, 2014). Also we see that it can be difficult for a therapist to realize the patient is tensed: sometimes the patient looks relaxed when his heart rate is actually very high. And also, the therapist can be too focused on the content of the session to be able to focus on signs of tension. In other words: these instruments are limited and it might take a while for the therapist to realize his patient is not fit to continue the therapy session and should actually do some emotion regulation. As long as the therapist continues therapy while his patient is above or below the window of tolerance, the therapy probably won't do any good: the patient will not benefit from the session because he is too stressed to process the content. Continuing the session in the normal fashion could even be counter-productive: the patient might associate therapy with being stressed out, and might begin to hate therapy. This might trigger avoidance responses, like dropping out, stop discussing important subjects, or cause crises (so the therapist will have to discuss the crisis, instead of the trauma). So it's crucial that the patient remains in the window of tolerance.

Study objective

The current research is focussing on a potentially new instrument to monitor the tension of patients, which is feedback of heart rate. Monitoring heart rate during therapy sessions could make it easier to detect tension early. Early detection of a heart rate running high or low, makes it possible to intervene earlier, and that would keep the patient in his window of tolerance longer.

One way would be through direct feedback: the patient wears a heart rate meter, and he (and the therapist) would be alarmed when heart rate would pass a threshold. But given the hypothesis about synchrony, we can possibly also use indirect feedback: the therapist would wear the heart rate meter, and we take an elevation of his heart rate as a sign that the heart rate of the patient is also elevated. The therapist could focus of regulating his own tension to indirectly lower this patient*s heart rate. The same goes for a lowering of heart rate.

A side effect of therapists monitoring their heart rate, and keeping themselves within their window of tolerance, could also be a better self care for therapists. Keeping patients within their window of tolerance would keep their therapists healthier, since both high and low heart rates might be contagious.

The research questions:
1. Is there synchrony of heart rate and/or HRV between therapist and patient?
2. Will the patient remain in his window of tolerance longer when he receives

direct feedback of his heart rate?
3. Will the patient remain in his window of tolerance longer when his therapist receives feedback of his heart rate?
4. Will the therapist remain in his window of tolerance longer when we receive direct feedback of his heart rate?
5. Will the therapist remain in his window of tolerance longer when his patient receives feedback of his heart rate?

Hypotheses per question:
1. Yes, there is synchrony of heart rate and HRV between patient and therapist, and this synchrony is stronger when the therapeutic alliance is stronger.
2. Yes, the patient will remain in his window of tolerance longer when he gets real-time feedback of his heart rate (because it makes early intervention possible)
3. Yes, the patient will remain in his window of tolerance longer when the therapist gets real-time feedback of his heart rate (because a better regulated therapist will lead to a better regulated patient)
4. Yes, the therapist will remain in his window of tolerance longer when he gets real-time feedback of his heart rate (because it makes early intervention possible)
5. Yes, the therapist will remain in his window of tolerance longer when the patients gets real-time feedback of this heartrate (because a better regulated patient will also lead to a better regulated therapist)

Study design

36 patient/therapist couples will be measured one session of 30 minutes. The session consists of three conditions, each lasting 10 minutes. During the 30 minutes the couples just do their normal therapy session. They are instructed (even thought this is standard in therapy sessions) to do emotion regulation exercises (like a breathing exercise, or orientation exercise) when tension is getting too high, of too low.

Both patient and therapist are wearing a heart rate monitor during the 30 minutes. It is connected through Bluetooth with an IPad, that gives real-time feedback of the heart rate. It also gives a little audio signal when the heart rate exceeds a threshold value.

The three conditions (each 10 minutes):
A: Both patient and therapist don't get feedback of their heart rate.
B. Patient gets real-time feedback of his heart rate, which the therapist can see as well. The therapist will not get feedback of his own heart rate.
C. Therapist gets real-time feedback of his heart rate, which the patient can see as well. The patient will not get feedback of his own heart rate.

The couples will be asked to turn the IPad away from them in the conditions where they are not supposed to receive feedback. They will be helped with a

whiteboard reminding them of the three conditions, and a bell that will ring after 10 and 20 minutes.

Afterwards, they will fill in the Session Rating Scale (SRS), which measures the quality of the therapeutic relationship. We expect this to be a moderator in the synchrony between patient and therapist.

Instructions
Both therapist and patient will get to hear the theory of synchrony and the window of tolerance before they start, and they will be told that heart rate is a measure (albeit an imperfect measure) of tension or stress, so they can use the feedback of their heart rate to regulate themselves. Furthermore, they are instructed to just have their regular therapy session.

Pre-research
In order to determine the thresholds for a too high or too low heart rate, we will do a pre-research with five therapist/patient couples. We will measure them for 30 minutes, without giving them feedback of their heart rate. We will use their mean heart rate and the standard deviation to determine cut-off points.

Before a session
We will ask the participants to sit down quietly for two minutes before we start measuring (to eliminate the effect of walking or stress on heart rate, just before the session). In these minutes we answer questions participants might have.
We ask the participants to not use any 'when necessary' medication, drink coffee, smoke cigarettes, or sport intensively in the hour before the session (because these things influence heart rate.

Instruments
Participants will wear a Polar H10 chest strap to measure heart rate and interbeat intervals. This sensor is connected to the IPad, which registers the data and gives real-time feedback.
Software: we use Heart Graph to provide real-time feedback, and Elite HRV to register interbeat intervals.
After the session, we ask the participants to fill in the Session Rating Scale (SRS), which measures the quality of the therapeutic relationship.

Analyses
We divide the techniques into the basics and the optional techniques. The optional techniques are very time consuming and might not be possible within the time available (but our aim is to use all of these techniques).

Basics
Research question 1:
The correlation between the heart rate of the patient and the therapist will be

calculated. We will then do a cross-validation analysis (see Liu, Shou, Palumbo & Wang, 2016). Furthermore, we will do a regression analyses to determine if the therapeutic relationship has a moderating effect on the correlation between both heart rates.

Research questions 2, 3, 4 and 5:
Post-hoc we will compare (with a two tailed t-test) the mean heart rate and standard deviation between the three conditions. If the hypotheses are correct, we will find a lower mean heart rate, and a smaller standard deviation in condition B en C comparing to condition A.

Optional techniques
Research question 1:
The same correlation will be calculated, but now for HRV. Again, we will do a cross-validation analysis after. As a measure for HRV we will use the RMSSD for blocks of 30 seconds.
We also want to use statistical techniques that can say something about causation (the analyses above is only correlation). We want to use a cross-lagged panel model for this (see for example Helm, Ferrer & Sbarra, 2014 en Hubler, 2013). It can provide further knowledge about the direction of the synchrony (do couple influence each other, or is it mainly one who is dominant?)

Questions 2, 3, 4 and 5:
We will determine the HRV over conditions A, B and C. If the hypotheses are correct, we will find a higher HRV in condition B and C, compared to condition A.

Intervention

Feedback of heart rate.

Study burden and risks

Participants will invest 45 minutes of time (30 minutes for the session, and 15 minutes for preparing and filling in the SRS). There are no big risks involved.

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

Early childhood trauma (diagnostically: (complex)PTSS, personality disorder or dissociative disorder)

Exclusion criteria

Pychotic disorder as a main diagnosis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL66667.058.18