A randomized controlled trial of an Internet-based emotion regulation intervention for sexual health: study protocol

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Keywords: internet intervention, emotion regulation, sexual health, randomized controlled trial, protocol

Posted Date: April 8th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-348308/v1

Abstract

Introduction: Emotion regulation difficulties have been associated with mental disorders and sexual dysfunctions. Traditional face-to-face transdiagnostic emotion regulation interventions have shown positive results for emotional and personality disorders. Only recently have the effects of these interventions on sexual health started to be investigated. Internet-delivered psychological interventions have several advantages over face-to-face interventions, such as cost-effectiveness, accessibility and suitability for people who experience shame because of their stigmatized problematic behaviors and those who avoid seeking help. The aims of the SHER 2 - TREpS (Portuguese acronym for Emotion Regulation training for sexual health) project are: a) determine the efficacy of an Internet-based emotion regulation intervention for sexual health and sexual satisfaction, and; b) explore the effects of the intervention on (1) emotion regulation skills; (2) mental health; (3) sexual self-perception.

Methods and Analysis

The study will use a randomized controlled trial design. Eligible participants will be randomly allocated to one of two groups: intervention (Internet-based emotion regulation training) or waitlist control. Assessments will take place before the start of the trial, at the end of the trial and at 6-month follow up, after which participants assigned to the waitlist control condition will receive the same intervention. Primary outcomes include sexual function and satisfaction, and secondary outcomes self-report measures of depression, anxiety, difficulties in emotion regulation, and sexual self-perception. This intervention study is financed by the Luxembourg National Research Fund (FNS).

Ethics and dissemination: Ethics approval was obtained from the Ethics Review Panel of the University of Luxembourg. Findings will be disseminated via peer-reviewed publications and conference presentations.

Introduction

Epidemiological studies suggests that 40–45% of adult women and 20–30% of adult men of the general population fulfil the criteria for at least one sexual dysfunction at one point in time during their lives (Lewis et al, 2010). Sexual Dysfunctions (i.e., difficulties in the ability to respond sexually or to obtain sexual pleasure; APA, 2013) are multifactorial and involve physiological, affective, interpersonal, and psychological, context-related-factors (Willi & Burri, 2015). They can only be understood by considering the constituent factors of sexual health, such as the experience and expression of thoughts, fantasies, desires, beliefs, attitudes, values, behaviours and practices (WHO, 2017). These factors may play a pivotal role in the development of sexual problems, and in maintaining sexual dysfunction in the long term (Brotto et al., 2016).

One important factor is emotion regulation (ER), defined as the way in which emotions are generated, experienced and used (Lumley et al., 2011). Such processes include emotional awareness (attention, differentiation, and labelling of emotions), expression (suppression versus expression of emotions), and

experience (accessing and reflecting on one's emotions and their consequences; Lumley et al., 2011). Emotion regulation difficulties have been associated with unhealthy coping strategies, mental disorders (Leahy, Tirch & Napolitano, 2013), and with difficulties in the sexual response cycle of both men and women (arousal, lubrication, orgasm, pain, erection and ejaculation; Pepping et al., 2018; Berenguer, Rebôlo & Costa, 2019).

A range of emotion regulation interventions have been shown as efficacious in the treatment of emotional and personality disorders, e.g. the Unified Protocol (UP; Barlow et al., 2017), and the Affect Regulation Training (ART; Berking & Whitley., 2014). In view of the high prevalence rates of emotion regulation deficits and comorbidity of sexual dysfunctions with other mental disorders (Jonusiene & Griffioen., 2013), such interventions might also be helpful in treating sexual dysfunctions.

Recently, two studies tested an in-vivo transdiagnostic approach to sexual problems. Parsons et al. (2016) conducted a pilot study with 13 HIV-positive gay and bisexual men reporting high rates of sexual compulsivity. After up to ten intervention sessions, improvements were observed in all psychological outcomes, including sexual compulsivity, depression, and anxiety, as well as decreases in drug use and HIV risk behaviours. Nonetheless, the initial small sample size (n = 13) and the fact that only 4 participants completed all sessions, limit the conclusions that can be drawn from these results. De Ornelas Maia et al. (2017) conducted an intervention to enhance quality of life and sexual functioning in unipolar depressive disorder or anxiety disorder participants. Both intervention groups (UP group intervention + pharmacological treatment, and pharmacological treatment only group) showed significant improvements in quality of life, anxiety, depression. Improvements in sexual functioning was also noticed, the effect size was larger for sexual dysfunction in the non-depressed group (d = 2.62) than in the depressed group (d = 1.04).

Although progress has been made in the psychological treatment of sexual problems, feelings of shame in meetings with physical face-to-face contact limit their dissemination. In contrast, internet-delivered interventions may offer a greater degree of perceived privacy and, therefore, appeal to those who otherwise would avoid seeking help. Additional advantages of internet-delivered interventions concern their cost-effectiveness and accessibility (Barak, Klein, & Proudfoot, 2009), and the possibility for patients to deal with their problem in their home environment (Marks, Cavanagh, & Gega, 2007).

Internet-delivered psychological interventions vary in the way they are delivered. They are usually composed of a package of comprehensive self-help material with which the patient receives information and exercises on a weekly basis (Andersson, 2009). The content is delivered in the form of text, video or audio, which is presented on a platform together with homework assignments and interactions with a clinician and/or automated support functions (i.e., self-guided treatments). Overall, there is evidence that I-therapy is more effective than no intervention and, more importantly, similar in efficacy to face-to-face treatments (Andersson et al., 2019).

Internet-delivered treatments have been applied in the area of sexual health care as well. Some studies have examined the effects of addressing sexual concerns using I-therapy. In a pilot study Van Diest et al.

(2007) tested an Internet-delivered protocol for different sexual dysfunctions and found improvements in sexual functioning in 67% of the participants (N = 39), with improvements maintained at 1-month follow-up. Van Lankveld et al. (2009) found that treatment was superior compared to waitlist control in an Internet-delivered sex therapy for Erectile Dysfunction. Similarly, Anderson et al. (2011) found that 7-week internet-delivered cognitive behaviour therapy significantly improved erectile performance when compared to an online discussion control group.

Recently, two studies have been registered aiming at investigating the effects of I-therapy on sexual health, one comparing two Internet-based interventions (cognitive behaviour therapy and mindfulness-based therapy) for the treatment of low sexual desire in women (Meyers, Margraf, & Velten, 2020) and one analysing the feasibility of a brief online psycho-educational intervention for Sexual Interest/Arousal Disorder (Zippan, Stephenson, & Brotto, 2020). However, there is a lack of studies examining the efficacy of Internet-delivered emotion regulation psychological interventions for sexual health.

Aim

The first aim of the SHER 2 - TREpS study is to determine the efficacy of an emotion regulation intervention for improving sexual health and sexual satisfaction.

The second aim is to explore the effects of the intervention on factors potentially mediating its effects, i.e. (1) emotion regulation skills; (2) anxiety and depression symptomatology; (3) sexual self-perception (sexual self-schema and automatic thoughts during sexual activity).

Research Questions

In more detail, the following research questions will be addressed:

1. Does the TREpS intervention increase sexual health and sexual satisfaction?
2. Does the TREpS intervention increase emotion regulation skills?
3. Does the TREpS intervention decrease anxiety/depression symptomatology?
4. Does the TREpS intervention improve sexual self-schema and decrease negative thoughts during sexual activity?

Methods

Design

A randomized controlled trial will be conducted. Participants will be allocated to either group 1 (intervention) or group 2 (waitlist).

Randomization will be performed prior to the enrolment of study participants. For each participant, a computer-generated random number will be used to allocate them to group 1 or 2 (targeted ratio 1:1). We will verify the balancing property of a set of observable characteristics (age and gender) between groups.

Analyses will be conducted and presented following the Consolidated Standards of Reporting Trials (CONSORT) statement (Schultz al., 2010; Montgomery et a2018).

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Participants

Inclusion Criteria

Individuals are eligible for participation if they meet the following criteria: (1) between 18 and 65 years of age, (2) fluent in Brazilian Portuguese, (3) self-reported sexual problems, assessed in men by a score of < 21 on the International Index Erectile Function (IIEF) and in women by a score of < 26 on the Female Sexual Function Index (FSFI); (4) in a stable relationship for at least the preceding 3 months.

Exclusion Criteria

Volunteers will be excluded if they report 1) medical conditions that can interfere with the outcomes of the intervention, e.g., diabetes, cancer, cardiovascular problems or (2) ongoing psychotherapy.

Recruitment

Recruitment will be conducted via the internet only. Advertisements concerning the project and invitations to take part in the study will be implemented using social media, targeting the Brazilian Portuguese speaking population. Additionally, participants of a previous online survey (SHER 1- study) who volunteered to participate in future studies will also be contacted.

Participants' information and consent

Written informed consent will be obtained from all participants before any data collection ensues. The information and consent form will explain the objectives of the study, that there is no incentive for taking part, that privacy and confidentiality is guaranteed as well as the right to withdraw from the study at any point in time without giving reasons or any negative consequences. If participants have any questions or wish to be informed of the results of the project and relevant publications, they are given with the opportunity to contact the principal investigator through the contact information provided in the online survey.

Sample size

Considering the number of variables of the study (with a power of .80 or greater and with a significance level set at $\alpha = .05$) the minimum sample size needed to find meaningful differences in sexual health is 102 participants, (51 in the intervention and 51 the control group; Wolf et al., 2013). Considering gender differences, we will aim to obtain twice this sample size (N = 204), i.e. 102 participants per gender.

Outcomes:

Primary outcome

1. Improvements in self-reported sexual health from baseline to 6-month follow-up.

Secondary outcomes

1. Emotion regulation improvement (from baseline to 6-month follow-up).
2. Reduction in automatic thoughts during sexual activity (from baseline to 6-month follow-up).
3. Reduction in anxiety scores (from baseline to 6-month follow-up).
4. Reduction in depression scores (from baseline to 6-month follow-up).
5. Improvement in sexual self-schema (from baseline to 6-month follow-up).

Measurements

Measurements will be undertaken at 3 time-points in each group: baseline, end of intervention and 6-month follow up.

Sexual health

Sexual health will be assessed using four questionnaires, two of which concern self-perception as a sexual person, thoughts and emotions during sexual activity and two questionnaires on sexual function.

Female participants will be asked to complete the Female Sexual Function Index (FSFI; Rosen et al., 2000), and the Sexual Quotient- female version (SQ-f; Abdo, 2006), while male participants will be asked to answer the International Index of Erectile Function (IIEF; Rosen et al., 1997) and the Sexual Quotient-male version (SQ-m; Abdo, 2007).

1. a) *Female Sexual Function Index (FSFI)* (Rosen et al., 2000): this is a 19-item questionnaire for the assessment of sexual functioning in women in domains of sexual functioning (e.g., sexual arousal, orgasm, satisfaction, pain). Answers are provided using a 5-point Likert scale. Hentschel et al. (2007) translated and validated the he FSFI into Portuguese, showing good internal consistency both for the evaluation of the total scale (α = .92) and for specific domains (desire = .67; excitation = .80; lubrication = .89; orgasm = .87; satisfaction = .85; pain = .86).
2. b) *International Index of Erectile Function (IIEF)* (Rosen et al., 1997). The *IIEF* is 15-item, self-administered questionnaire for assessing sexual functioning in men. Answers are given on a 6-point Likert scale. The *IIEF* encompasses five different domains of sexual functioning: erectile function, orgasm function, sexual desire, intercourse satisfaction and overall satisfaction. Ferraz and Cicconelli (1998) translated and adapted the scale to Brazilian Portuguese. Its psychometric properties were assessed by Gonzáles et al. (2013), showing good internal consistency for both the full scale (α = .89) and the specific domains (erectile function = .86; orgasmic function = .63; sexual desire = .77; sexual satisfaction = .60; general satisfaction = .73).
3. C) *Sexual Modes Questionnaire (SMQ)* – Automatic Thoughts subscale - (Nobre & Pinto-Gouveia., 2003). This self-report scale consists of 30 items in the male version, and 33 items in the female

version. Respondents are asked to rate the frequency (from 1 [never] to 5 [always]) with which they have experienced specific automatic thoughts during sexual activity. The psychometric properties of the Brazilian adapted version were evaluated by Lucena (2019), with an internal consistency of α = .92 and retest reliability of r = .8 (p < .05) for the female version, and α = .95. and r = .82 (p < .05) for internal consistency and reliability, respectively, for the male version.

4. D) *Sexual Quotient (QS)* (Abdo, 2006; Abdo, 2007). The *QS* is a brief and comprehensive tool composed of 10-questions, which are answered on a scale from 0 (never) to 5 (always). It addresses general sexual function, and stages of the sexual response cycle (desire, arousal, orgasm) and sexual satisfaction. The female version showed excellent internal consistency, both for the questionnaire as a whole (α = .98) and for each of its domains (all with α ≥ .9) (Abdo, 2006). The male version showed satisfactory internal consistency for the questionnaire as a whole (α = .6) and for the separate domains (all with α ≥ .6).
5. E) *Sexual Self-Schema Scale (SSSS)*. Originally developed by Hill (2007), the Brazilian version of the *SSSS* consists of 30 items assessing respondents' perception of themselves as a sexual person compared to others of the same gender and age. Answers are provided using a 5- point Likert scale ranging from 1 (not at all descriptive of me) to 5 (very much descriptive of me). It has good test-retest reliability (r = .6, p < .05), and internal consistency (scale total Cronbach's alpha of .8, ranging from .61 to .85 for the three factors; Lucena, 2019).

Mental Health assessment

for the assessment of mental health problems participants will complete the *Patient-Heath Questionnaire (PHQ-9)* and the *Generalized Anxiety Disorder 7* (*GAD-7)*. Both instruments are frequently used self-report diagnostic tools for the assessment of mental disorders.

1. a) The *Patient Health Questionnaire-9 (PHQ-9)* is a nine-item screening instrument, which also provides an assessment of the severity of depression. The diagnostic validity of the tool has been established for its English language version (Spitzer, Kroenke & Williams, 1999) as well as for the Brazilian version (de Lima Osorio et al., 2009). The questionnaire has good psychometric properties (77.5% sensitivity and 86.7% specificity) (Santos et al., 2013).
2. b) The *General Anxiety Disorder – 7 (GAD-7)* is a brief self-report measure specifically developed to assess Generalized Anxiety Disorder (Spritzer et al., 2006). It has good reliability, as well as criterion, construct, factorial, and procedural validity. The Brazilian version has good internal consistency and reliability with Cronbach's alpha of α = .916 and a rho composite reliability coefficient of ρ = .909 (Moreno et al., 2016).

Emotion Regulation assessment. For the assessment of emotion regulation, the *Difficulties in Emotion Regulation Scale (DERS)* will be used. The *DERS* is an empirically grounded assessment instrument measuring emotional regulation using a multidimensional framework, developed by Gratz and Roemer (2004), and validated in Brazil by Miguel et al. (2017) with its psychometric properties confirmed (α = .94 for the overall scale, ranging from 0.79 to 0.88 on subscales; Cancian et al., 2018). The *DERS* assesses

several facets of emotion regulation, including difficulties relevant to an individual's (a) acceptance of emotional responses, (b) ability to engage in goal-directed behaviour under distress, (c) ability to control impulsive behaviours when distressed, (d) access to emotion regulation strategies, and (e) emotional clarity. Participants rate their degree of agreement with each statement on a scale from 1 (almost never; 0 to 10%) to 5 (almost always; 91 to 100%).

Intervention

The intervention will involve an online emotion-regulation skills training for individuals with sexual problems. The protocol was developed based on existing emotion-regulation therapies (Leahy, Tirch & Napolitano, 2013; Gilbert, 2014; Berking & Whitley., 2014; Barlow et al., 2017; Brotto,2018). It will last for 8 weeks, encompassing psycho-educational and emotion-regulation skills components. Every week participants will gain access to a different intervention module of the training, containing videos, presentation slides, written support material and a recommendation of activities to be completed until the following week of training. Participants are expected to dedicate 30 minutes to one hour per week to complete each module.

The intervention is structured as follows:

Table 1
Summary of intervention modules.

	Module	Content
Week 1	psycho-education on sexual function	covers information about sexuality, sexual response cycle (desire, excitement, plateau, orgasm, resolution) and main difficulties that men and women may face in their sexual health, such as erectile dysfunction, premature ejaculation, desire disorders, pain disorders and anorgasmia. It also differentiates the psychological characteristics of functional sexual response from a dysfunctional sexual response as well as the difference between sexual function and sexual satisfaction.
Week 2	psycho-education on emotions and emotion regulation	covers the definition of what emotions are, evolutionary aspects of emotions, emotion functions, emotion response cycles, emotion components (physical sensations, thoughts and behaviors), and long-term consequences of maintaining an emotional state for a longer period of time. It also defines pleasant and unpleasant emotions, the relationship between unpleasant emotion and avoidance behaviors, and avoidance strategies (emotional suppression, distraction and behavioral avoidance).
Week 3	relaxation strategies: breathing and muscle relaxation	informs about the common physiological response to anxiety and stress (e.g. increases in heart rate, respiration and muscle tension) and teaches two relaxation strategies: breathing relaxation and progressive muscle relaxation.
Week 4	cognitive flexibility	refers to the rational component of emotion regulation. Aims to conceptualize and enhance cognitive flexibility, the triad situation-thought-emotion is explained and detailed through the concepts of what distinguishes thoughts and interpretations, what automatic thoughts and cognitive distortions are, and the identification of negative thought patterns and most common cognitive distortions related to sexuality are described.
Week 5	non-judgmental awareness	aims at teaching participants to experience their emotions in the present moment in a nonjudgmental way. The module also differentiates between experiencing an unpleasant emotion from experiencing an unpleasant emotion resulting from negative beliefs and reactions to experiencing it (snowball effect).
Week 6	self-acceptance and compassion	focuses on two psychological concepts necessary for a better emotion management: acceptance and self-compassion. These are important in order not to avoid emotional experiences and to diminish self-criticism associated with sexual difficulties.
Week 7	Emotion analysis	presents a step-by-step flow-chart of how to identify emotions when experiencing them. By identifying emotions properly, we facilitate effective emotion regulation. The flow-chart is composed of 6 items to pay attention when identifying an emotion: 1) emotion, 2) event-trigger situation, 3) evaluation/interpretation, 4) physical sensations, 5) previous similar experiences and 6) behavior.

	Module	Content
Week 8	Sexual emotional exposures	makes a summary of all previous modules and suggests a series of sexual experiences paying attention to the emotions experienced during the activities (exposures). Such gradual approach diminishes the risk of intense emotions and avoidant behaviors. By succeeding on the exposures, obtaining pleasure on the activities, assessments of danger/discomfort diminish and more adaptive evaluations arise, facilitating the identification and modification of emotional behaviors.

Control

The control group will not receive any intervention during the trial but will be offered the same treatment at the end of the six-months follow-up assessment (waitlist-control).

Data analysis

Data will be analysed based on three measurements: baseline, end of intervention and follow-up six months later. Analyses will be conducted to ascertain the balance on the measured covariates between the treatment and the control group.

To avoid potential post-treatment complications, such as noncompliance behaviour after treatment assignment, the standard intention-to-treat estimate will be performed. To assess mean differences in the different domains (sexual health, emotion regulation, mental health and sexual self-perception) over time and between groups, repeated-measures analysis of variance will be performed, with time (assessment point) as the within-subject factor, and intervention (group) as the between-subject factor. In case of violation of normality, changes over time in groups will be assessed with related-samples Wilcoxon tests. Multiple-imputation-based methods will be used to address missing data at follow-ups.

Intervention adherence will be monitored by the number of participants accessing the weekly training modules.

Declarations

Ethics approval

The trial will be conducted according to the guidelines laid down in the Declaration of Helsinki, the guidelines of the Ethics Review Panel (ERP) of the University of Luxembourg and the European Union General Data Protection Regulation (GDPR). The study design was approved by the ERP on 26th June 2020 (ERP 20-029 SHER). In case of amendments, prior approval to the UL's ERP will be seek.

The study is registered on ClinicalTrials.gov (NCT04792177); all necessary information according to the WHO recommendations is provided (table 2). just say that for any amendments you will seek prior approval to the UL's ERP

Data protection

All necessary precautions will be taken to maintain the confidentiality of study participants. Information collected will be pseudonymised so that individual identities cannot be revealed. For each study participant, a unique identifier will be generated and associated with his/her data records. The identifier key list containing personal identifiers (name, address, phone number, etc.) will only be accessible to the investigators of the study. The key list will be stored in locked cabinet in the premises of the researcher's institution (University of Luxembourg) and will be destroyed after the trial has come to an end.

Consent forms will contain the participant's signature and his/her unique identification number.

The controlled access to the intervention platform will guarantee the confidentiality of personal identity, and the right to the protection of personal data and privacy of individuals involved in the data collection.

Study results will be presented as aggregated data, with no personal information. No reference to individual participants will be made in a way that allows for identification.

Dissemination plan

Study findings will be disseminated through peer-reviewed publications, conference presentations, posters and social media channels. The research findings will provide important information concerning the efficacy of an Internet-based emotion-regulation intervention for sexual health. The outcomes of the study have the potential to establish the evidence-base for an Internet-based emotion-regulation intervention for sexual dysfunctions. The results will also contribute to the identification of the processes involved in the effects of improved emotion regulation skills on depressive and anxiety symptoms, and on sexual self-schema.

Comment

To our knowledge, this will be the first Internet-based emotion regulation intervention to promote sexual health.

Role of the funding source

The SHER 2 study has received financial support from Luxembourg National Research Fund (FNR). The funder of the study had no role in the study design and preparation, and will have no role in the data collection, analysis and interpretation or writing of the publications.

Patient and public involvement

Patients and the public were not involved in the design of the protocol. After completion of the study, results will be disseminated to the study participants and the general public.

Contributors

VJF, GA, JB and CV conceived of the study and developed the design and protocol. VJF wrote the first draft of the manuscript and all authors contributed to revising it critically.

Conflict of interest

The authors have no conflicts to declare.

Funding:

VJF received a PhD support grant from the Luxembourg National Research Fund (FNR). The funder of the study had no role in the study design and preparation, and will have no role in the data collection, analysis and interpretation or writing of the publications.

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Table 2

Table 2: WHO trial registration dataset

Data category	Information
1. Primary registry and trial identifying number	ClinicalTrials.gov NCT04792177
2. Date of registration in primary registry	29 January 2021
3. Secondary identifying numbers	-
4. Source(s) of monetary or material support	University of Luxembourg, Luxembourg National Research Fund
5. Primary sponsor	University of Luxembourg
6. Secondary sponsor(s)	FNR – Luxembourg National Research Fund
7. Contact for public queries	Vinicius Jobim Fischer, MSc, University of Luxembourg, Esch-sur-Alzette, Luxembourg; email: vinicius.fischer@uni.lu
8. Contact for scientific queries	Vinicius Jobim Fischer, MSc, University of Luxembourg, Esch-sur-Alzette, Luxembourg; email: vinicius.fischer@uni.lu Gerhard Andersson, PhD, University of Linköping, Linköping, Sweden; email: gerhard.andersson@liu.se Joël Billieux, PhD, University of Lausanne, Lausanne, Switzerland; email: joel.billieux@unil.ch Claus Vögele, Dipl. Psych., PhD, University of Luxembourg, Esch-sur-Alzette, Luxembourg; email: claus.voegele@uni.lu
9. Public title	Internet-based emotion regulation intervention for sexual health
10. Scientific title	Internet-based emotion regulation intervention for sexual health (SHER 2)
11. Health condition(s) or problem(s) studied	Sexual health, mental health, emotion regulation
12. Intervention(s)	*Emotion regulation skills training*: The intervention will consist in an online emotion-regulation skills training for individuals with sexual problems. It will last for 8 weeks, encompassing psycho-educational and emotion-regulation skills components. Every week participants will gain access to a different intervention module of the training, containing videos, presentation slides, written support material and a recommendation of activities to be completed until the following week of training. Participants are expected to dedicate 30 minutes to one hour per week to complete each module.
13. Key inclusion and exclusion criteria	*Inclusion Criteria for participants:* 1. Between 18 and 65 years of age. 2. Fluent in Brazilian Portuguese. 3. Self-reported sexual problems, assessed in men by a score of < 21 on the International Index Erectile Function (IIEF) and in women by a score of < 26 on the Female Sexual Function Index (FSFI). 4. In a stable relationship for at least the preceding 3 months. *Exclusion Criteria for participants:* 1. Medical conditions that can interfere with the outcomes of the intervention, e.g., diabetes, cancer, cardiovascular problems. 2. ongoing psychotherapy.
14. Study type	Type: interventional

	Study design: 1. Allocation: randomized. 2. Intervention model: parallel assignment. 3. Masking: none (open label) 4. Primary purpose: treatment
15. Date of first enrolment	10 March 2021
16. Sample size	102
17. Recruitment status	Enrolling
18. Primary outcome(s)	- Change in Female Sexual Function Index (FSFI) at 6 months (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). - Change in International Index of Erectile Function (IIEF)at 6 months (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). - Change in Sexual Quotient (QS) at 6 months (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up).
19. Key secondary outcome(s)	Change in Sexual Modes Questionnaire (SMQ) - Automatic Thoughts subscale (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). Change in Sexual Self-Schema Scale (SSSS) (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). Change in Patient Health Questionnaire-9 (PHQ-9) (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). Change in General Anxiety Disorder - 7 (GAD-7) (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up). Change in the Difficulties in Emotion Regulation Scale (DERS) (time frame: baseline, 2 months after baseline (end of intervention), 8 months after baseline (follow-up).
20. Ethics review	Ethical approval has been obtained from the Ethics Review Panel of the University of Luxembourg (ERP 20-029 SHER).
21. Completion date	30.04.2022 (anticipated)
22. Summary results	n/a
23. IPD sharing statement	Undecided