DIGITAL INTERVENTIONS FOR EMOTION REGULATION IN EMOTIONAL DISORDERS

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Summary

Ample evidence supports the efficacy of psychological interventions, specifically to treat emotional disorders. However, there are two major pitfalls in the field. First, there are many people in need who do not have access to these interventions. Second, some people who do receive these treatments do not benefit from them, either due to deterioration or inert effect of the treatment, dropout or relapses.

A robust body of literature has been produced in the last years in order to explain and find solutions to the so-called gap between research and practice. This phenomenon is expressed, for example, in the need of a more clinically relevant diagnostic system, the predominance of efficacy over effectiveness studies, the discussion about the value of manualizing therapy, the lack of communication between researchers and practitioners or the importance of disseminating empirically supported treatments.

This dissertation seeks to shed light into two different but complementary aspects of this discussion. First, a conceptual and empirical argument that deals with how (identification of mechanisms of change) and for whom (identification of moderators) psychological treatments do work. This initial objective includes a discussion around the necessity to build a parsimonious and integrated theoretical understanding of dysfunction that may shed light into potential targets of treatments. In that sense, this dissertation presents a description of the current psychopathological transformation in order to outline the role of emotion regulation (ER) as an overarching transdiagnostic and transtheorical factor that can be targeted from different approaches (i.e. theoretical schools) and modalities (traditional in-person or online treatments).

To shed light upon how digital technologies may play an instrumental role in our capacity to understand, disseminate and improve psychological treatments. This conceptualization gives place to the DIU framework (disseminating, improving and understanding). Specifically, this dissertation applies this framework to ER in emotional disorders, trying to synthetize the available literature on how technology can help to disseminate, improve and understand treatments in which ER is targeted. In that sense, apart from a synthesis of the available literature, a series of studies are provided in which affect and ER as a transdiagnostic mechanisms of change were tested.

First, a large clinical study explored the between and within-patient effects of emotion regulation on outcome in a sample receiving videoconferencing psychotherapy during the pandemic. This study contributes to the purposes of the dissertation in various senses: (a) the possibility to disseminate psychotherapy in the context of the pandemic in which otherwise patients would not have received any treatment, in particular due to the fact that the research was conducted in a naturalistic setting; and (b) the contribution of ER as a mechanism of change in a novel way drawing on the latest statistical models and understanding of process and outcome research.

Second, the contribution of a higher order factor intimately related with emotion regulation, such as affect regulation, as a mechanism of change in a guided internet intervention, a technological development that has emerged in the last years a principal complement to scale psychological treatment. In particular, this study not only constitutes the first study to look into affectivity as a mechanism of change in internet interventions, but also the first in adults to study mechanisms of change beyond lineal mediation. Altogether, these two contributions are a clear manifestation of how the two purposes of this dissertation are reciprocally potentiated. Digital technologies may help to disseminate treatments and that permits to study how these treatments work.

Next, a series of contributions on the other facets of the DIU frameworks are presented. The two principal improving technologies are virtual reality and biofeedback. Regarding virtual reality, it has been used as an exposure tool. In that vein, a perspective on how promoting exposure is a way of facilitating the adoption of adaptive emotion regulation. While there is ample evidence showing the efficacy, a major unanswered question revolves around the potential negative effects. Therefore, an individual patient meta-analysis exploring the deterioration rates in virtual reality was conducted, revealing that this technology yields similar deterioration rates as in vivo exposure and significantly less than waiting lists.

However, virtual reality has been shown that permits to facilitate many other interventions beyond exposure. Hence, a simple intervention was designed and tested based on consumer virtual reality hardware and a freely open-source application such as *Google Earth* VR. Using a single case experimental design and ambulatory assessment, this intervention was suggested as a way of upregulating positive affect and positive emotions by means of positive autobiographical memory recall. Moreover, this type of design is an optimal design when larger studies are unfeasible given that each individual act as their own control.

Meanwhile, bio- and neurofeedback interventions are increasingly integrated to psychotherapy, what their actual contribution is still a matter of discussion. Given that biofeedback had been meta-analytically studied for anxiety but not for depression, a meta-analysis on depressive symptomatology in major depressed patients as well as patients with other conditions was conducted.

Undoubtedly, one of the most powerful uses of technology is to help to understand how psychological treatments work. That is, apart from intervening through the different technologies by means of disseminating or improving technologies, a major affordance of novel digital technologies is to incorporate them in technologically based or not technologically based treatments to assess both through the so-called passive assessment and active assessment.

In that sense, an overview of the behavioral and psychophysiological is presented, and particularly a comprehensive review of the role of vagal tone to the process and outcome of psychological treatments. Besides, the contributions of ambulatory assessment are described. It is expected to especially increase its importance given that it permits to track both passive and active dynamics in real-world settings.

Finally, the integration of the DIU framework is presented as the principal future avenue to expand the role of digital technologies. There are already available examples of mobile just in time interventions that gathers clinical data, usually using ambulatory assessment, and based on that data trigger personalized interventions. There are also mobile and standalone VR as well as mobile biofeedback developments. Taken together, these are all examples of how the DIU framework can be integrated combining in different ways the aforementioned affordances of digital technologies.

In that sense, two examples of integration of the DIU framework that have been developed for this dissertation are presented. First, a protocol to integrate standalone VR and ambulatory assessment prior and throughout the treatment. It is designed to explore mechanisms of change in different and novel ways, such as an intensive ecological momentary assessment before and after the treatment. Besides, it integrates exposure to imagery rescripting, a powerful integrative intervention that operates on distressing dysfunctional memories that are particularly activated and therefore experienced with high intensity. Apart from the protocol, a case study is presented as a proof of concept.

Finally, the development of a mobile based VR biofeedback application is presented. This application is one of the first to integrate VR and biofeedback in mobile devices, and particularly directed to target heart rate variability. Given that it is designed to collect information and based on that information to suggest interventions and those interventions are delivered through a combination of VR and biofeedback and in mobile devices, it constitutes the concretion of the DIU framework in its maximum expression. Preliminary data of its usability is provided, as well as some details and illustrations of the development process.

It must be clarified that these two examples of integration of the DIU framework were the initial goal of the present dissertation. Given the outbreak of the pandemic it was impossible to continue with the respective studies. In the case of the imagery rescripting plus one session virtual reality protocol, 25 patients were admitted throughout February 2020, and were starting the study when the restrictions due to the pandemic were imposed. On the other hand, the VR biofeedback was planned to be applied to a sample of university students with difficulties in regulating emotions, but given the restrictions of the pandemic, it this study was stopped as well.

The three aspects of DIU framework, together with the cutting-edge perspective on transdiagnostic processes and mechanisms of change of psychological treatments, aim to make a modest contribution toward the articulation between research and practice. Overall, this dissertation boosts the discussion concerning some of the current debates in clinical psychology and suggests theoretical and empirical answers in order to improve the field.

1. Introduction

The World Health Organisation lists mental health disorders as one of the principal causes of disability worldwide. Specifically, 4.4% of the global population suffer from a depressive disorder, and 3.6% suffer from an anxiety disorder (WHO, 2017), which together have been denominated emotional disorders.

An emotional disorder can be understood as a clinical condition in which individuals experience frequently and intensively negative emotions, they normally have aversive reactions to those negative experiences, and thus an effortful pursuit to dampen, escape or avoid from them (Bullis et al., 2019). They are prevalent, costly, chronic and recurrent. Therefore, having an emotional disorder is associated with significant impairment in many areas of life, in particular quality of life and social functioning, as well as direct and indirect costs (Angermeyer et al., 2002; Lahey, 2009; Olatunji et al., 2007; Zuelke et al., 2018).

While it is unarguable that the field of clinical psychology has made significant advancements, in particular in the field of emotional disorders, the current challenges are not few. Despite the fact that the efficacy of psychological treatments is well-established (Nathan & Gorman, 2015), a vast array of pitfalls can be identified. First and foremost, millions of people in need do not receive any psychological treatment (McHugh & Barlow, 2010). Moreover, the replication crisis is casting doubts on the obtained results (Tackett et al., 2019), with evidence showing that existing empirical supported treatments (ESTs) usually fail to meet quality standards (Sakaluk et al., 2019). Besides, the predominance of efficacy over effectiveness studies (Hunsley et al., 2014) expresses an epistemological problem of how knowledge is generated that goes beyond a mere issue of dissemination (Fernández-Álvarez et al., 2020). Moreover, there are comprehensive meta-analyses that even question the aforementioned well-established efficacy of psychological treatments (Johnsen & Friborg, 2015). At least, the effect sizes are similar today than many decades ago (Weisz et al., 2019) and the great enigmas still do not have definitive answers, in particular, about the moderators and mechanisms of change of psychological treatments (Kazdin, 2007; Zilcha-Mano, 2020). But most probably the most concerning weakness is the preparadigmatic state of our discipline (Goldfried, 2019). The quarrel between acronyms of three letters that have dominated the last decades, hinder the progress of the field (Hofmann & Hayes, 2019; Wampold & Imel, 2015). So, although psychological treatments should be further disseminated because there is compelling evidence supporting its efficiency (Nathan & Gorman, 2015) as well as more well acceptable than psychopharmacology (McHugh et al., 2013), it is paramount to hurdle the existing barriers in order to build a more robust field.

Over the last years, the incorporation of digital technologies has been gained a lot of interest from the scientific community as a way to boost the field (Kazdin & Blase, 2011). As presented by

Imel, Caperton, Tanana and Atkins (2017), technology-enhanced human interaction can be useful both for research and practice. That is, to understand how interventions work and to provide technology-mediated psychological treatments. The exponentially growing evidence that has emerged in the field of technology and advantages of digital technologies can be resumed in three verbs: a) disseminate, b) improve, and c) understand.

The principal and most described advantage of digital technologies revolves around the possibility of providing treatment to people who otherwise cannot have access to psychological help. The dissemination problem has been largely discussed in the literature (e.g., Fairburn & Patel, 2012; McHugh & Barlow, 2010) and digital technology-based treatments have already proven to be a powerful tool to reach underserved people (Carter et al., 2021; Kazdin & Blase, 2011).

Meanwhile, digital technologies can foster the improvement of psychological treatments. That is, there are certain technologies that permit to bring forth interventions that without the technological input would not be possible. This third category differentiates from the first in that the first is focused on the use of technologies for the assessment of clinical interventions, while this third is based on the delivery of the interventions themselves.

Finally, by understanding we mean that digital technologies can help to study how interventions work, for whom and other relevant questions for research purposes. That is, the incorporation of technological developments permits to gauge certain processes and dynamics of change that otherwise would not be possible. Digital technologies may incorporate active and passive assessments through a myriad of different tools that permits to access to unprecedent amount of data. Altogether with innovative techniques of data analysis, such supervised and unsupervised learning algorithms. In that sense, digital technologies may foster the exploration of mechanisms of change of psychological treatments.

Altogether, these three categories can be used to organize the advancements in any area of clinical psychology. In this dissertation this framework will be applied to emotion regulation (ER) in emotional disorders. From the ample existing evidence, interventional studies have increased and technological solutions to improve ER have been greatly expanded. Hence, in the following sections we will first present the affordances that digital technologies entail in order to better understand ER interventions in clinical settings, and secondly, we will overview the existing developments to facilitate the dissemination and the improvement of clinical interventions through digital technologies. Figure 1 illustrates the DIU framework

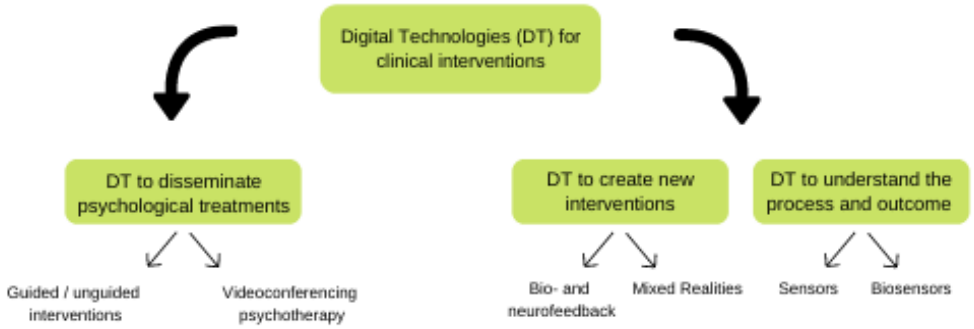

Figure 1. Illustration of the DIU framework: dissemination, improving and understanding

1.1 *Emotion Regulation: Psychopathological transformations, new clinical targets*

The psychopathological taxonomy of mental disorders is facing a deep transformation (Kotov et al., 2017). Traditionally, clinical psychology research followed a biomedical paradigm, in which prevailed a disorder-oriented diagnostic perspective and acronyms emphasizing the supremacy of one component of human functioning over others (Hofmann & Hayes, 2019; Paris, 2013). Therefore, clinicians were trained to explore syndromes which was the way to access to a deep, functional understanding of psychopathology. Accordingly, randomized controlled trials (RCTs) constituted the gold standard in order to test whether an intervention worked and the adherence to the manual the way to measure therapist's skillfulness (Hofmann & Hayes, 2019).

In the last decades, nosological diagnoses had been primarily driven by categorical manuals, which were organized in the existence of multiple specific disorders, independent among each other. Despite some putative advantages of specific categorical diagnostic tags, their pure forms are only rarely manifested in reality. Heterogeneity within a single diagnosis and comorbidity among sets of diagnoses represent serious problems that call into question the utility of classical diagnostic manuals (Hopwood et al., 2019). Indeed, psychopathological research has showed that mental dysfunction is concentrated in certain individuals who present comorbid conditions. This is of particular importance in the case of emotional disorders, with evidence indicating that there is a lifetime prevalence comorbidity of 76% (Brown et al., 2001).

Based on motivation theories, it has long been suggested that there are two central mechanisms that identified with the regulation of emotions and behaviours. The most prominent and cited theory is the reinforcement sensitivity theory (Gray, 1970) that postulates that the approach systems orients the individual toward rewarding attitudes, emotions and behaviors, and the withdraw system that orients the individual toward avoidant attitudes, emotion and behaviors. Although emotional disorders have been conceptualized as involving both defense system excesses and appetitive system deficits, the majority of conceptualization to date have mostly focused on the negative valence associated with the defensive system (Craske et al., 2016).

This sets out two important points. First, the intimate link of two systems with the concepts of positive and negative affect and emotions. Second the relevance of considering positive affect as a different facet from negative affect, and the implications this entails for the regulation of affect and particularly of emotions as a lower order factor. Research suggest that the two-factor solution of affect may be a suitable construct to establish differences between individuals, and discrete emotions within-person differences (N. C. Jacobson et al., 2020), but both should be considered.

Compelling research has demonstrated that higher-order variables, such as neuroticism or extraversion, are greatly associated with the development, maintenance, and severity of emotional disorders (Barlow et al., 2014). In particular, research linking neuroticism and psychopathology has a longstanding tradition (Eysenck, 1947), but also extraversion (Watson et al., 2019).

Neuroticism and negative affectivity are central in the prediction of emotional disorders as a spectrum beyond specific disorders (Brown & Naragon-Gainey, 2013). This has been studied not only cross-sectionally but also longitudinally (Jeronimus et al., 2016; Khazanov & Ruscio, 2016). Despite the increased understanding of how emotional disorders co-occur, it is of paramount to clearly identify intermediate transdiagnostic mechanisms that are more related to clinical utility (Ruggero et al., 2019). Naragon-Gainey and Watson (2014) found that clinical traits (e.g., anxiety sensitivity, perfectionism) were strongly related to neuroticism and generally showed limited incremental predictive power beyond it, although anxiety sensitivity made notable incremental predictive contributions in several cases (e.g., PTSD and panic). Thus, these findings clearly indicate that clinical traits overlap considerably with neuroticism. As it has been found with other clinical traits, the subscales of the DERS would be expected to overlap especially strongly with neuroticism (Stanton et al., 2016).

Likewise, extraversion is intimately linked with positive affectivity, which indicates the possibility of encountering potentially pleasurable intra and interpersonal experiences (Watson et al., 1992; Watson & Naragon-Gainey, 2014). Those individuals who present higher levels of positive affectivity tend to experience more pleasure events and make more effort to obtain those situations. However, clinical traits are of paramount importance because they reflect proximal individual differences that differentiates in a better way those individuals who may develop specific dysfunctional symptoms (Naragon-Gainey et al., 2018).

After many decades using the biomedical paradigm, the scientific community has started to call into question not only the metaphysical veracity of this taxonomy and treatment conceptualization, but also its usefulness for the clinical practice (Cuthbert, 2014; Kotov et al., 2017; Krueger et al., 2018). This justifies the worldwide efforts done by psychopathologists and clinical researchers to develop a new paradigm of human suffering. In that sense, the appearance of new systems of classification in line with the irruption of the study transdiagnostic processes that are thought to mediate between the vulnerabilities and the dysfunction are transforming the field in unprecedent ways.

It gains relevance to build an integrative psychopathological model focused on personality functioning as well as transdiagnostic mechanisms and processes of change. The HiTOP represents a

taxonomy that considers psychopathology principally as a maladaptive deviation from normal personality functioning. Incorporating this kind of dimensional and hierarchical approach is not only more consistent with the existing empirical data but it also allows for the integration of research findings on both normal trait dimensions and their more maladaptive variants (Conway, 2019).

Contemporaneously to the HiTOP, the RDoC project has adopted a new agenda, intending to guide mental health research by focusing on how functional psychological processes, such as those involved in healthy emotional functions, deviate from normal and become dysfunctional. The understanding of dysfunction goes beyond descriptive categorical clusters of symptoms and seeks to capture the continuum of emotional experiences and pathophysiology (Insel et al., 2010).

Ideally, the HiTOP and the RDoC will be integrated into a unique comprehensive psychopathological model, to preserve the best of the two conceptualizations. Some efforts have been recently presented (Michelini et al., 2021). Both conceptualizations are genuinely dimensional, pursuit to transcend the categorical nosology and may serve to create an integrative comprehensive psychopathological model.

That is, dysfunctional expressions of behavior are always anchored in a particular organization of personal experience and this organization is structured in several levels of complexity based on the primary patterns that derive from the basic personality traits. Personality is, therefore, the system in which all the individual's behaviors, both explicit and observable as implicit and inferred, do unfold. Various cognitive, emotional and social regulation mechanisms operate as modulating variables between behavior and experience. Hence, difficulties in regulating emotions, cognitive processes or interpersonal relationships may be primarily understood as an exacerbation of personality patterns that hinder people from being flexible enough in order to implement other strategies (Livesley, 2012).

In fact, there is an increasing body of evidence that shows the paramount importance of personality to explain ER capacities (Hughes et al., 2020; Stanton et al., 2016). This could be arguably extended to any regulatory process, and overall, it could be understood as the key relevance of personality as the basis in which experiences and behaviors are anchored. Accordingly, personality dysfunctions can be understood as the deployment of maladaptive patterns of cognitive, affect, social, behavioral and perceptual regulation (Pincus & Hopwood, 2012).

In this sense, ER is not conceptualized as yet another transdiagnostic process or mechanism of change of psychological treatments. Although it goes beyond the scope of this dissertation, it is defended the idea the field needs a parsimonious conceptual and empirical chart of mechanisms of change, and all forms of regulation may serve as an organizing axis, following a long-standing tradition in research areas such as personality, developmental and motivation psychology (Dweck, 2017).

1.2 *Conceptualizations of Emotion Regulation*

> "ER research is flourishing. However, enthusiasm for this topic has outpaced conceptual clarity, resulting in a maelstrom of disparate findings" (Ford & Gross, 2018)

There is no doubt that ER plays an essential role in the current psychopathological transformation and that it has gathered compelling evidence to support its transdiagnostic status. However, since the appearance of ER, several conceptualizations have been proposed. Although there is an increasing effort to integrate different frameworks, it still constitutes a fragmented field. Taken into consideration the most prominent model, ER could be defined as a dynamic process that aims to modify the emotion generation and expression by down- or up-regulating emotions in order to reach desirable states (Gross, 1998) by means of strategies (Gross & Jazaieri, 2014) and skills (Gratz & Roemer, 2004). This strategies and skills are either intra- or interpersonal (Barthel et al., 2018), controlled- or automatic, as well as explicit or implicit (Gyurak et al., 2011). The process of regulating emotions not only entails the management of negative but also positive emotions (Carl et al., 2013; Silton et al., 2020). So, strictly speaking, ER can be understood as anything that we think or do and that has an effect on the way we feel. Like all mental processes, ER is composed by an experiential dimension (i.e. cognitions and feelings), a behavioral dimension and physiological correlates that support the whole process.

There are a number of ER conceptualizations that build on models of self-regulation. In contrast to the models that have an affective focus and therefore distinguish between emotions, moods and affect, these models attend to motivational concepts and conceptualize ER as an instantiation of motivated regulation in the emotion domain. Motivated ER is always directed to modify current emotions toward desired emotions, according to the goals of the individual. In that sense, key aspects of the regulatory process are the nature of goals, organization and dynamics of goal pursuit (Tamir et al., 2020)

The cybernetic model is an illustrative example and is very relevant to account for the reasons that motivate to regulate emotions. This model permits to integrate ER into the broader concept of self-regulation given that the regulation of emotion is similar to the regulation of other targets (Webb et al., 2012) and into the personality literature as previously described (DeYoung, 2015). A fundamental aspect of the cybernetic model revolves around emotional goals, which are representations of desired (or undesired) endpoints stored in memory.

ER goals may be hedonic or instrumental (Tamir, 2015). For example, expressive suppression is more likely to be used when people are socially motivated to act (i.e. instrumental goal) and distraction and reappraisal when people pursue hedonic goals (English et al., 2017). Moreover, there is a distinction between goal setting and goal striving. While goal setting consists on which goals to pursue and is related to selection stage of identification stage of Gross' model, goal striving is the behavior (or cognition) that is deployed and is related to both selection and implementation stage of Gross' model (Tamir et al., 2020).

Concretely, research on the field of ER has traditionally focused on outcomes and means, such as strategies and tactics. Usually, the literature considers the effects of using a certain strategy but without considering the effects of trying to regulate *per se* (Tamir et al., 2019). In that sense, it is much

more common to explore if and when a strategy like cognitive reappraisal or suppression is implemented than the reasons that motivate to use cognitive reappraisal or suppression. That is, there is more emphasis on the means than the ends (Tamir, 2021). The proposed cybernetic analysis is but one step toward addressing these issues.

Likewise, self-determination theory is also based on motivational theory, which put the emphasis on the concept of autonomy. In light of this theory ER is a process that fosters the psychological growth of the individual and the development of a coherent sense of self. The framework that links ER and self-determination theory suggest three types of regulatory styles. While integrative ER style facilitates the autonomy of the individuals, suppressive and dysregulation are nonautonomous styles (Benita, 2020).

The classical temporal and strategy-based model is not as clinically relevant as the cybernetic model but is by far the one that has gathered more empirical evidence. Based on the operationalization of Gross (1998) it constitutes a very useful framework to understand the process in terms of temporal deployment. Besides, it has divided the strategies into putative adaptive and maladaptive strategies which has useful for psychopathological research in general and experimental psychopathological research in particular.

Meanwhile, Gross' model emphasized five points in the emotion generative process, in which regulatory strategies could be implemented. These five stages were organized in a temporal timeline, including situation selection, situation modification, attentional deployment, appraisal or cognitive change and response modulation (Gross, 1998). While the first four are considered antecedent-focused emotions, the last one is a response-focused emotion. In the extended model, the conceptualization was complexed considering the cybernetic notion of perception, valuation and action, which is a turning point in Gross' pursuit to integrate the model into the described models focused on the broader concept of self-regulation. Besides, this reformulation of the model distinguishes three stages of the emotion regulatory cycle (identification, selection and implementation), which together with the interaction of first and second order valuation systems incorporating the recursive dynamic of ER (Gross, 2015).

An important clinical contribution for the further development of Gross model was its rapid incorporation to psychopathological studies. The strategy-based model applied to clinical populations has particularly focused on the putatively adaptive and maladaptive ER strategies. Aldao, Nolen-Hoeskema, and Schweizer (2010) conducted a large meta-analysis in which acceptance, suppression, rumination, problem solving, reappraisal, and avoidance were studied in anxiety, depression, eating disorders and substance-related disorders. Overall, the authors demonstrated that particularly rumination but also avoidance and suppression are maladaptive strategies of ER. Likewise, problem solving and to a lesser extent acceptance and reappraisal are adaptive strategies. Although both internalizing and externalizing disorders have been associated with emotion dysregulation (Beauchaine & Crowell, 2020), internalizing disorders are more strongly associated with maladaptive ER strategies. Table 1 summarizes the main available strategies.

Table 1. Overview of some therapeutic tactics in light of Gross ER model

STRATEGIES	TACTICS
SITUATIONAL STRATEGIES	● Avoidance ● Behavioural activation ● Exposure
ATTENTIONAL STRATEGIES	● Distraction ● Mindfulness ● Concentration ● Rumination
COGNITIVE STRATEGIES	● Cognitive restructuring ● Meaning elaboration ● Insight ● Acceptance
RESPONSE MODULATION STRATEGIES	● Defusion ● Supression ● Breathing / relaxation ● Problem solving

The ability-based model of Gratz and Roemer (2004) is another widely used and accepted conceptualization model. Consistent with research on the functionality of emotions and paradoxical consequences of efforts to avoid or control emotions, this definition focuses on adaptive ways of responding to emotional distress, including the awareness, understanding, and acceptance of emotions, ability to control impulsive behaviors and engage in goal-directed behaviors when experiencing negative emotions, flexible use of situationally appropriate strategies to modulate the intensity and duration of emotional responses in order to meet individual goals and situational demands, and a willingness to experience negative emotions in pursuit of desired goal. Thus, emotion dysregulation could be grasped as a deficiency of these abilities. Contrary to strategy-based models, this offers a less fragmented perspective of ER. Indeed, the Difficulties in ER Scale is one of the most used questionnaires in order to measure overall deficits of ER.

Based on the strategy-based model and ability-based model, a comprehensive meta-analysis has shown that there are three overarching factors (disengagement, aversive cognitive perseveration and adaptive engagement) that constitute the core of the structure of common ER strategies (Naragon-

gainey et al., 2017). However, as concluded by the author of this study, there is no single measure that gathers all aspects of ER. There is a myriad of fragmented traditions, but there is an urgent need to integrate the efforts in order to foster the advancement of a promissory field.

This fragmented structure of strategies does not represent the real world, given that the process of regulating emotions is usually much more complex than instructing people to use putative adaptive strategies. First, because the adaptiveness can only be considered in terms of the context and therefore a putative maladaptive strategy like suppression may be the most convenient solution depending on the situation. Second, because people usually use more than one strategy at the same time (Ford, 2019) and in a spontaneous rather than instructed way (Szasz et al., 2018).

In that vein, interpersonal ER is emerging as one of the key developments within ER literature with diverse and solid frameworks (Barthel et al., 2018; Dixon-Gordon et al., 2015; Hofmann, 2014; Marroquín, 2011; Williams et al., 2018; Zaki & Craig Williams, 2013). It is possible to identify recent new scales on interpersonal ER in the literature (Dixon-Gordon et al., 2018; Hofmann et al., 2016), which will permit to further explore this in clinical interventions in general, and digital clinical interventions in particular.

Research in this direction is of vital importance given that we tend to think in lineal and simple ways and accordingly to take for granted unexplored questions. For example, research has shown that in certain individuals it may be detrimental to have too many strategies available when regulating negative emotions (Bigman et al., 2017). Consistent with this concept, individuals are not always motivated to decrease their experience of anger. While this is the case in situations that require interpersonal collaboration, the opposite occurs when they need to complete tasks that require active confrontation (Tamir et al., 2008). Even with the emotion of happiness that in our contemporary society is deemed as an ideal emotional state, there is research that shows that not always is beneficial to experience it (Gruber et al., 2011). These results reveal that depending on situation it may be more useful or desirable to experience negative to positive emotions.

Flexibility represents a key concept when analyzing ER, and variability constitutes, in turn, an essential component. In that sense, the majority of available evidence has been conducted on trait ER, while ever-growing literature is showing that fluctuations over time is an indispensable feature in order to fully grasp its nature. This is particularly important when considering ER as a mechanism of change. It may be the case that individuals largely vary across situation and even within same situation but with a different contextual trigger (e.g., type of activity or type of company).

Accordingly, ER and dysregulation is an emergent property that arises from the interaction of a range of top-down and bottom-up processes, in a context-sensitivity (Aldao, 2013) and dynamic way (Bylsma & Rottenberg, 2011). The process of ER is multilayered (Southward et al., 2021). For example, discrete strategies have the principal goal to influence an emotional experience may exert different results in the short and in the long term. That is, over the short term ER strategies can fluctuate from

effectiveness to *ineffectiveness* (minutes to hours from the moment of regulation), defined as the degree to which a strategy helps a person "reach their desired emotional outcomes" (Ford et al., 2019).

Over the longer term, ER strategies may be classified as *adaptiveness* to *maladaptiveness*, conceived as the extent to which the habitual use of a strategy "is associated with better longer-term outcomes" (Ford et al., 2019). These outcomes, as aforementioned, include personality functioning (Borges & Naugle, 2017), personality dysfunction (Mahaffey et al., 2016), resilience (Polizzi & Lynn, 2021), general well-being (Kraiss et al., 2020) and physical health (DeSteno et al., 2013). Strategies associated with better long-term psychological functioning can be classified as *adaptive*, while those that tend to promote worse outcomes can be classified as *maladaptive*. A vast array of contextual factors (e.g., biological, developmental, environmental, and individual difference factors) may have an influence on the effectiveness and adaptiveness of strategies in specific contexts (Aldao, 2013). However, classifying strategies by their effectiveness and adaptiveness is a useful heuristic for summarizing the great body of literature, and it may facilitate translation between basic affective science and intervention research (Southward et al., 2021).

Another difference worth making is between the quantity, frequency and quality. While the quantity refers to the range of strategies that a certain individual uses over time, the frequency refers to how often strategies are utilized. Although strongly correlated, they are separated processes. A person could present a very broad repertoire (high quantity) but each of them used very rarely (low frequency). Finally, quality refers to how well a certain strategy is used (Southward et al., 2021).

The aforementioned conceptualizations are primarily focused on explicit ways of ER, either automatic or controlled driven. However, implicit processes, understood as regulatory processes that do not involve the conscious desire to change emotional responding (Braunstein et al., 2017), have shown to be paramount, yet usually undermined in the previous models of ER. That is, the most used ER frameworks are built upon a classical representational model that conceives the process as sequential and brain-centered process. But other forms of cognition have proven to be equally important in the process of regulating emotions.

This is the case, for instance, of embodied cognition that considers the role of the body in the instantiation of emergent intentional processes such as beliefs, emotions, desires and the whole mental activity. This research line has the principal aim of incorporating the body as a core component of the emotional experience and its regulation. The embodied approach takes into account, for example, facial expressions, bodily postures, corporal movements (Koole, 2009) as well as psychophysiological responses (Appelhans & Luecken, 2006). It has been used to develop psychotherapeutic interventions (Fuchs, 2020).

Overall, the greatest advances on ER provides a still fragmented chart of developments that needs to be integrated in order to take stock of the respective advancements in the field. In particular, the clarification of how the different perspectives of ER impact on the appearance and maintenance of

human suffering it is of utmost importance to tackle patients' ER difficulties in the clinical context and improve treatment outcomes.

1.3 *Emotion Regulation: Its transdiagnostic nature*

Any cognitive or emotional process that is identified across many disorders, and that causally explain the appearance and maintenance of those disorders can be conceptualized as transdiagnostic (Harvey et al., 2004). As a general theory of dysfunctionality, transdiagnostic processes permit to identify shared, overarching processes that cut across a range of clinical conditions.

Throughout the last years, research has increasingly identified processes across a range of clinical conditions, and thus treatment procedures have begun to be applied transdiagnostically. This expansion has led to a variety of conceptualizations of what transdiagnostic means, namely three main groups as described by Sauer-Zavala and colleagues: a) universally applied therapeutic principles; b) modular treatments, and; c) shared mechanisms treatment (Sauer-Zavala et al., 2017).

One of the most interesting avenues to explore within transdiagnostic processes is the identification of basic psychological processes, which operate as active functions underlying varied and heterogeneous clinical conditions. This perspective permits to take a very important step towards a better connection between clinical interventions and basic processes. In this sense, despite the proliferation of numerous transdiagnostic processes, many of which have been suggested to be relevant in the appearance and maintenance of specific disorders (e.g. panic disorder), clusters (e.g. anxiety disorders) as well as overarching categories (e.g. internalizing disorders), there is an increasing consensus regarding the necessity of finding more parsimonious psychopathological explanations and accordingly therapeutic interventions (Mansell, 2018). In other words, it would be against the spirit of a transdiagnostic conceptualization to have a myriad of overlapping processes, and therefore there is a need of finding a common structure that permits to embrace the unity of psychopathology without disregarding the multiplicity of manifestations and pathological organizations that experience and behaviors may adopt (Mansell & McEvoy, 2017).

There is no doubt that the transdiagnostic conceptualization is leading the current psychopathological and clinical understanding of dysfunction. Particularly, regulatory processes such as ER plays an instrumental role in this new chart of the field. Indeed, there is a general agreement that ER is a transdiagnostic process since mounting evidence has shown that difficulties, inabilities and maladaptive strategies occur when pursuing to manage emotional experiences in a range of mental dysfunctions, both in adults (Aldao et al., 2010; Cludius et al., 2020) and youth population (Schäfer et al., 2017).

Although ER is relevant in all clinical conditions, and even in healthy population to explain a range of processes (e.g. decision making or well-being), it is important to acknowledge that ER has been principally studied in some conditions. Indeed, ER was first described as a core dysfunction in

borderline personality disorder and later it has become the most studied process in emotional disorders (Ann M. Kring & Sloan, 2010). However, in the last years practically the whole psychopathological spectrum has been associated with an impairment in some dimension of the previously complex process of regulating emotions (Sheppes et al., 2015).

Although ER is a shared mechanism in different conditions (Sauer-Zavala et al., 2017), the differences emerge regarding specific facets of its complex structure. For example, depressed people, present a low ability to select the right strategy rather than its execution. Meanwhile, social anxiety disorder individuals present a problem in the implementation of the strategy (Dryman & Heimberg, 2018). Moreover, individuals with MDD characterize by an increased use of rumination and decreased use of reappraisal in comparison to social anxiety individuals, who present an increase in the use of expressive suppression in comparison to MDD individuals. Likewise, the literature shows in a number of studies that social anxiety presents more suppression than cognitive reappraisal (Blalock et al., 2016; Goldin et al., 2014; Jazaieri et al., 2015).

With the aforementioned predominance of categorical taxonomies, most of the differences has been established between discrete disorders. However, other between subject variables, and especially within subject trajectories, are starting to emerge as a more idiographic, nuanced and therefore useful differentiation of unsuccessful ER deployment (Wright & Woods, 2020).

Overall, there are numerous differences between and within clinical conditions, depending on a vast array of variables, such as gender, age or socio-cultural factors, which together present heterogenous difficulties with the identification, strategy selection, implementation and monitoring (Sheppes et al., 2015). Furthermore, certain strategies like cognitive reappraisal and rumination have been carefully examined in light of Harvey et al. (2004) criteria in order to be considered a transdiagnostic process (Cludius et al., 2020). The two criteria are evidence of presence across disorders and causality. Despite the growing body of literature, the authors conclude that ER still needs from further theoretical refinement, to design ecological longitudinal studies or experimental studies to test causality, and to recruit heterogenous samples to investigate ER across the psychopathological spectrum.

If these endeavors are not further developed the field has the risk to remain in the middle of the bridge. Dalgleish et al. (2020) described the current use of transdiagnostic concepts as a soft transdiagnostic approach. That is, putting emphasis on the underlying shared mechanisms that explain mental disorders, but still preserving the classical diagnostic classification of specific disorders. An illustrative example is the Unified Protocol, that is a transdiagnostic ER based interventions but includes the discrete specific disorders diagnosis conceptualized by the DSM (Sakiris & Berle, 2019). In contrast, more radical, “hard” transdiagnostic approaches dispense with the diagnostic system altogether, seeking to replace it with alternative frames of reference that characterize mental ill health in new ways.

Having a comprehensive model of dysfunction as previously reviewed, permits to explain that ER is a common transdiagnostic process. Precisely, in a data-driven model like HiTOP, borderline personality disorder is organized in the same subfactor (i.e., distress) than generalized anxiety disorder, dysthymia or major depression (Conway et al., 2019), permitting to understand why individuals suffering from any of these disorders benefit in average from the same treatment. However, affective research and intervention research have not harnessed the potential of a multilayered process like ER. These questions need to be addressed considering the change of paradigm that is occurring in the psychopathological realm.

1.4 *Emotion Regulation: Its transtheoretical nature*

Although it is true that there exists an enormous number of psychological treatments, it is suggested that all of them can be organized considering cognitive-behavioral, psychodynamic, humanistic-existential approaches and systemic (Längle & Kriz, 2012). As described by Gratz, Weiss and Tull (2015), different psychological treatments consider ER in a different manner, but all of them include it as a key target.

For example, in psychodynamic therapies, defense mechanisms can be conceived as implicit forms of ER, which can be either unsolved conflicts that are at the root of the individual's motivations or adaptive as forms of promoting self-esteem or self-integration (Messina et al., 2016). Moreover, psychodynamic work has first theorized about the complexity of ER, given that defense mechanisms could not be rigidly considered adaptive or maladaptive. It is possible to affirm that psychodynamic theories introduce the idea of ER flexibility, and thus the need of considering the context to determine what is adaptive (Aldao et al., 2015). Developments in psychodynamic theory proposes the central role of affect regulation in the development of mentalization, which is regarded as the capacity to reflect on and interpret one's own behavior and that of others based on intentional internal mental states. The ability to mentalize one's own experiences and those of others enable an adequate regulation of affect and emotions (Fonagy et al., 2002).

In the same vein, all humanistic-existential approaches target ER as a key therapeutic construct. An example is emotion focused therapy (Greenberg, 2019). From this perspective, ER is comprised as a facet of emotional processing, entailing two types of strategies. In the short term, the main aim of regulating emotions is the downregulation. Meanwhile, the process of ER in the long term is understood as the process of self-development that is deployed in a gradual manner, such as the case of making personalized meaning (Pascual-Leone et al., 2016). The reflection on emotion, like narrative reframing, is an important aspect of this conceptualization. Contrary to conceiving the regulation of emotions as a mere behavioral strategy, which may be particularly useful in highly arousing and highly distressing situations, narrative reframing comprises a longer-term process.

In the same vein, ER is a principal targeted process in cognitive behavioral therapies. On the one hand, CBT considers cognitive reappraisal or cognitive change a central key target (e.g. Strauss et al., 2019). On the other hand, both classical behavioral approaches as well as *third wave* therapies have emphasized the role of avoidance, suppression and distancing as maladaptive strategies that should be overcome with repetitive exposure to feared situations and distressing experiences. Indeed, the core function of ACT is psychological flexibility which is produced through six processes: acceptance, defusion, contact with the present moment, enhancing a self-as-context perspective and identifying values and doing effective actions toward those values.

Indeed, some of the most prominent treatments focused on ER are derivations from this broad conceptualization of CBT, including the more recent contributions (Fresco & Mennin, 2019). Illustrative examples are the emotional dysregulation model (Hofmann et al., 2012), the Unified Protocol (Barlow et al., 2004), the Dialectical Behavioral Therapy (Linehan, 1993), the Emotion Regulation Therapy (D S Mennin et al., 2018), Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 2003), Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2002), or Acceptance and Commitment Therapy (ACT; Hayes et al., 1999), just to mention some of the most prominent treatments.

Furthermore, all the principal theoretical frameworks conceive the described aspects of ER as the emergence of the interaction of the individual and others (Barthel et al., 2018) and in a specific context (Aldao et al., 2015a). In this sense, ER is a dynamic process and its dysregulation could only be fully grasped if contextual and family environments that shape emotional demands are considered (Thompson, 2019). Therefore, the assumptions of systemic and family therapy are of utmost importance to understand how ER is deployed in the therapeutic context.

Given the transtheoretical nature of ER, it is unsurprisingly that perspectives that seek for common processes also regard regulatory mechanisms as essential therapeutic ingredients. For example, Koole and Tschacher (2016) explicitly interrelated how therapeutic alliance and ER may be associated through the embodied interaction of verbal and nonverbal synchrony between patient and therapist. The In-synch model represents an effort to explain the interaction of cognitive processes and their impact on the psychotherapeutic process, in which synchrony constitutes an important ingredient of psychotherapy due to its role in the establishment of therapeutic alliance and the interpersonal regulation of emotions.

Overall, all psychotherapies foster corrective emotional experience, emotional awareness or insight and exposure to emotion (Greenberg et al., 2019; Wampold & Imel, 2015). Furthermore, there is compelling evidence showing that ER can be trained both in health and clinical populations (Denny, 2020). Both cognitive behavioral models of ER and experiential-dynamic models of ER address complementary aspects of ER. Therefore the treatment modalities, the therapeutic strategies, the biological mechanisms of regulation, the neural processing as well as the neural basis are different in both conceptualization (Grecucci et al., 2020)

That makes of ER a general principle of change. While theories are too abstract and techniques too specific, principles of change are the ideal level of abstraction that would permit to find commonalities among them and build an integrated discipline (Louis G Castonguay & Beutler, 2006; Goldfried, 2019). In this vein, the target of regulatory processes can be conceptualized as a principle of change that all psychological treatment pursuit, despite the existence of a myriad of techniques and procedures.

In this regard, there are interventions that are not directly designed to target ER but have an influence on it, whereas other interventions do explicitly target ER. From these, some target ER as one component of a more comprehensive treatment and others are specifically focused on ER (Gratz et al., 2015). Finally, there are also a great number of treatments that do not consider ER explicitly, but still produce changes on them (Sauer-Zavala et al., 2017).

1.5 Emotion Regulation: A transdiagnostic and transtheoretical mechanism of change

After many decades of research, different mechanisms and processes of change have been suggested and tested, but only few have accumulated consistent evidence so far (Zilcha-Mano, 2020). The field has failed to demonstrate common mechanism and processes of change through different psychotherapies (Cuijpers et al., 2019). Within models of therapy, there are mixed results even in long standing believed mechanisms of change, such as cognitive change in cognitive behavioral therapy (Lorenzo-Luaces et al., 2015) as well as emotional theory (Meuret et al., 2012) or inhibitory learning (Craske et al., 2014) which are thought to be well supported mechanisms of change in exposure therapy. Without understanding processing how and why treatments work, it will be impossible to improve the current outcomes (Kazdin, 2007).

It is worth differentiating two types of therapeutic components linked to the results of psychological treatments. On the one hand, the so-called change process, which can be defined as experiences that occur during therapy and are linked to the results (Doss, 2004). The most comprehensive and integrative framework identifies two fundamental change processes: experiences of mastery in problem solving and experiences of clarification (Grawe, 2004). On the other hand, the mechanisms of change, understood as the modifications that occur in certain stable characteristics of the patient and that explain the effect of the treatment (Doss, 2004).

As described in previous sections of this dissertation, there is compelling evidence to suggest that ER is a key transdiagnostic and transtheoretical mechanism of change in psychological treatments. But in order to be considered a mechanism of change it requires to be tested empirically. Therefore, research should focus its efforts on the identification of specific components that may be possible sources of treatment, as well as the study of variability between patients to determine who can benefit from said interventions. This line of research puts the emphasize on the development of personalized interventions (Delgadillo & Lutz, 2020).

Although the most rigorous way to determine a mechanism of change is a dismantling trial, these studies are not free of pitfalls given the multiple intervening factors in psychotherapy research. Even if dismantling trials are specifically designed to detect causal effects, it is very uncommon that single components will present a big contribution to the overall treatment effect. Moreover, some mechanisms cannot be manipulated or removed due to ethical and/or conceptual reasons, such as the therapeutic alliance.

A very often implemented alternative to explore mechanisms of change is mediation analysis derived from randomized control trials. These studies entail the assumption that the treatment effect on final outcome is the consequence of an improvement in a mechanism throughout the treatment. Nonetheless, in RCTs the treatment is randomised instead of the mediator so there is risk of confounding and thus hindering from establishing causality (VanderWeele, 2016), unless specific procedures are implemented that prevent from confounding such as detrending (Falkenström et al., 2017).

That is, mediation has been mainly studied by implementing linear regression models, which undoubtedly do not fit the actual behavior or psychological variables in general, and therapeutic variables in particular. Instead, many scholars claim for the incorporation of idiographic approaches to shed light upon how, why and for whom psychological treatments work (Hofmann et al., 2020; Piccirillo et al., 2019). Moreover, mediation is only a proxy of mechanisms of change. For instance, Tyron (2018) established a parallelism between mediation and mechanism of change with correlation and causation, in that mediation is necessary condition to establish why and how an intervention work but not a sufficient condition.

There are traditional methods in order to study change processes, such as functional analysis, case formulations or qualitative research. However, the only traditional method that permit to experimentally determine the effect of a single intervention or a whole treatment is Single Case Experimental Design (SCED). SCEDs are a practical research methodology that entails repeated observations over time which permits to conduct fine grained analysis of intra-individual variability, visual analysis and temporal changes of dependent variable and/ or maintenance patterns (Kazdin, 2018a).

In naturalistic studies, experts suggest incorporating a different analytic approach that entails a longitudinal measurement throughout treatment in order to test temporal associations between variables. A rule of thumb indicates that with 30 repeated measurements the best statistical choice is to conduct time series analysis, while with 20 repeated measurements or less the right choice should be panel data analysis (Falkenström et al., 2020). Besides, hierarchical level models permit to deal with the nested structure of the data and to estimate the slopes when there is missing data (Gómez Penedo et al., 2019).

In the case of ER, there are different interventions that are conceptually based on the regulation of emotions, as seen in the previous section. However, it has not always been specifically measured whether ER improves between the beginning and the end of treatments, yet alone those changed are

measured throughout treatment. These longitudinal designs are essential to unravel how trait-like processes are related to state-like processes (Zilcha-Mano, 2020).

In a systematic review that included 67 studies in which ER was measured at the beginning and at the end of the treatments, it was observed that this process improved in practically all cases (Sloan et al., 2017). However, one of the main conclusions of this review is the lack of studies that evaluated ER as a mechanism of change throughout the treatments and thus establish the role as a predecessor of symptomatic change. Only the study by Radkovsky et al. (2014) identified that increases in adaptive ER skills are associated with a reduction in depressive symptoms.

Apart from this review, it is possible to find a few examples that were focused on ER as a mechanism of change in emotional disorders. For example, based on a clinical trial for social anxiety in which ER was measured each session, Goldin et al. (2014) established how cognitive behavioral therapy (CBT) generates changes from an increase in cognitive reappraisal and a decrease in suppression. Likewise, Goldin et al. (2017) tested a clinical trial also for social anxiety in which a CBT group was compared with a mindfulness group, showing that the CBT group obtained changes due to improvements in cognitive reappraisal and the condition of mindfulness due to improvements in acceptance.

More recently, other studies have been carried out that study the role of ER intensively during treatments. For example, Strauss et al. (2019) examined the change in cognitive reappraisal and suppression in patients with panic disorder, showing that both strategies evolve in a non-linear manner and identifying that only suppression presents a significant bidirectional relationship with symptomatic improvement. This is in line with the findings obtained by Kivity and colleagues (2021), who also revealed that suppression but not reappraisal predicts subsequent anxiety in panic disorder.

Meanwhile, O'Toole et al. (2019) demonstrated in a treatment specifically designed to intervene in ER in patients with generalized anxiety disorder that metacognitive ER explains the reduction in worry and anxiety. Mechler et al. (2020), studying a sample of adolescents with depression, found evidence in favor of the improvement in depressive symptoms as a result of the previous increase in ER. In addition to working on a different age group, it is the first study to explore ER in a psychodynamic treatment.

Although there is a growing body of evidence exploring ER as a mechanism of change, these studies have divergent conceptualizations of ER and are focused on different components (e.g., strategies). In order to further explored the black box of psychotherapy, it is very relevant to distinguish between the trait-like and state-like distinction (Zilcha-Mano, 2020). Given the scarcity of evidence in this area of research and its clinical relevance, it is necessary to continue to study empirically the potential role of ER as a mechanism of change in psychological treatments.

In particular, the exploration of mechanisms of change in technologically based treatments is of particular relevance. Despite the fact that they are gaining preponderance in the delivery of psychological interventions, the literature on mechanisms of change is scarce. As will be explained, the

characteristics that should be described regarding the role of technologies and mechanism of change are twofold: On the one hand, technologies are a way of delivering treatments in order to modify a putatively key mechanism (ER) in emotional disorders. On the other hand, technological affordances may serve to explore therapeutic dynamics in a more ecological way. Examples will be given concerning how technological solutions can play in this regard a paramount role in order to bolster the understanding of how regulatory processes, such as ER, interact in psychological treatments.

To present these technologies we will use the DIU framework, that in turn permit to organize the existing technologies in two overarching categories: the existing technologies, and the future technologies. That is, while dissemination technologies are already a reality, improving and understanding technologies are only starting to be incorporated into real world as clinical interventions.

2. The state-of-the-art: Disseminating Technologies

Telepsychology, online psychotherapy or internet interventions are only a few of the myriad of denominations that have been used to refer to technologically based interventions. Usually, these are used in an indistinguishable way and the nomenclature is not even an agreed issue within the scientific community (Smoktunowicz et al., 2020).

While some technologies replicate the modality of in-person treatments, that is, providing synchronous interaction between a clinician and a therapist, over the last years there has been an increase of asynchronous modalities. Both types of interventions have been incorporated in order to improve the dissemination of psychological treatments. This dissemination was already occurring (McHugh & Barlow, 2010), but with the irruption of COVID-19 pandemic the use of these modalities become the norm (Wind et al., 2020). Worldwide, an unprecedent number of therapists were forced to start seeing their patients in remote modalities.

Synchronous technologies entail a number of technologies, of which undoubtedly videoconferencing is the most used. The reason is that unlike telephone-based interventions or other kind of technology-based interventions, therapists can replicate the traditional in-person therapy, either in individual or group modalities. Mounting evidence supports the acceptability and efficacy of these interventions, and they even propose equal benefits than traditional modalities (Batastini et al., 2021; Thomas et al., 2021).

Asynchronous technologies are less used in the real world (with the exception of text messages or e-mails), but instead have greatly proliferated in research. Some of the existing variants are asynchronous videos, computerized guided or unguided therapy, text messages and mobile app-based psychotherapy and psychoeducation (Chan et al., 2018). In particular, self-guided and guided interventions have arisen a spark of interest in the last years (Andersson, 2018). A common way for involving both self-applied and guided interventions is Internet interventions. Compelling evidence

demonstrates that internet interventions are efficacious, effective and efficient providing treatment for a wide range of psychological disorders (Andersson, 2016). Table 2 summarizes these technologies.

Table 2. Digital technologies for the dissemination of existing interventions. Based on Bielinski & Berger (2020)

Format of intervention	Definition	Human support	Synchronous / Asynchronous
Unguided	Self-help programs that do not entail therapeutic contact. The Internet permits to provide information to the patient. Often patient work on different modules within a specified timeframe, for example, one module a week. These modules comprise text, audio, or video content.	No	Asynchronous
Guided	Self-help programs with different degrees of contact with a therapist. This contact is often online, synchronous or asynchronous.	Different levels	Asynchronous
Blended	A combination of unguided or guided and in-person intervention. Internet interventions can be used in direct combination with face-to-face treatment, before face-to-face treatment or after face-to-face treatment.	In-person	Synchronous and Asynchronous
Videoconferencing	It is a medium of communication between the therapist and the patient	Remote	Synchronous
Mobile apps	Software that are designed to provide an intervention or a whole treatment through mobile devices.	Variable	Synchronous and Asynchronous

A recurrent concern in the use of these technologies revolves around the possibility of developing a strong therapeutic alliance. Undoubtedly, the therapeutic alliance constitutes a core element in all psychological treatments (Flückiger et al., 2018). Indeed, the therapeutic alliance may be conceived as a moderator or an active mechanism of change (Baier et al., 2020; Zilcha-Mano, 2017).

The longstanding tradition of therapeutic alliance research in in-person psychotherapy has produced several lines of research that have provided profound insight into how it is deployed (Norcross and Lambert, 2019). However, there is little research thus far on the role of the therapeutic alliance in treatment in technological media research compared to in-person psychotherapy.

A growing body of evidence shows that a therapeutic alliance can be established in technologically-mediated treatments, presumably with comparable results to in-person psychotherapy (Berger, 2017; Cataldo et al., 2021; Lopez et al., 2019; Norwood et al., 2018; Simpson & Reid, 2014). Indeed, Lopez et al. (2019) conclude online therapy "*…is a viable modality with the potential to improve access to care with a low impact on therapeutic alliance*." That is, there is a consensus on the idea that therapeutic alliance is not particularly affected and therefore it does not hinder any therapeutic progress.

Not only does matter the discussion on therapeutic alliance to know the extent to which these technological-based treatments do work and why they do work, but also for the specific discussion around ER. As aforementioned, the therapeutic relationship is fundamentally a way of achieving interpersonal regulation of the individuals (i.e., coregulation). The establishment of a strong bond

between the therapist and the patient facilitates the affective and ER (Koole et al., 2020). Indeed, psychotherapy as a practice can be conceived as a relationship in which the therapist helps one or more patients to regulate their affect and emotions.

In the subsequent section we will delve into the two main technological formats: Videoconferencing psychotherapy and self-guided and guided interventions for being the two more extended ways in which standardized psychological treatments have been delivered.

2.1 *Videoconferencing psychotherapy*

Fundamentally, the application of videoconferencing psychotherapy (VCP) in routine practice has been progressive and is mainly explained by practical reasons, such as geographical barriers, treatment-seeking stigma, or flexibility in scheduling sessions (Backhaus et al., 2012; Nickelson, 1998). With the increasing use of videoconferencing, there was also a rise in the evidence showing its efficacy. Overall, the results demonstrate comparable results to in-person therapy (Batastini et al., 2021; Thomas et al., 2021; Varker et al., 2019).

As described, in March 2020 with the sudden and unexpected confinement due to the coronavirus, many therapists closed their offices and started to deliver principally VCP. The reason for the massive adoption of VCP (Sammons et al., 2020; Wind et al., 2020) is that it constitutes a similar way of delivering therapy to traditional in-person psychotherapy, and thus therapists could relatively continue their usual work.

This adoption of VCP was massive, and there is data showing that it was incorporated by therapists' of different therapeutic orientations, for a vast array of clinical conditions and even by therapists' with heterogenous previous experience with technology (Humer, Stippl, et al., 2020; Sammons et al., 2020).

There is compelling evidence that shows that the adoption of VCP greatly depends on the attitudes of the clinicians. In that sense, previous experience with VCP is highly related to having positive attitudes toward it, while therapists' satisfaction levels with VCP are overall high (Connolly et al., 2020). A number of studies have revealed that the massive adoption of VCP have positively impacted overall therapists' attitudes towards its use (e.g. Békés & Aafjes-van Doorn, 2020; Humer et al., 2020a; Jurcik et al., 2020; Probst et al., 2020a), foreseeing a bright future even when the restrictions due to the pandemic will end. For this reason, Wind et al. (2020) described the pandemic as a turning point for technological solutions in mental health.

With regards to the patients' attitudes, when VCP emerged it was considered that they would be resistant to VCP. Nonetheless, there is evidence showing that generally patients have positive attitudes toward VCP (Bleyel et al., 2020; Trondsen et al., 2014). However, there might be a big difference according to the experience of the patients with technology as well as with previous psychological treatments.

Given the numerous differences between in-person and VCP, process and outcome research have to be explored in VCP regardless of the ever-growing literature demonstrating its efficacy. There is a great difference concerning the establishment of the therapeutic alliance between treatments that begun with an in-person modality and transitioned to VCP and treatments that were delivered remotely from the beginning. In treatments that make a transition to VCP, it is important to consider the necessity of making a new contract (Inchausti et al., 2020). Beyond the bond, the classical conceptualization of the therapeutic alliance entails objectives and tasks. Even though the bond may be very strong, the tasks and specific goals previously agreed upon should be closely examined to determine whether it is necessary to introduce changes given the new circumstances. Concerning specific objectives, there may be some nuances, but overall, they are also transferable from in-person to VCP. The greatest difference between in-person and VCP may lie in the tasks. Due to either the modality or the context, the usual tasks cannot be conducted. Commonly used techniques in in-person psychotherapy may need a process of adaptation to be implemented in VCP.

From all the interventions that have been adapted to VCP, it is worth mentioning the adaptation of the tele-chairwork (Pugh et al., 2020) given that is an intervention that has proven to improve ER (Pos & Greenberg, 2012). Besides, it is a clear example of how techniques that are rooted in experiential, gestaltic and psychodramatic traditions can be also translated into an online modality and successfully incorporated in current time. Likewise, imagery rescripting has also been adapted to remote modalities, with clinical recommendations on how to deliver this technique in VCP and other online modalities (Paulik et al., 2021).

In VCP both therapists and therapists can receive feedback from their videocameras. Certain profiles of patients (e.g. narcissistic or socially anxious individuals) may over focalized the attention to their own behavior, which can be negative for the therapeutic communication (Payne et al., 2020). Furthermore, in-person psychotherapy takes place in a tangible shared environment, resulting in a more immediate sensory experience and, as a result, a qualitatively different exchange. The most noticeable distinction between in-person psychotherapy and VCP is the possibility of technological issues with the latter. An unreliable connection, a frozen screen, delayed audio, or bad lighting, as described by Markowitz (2020), are just a few of the issues that might hinder treatment involvement. Direct eye contact, tone of voice, the capacity to maintain an open posture, bodily motions, synchronization, and attunement are some of the communication channels that may be impeded in VCP, according to Thompson-de Benoit and Kramer (2020). That is, communication's paralinguistic, nonverbal, and prosodic elements may be altered. Physicality is critical for information processing, incorporating bodily characteristics that may not be transferrable to distant modalities, according to the principles that underpin embodied cognition (Caramazza et al., 2014). In VCP, a stooping posture, a trembling leg, or a clinched hand are all unnoticeable. Both therapists and patients are missing out on important information in VCP.

Not taking into consideration the distinctions between modalities may have an impact on the treatment process and, as a result, result in early dropouts. Other ruptures in remote psychotherapy may be worsened by the aforementioned technological issues or unhappiness with the limited options available through this method. Identifying both confrontational and withdrawal ruptures, as well as applying strategies to reconcile them, is critical, and there are some preliminary ideas in VCP on how to do so (Dolev-Amit et al., 2020).

The attachment bond is frequently coupled with the 9-amino-acid cyclic neuropeptide oxytocin (Schneiderman et al., 2014), which is a marker of the therapeutic alliance and alliance ruptures (Zilcha-Mano et al., 2018, 2020). Furthermore, research has shown that increased in-session heart rate variability (particularly the high frequency power) enhances the building of therapeutic alliance and predicts symptomatic improvement (e.g. Blanck, 2019), according to the polyvagal theory (Porges, 2007). It will be relevant to show that similar relationships exist in remote modalities as well in order to know how psychotherapy should be adjusted.

On the other side, it has been discovered that VCP can encourage more disinhibition and openness by creating a sense of safety and a more neutral power balance. This neutral disposition can stimulate greater disclosure among patients who have particular interpersonal characteristics (e.g. submissive patients) and may benefit from a less confrontational interaction at the start of treatment (Simpson et al., 2020).

Before beginning a VCP therapy, it is important to examine certain factors including socioeconomic status and computer literacy (Markowitz et al., 2020; Nelson et al., 2017). That implies the therapist must create particular tasks and objectives that are tailored to the patient's unique characteristics, requirements, and preferences. This is especially true considering that the individuals who suffer the most are the most vulnerable and disadvantaged (Frankham et al., 2020). In this sense, the current scenario regarding the occurrence of the COVID-19 pandemic is an exception to the rule. People who are socioeconomically excluded or at high risk, such as the elderly, are logically those who would require greater assistance in these conditions, but they also have less access to psychotherapy, including VCP.

Despite the massive implementation and proliferation of research, the research on process and outcome in VCP is very scarce. That is, it is an agreed issue that VCP can work, but this has not been demonstrated by empirical data during the pandemic. Given the scarcity of evidence in this area of research and its clinical relevance, it is necessary to continue studying the potential role of ER as a mechanism of change in psychotherapy. Therefore, a study was designed with the aim of analyzing how the longitudinal improvement of ER is associated with therapeutic benefit disaggregating the between-person and within-person effects. On the one hand, to study how the average levels of ER in patients can be associated with clinical severity; that is, between-patient effects, which is the strategy that has traditionally been used the most in process and outcome research (Zilcha-Mano & Errázuriz, 2015). Furthermore, in order to explore the variability in individual ER dynamics, it is necessary to study the

effects of fluctuations in ER during psychotherapeutic approaches on the clinical severity of patients; that is, within-patient effects. Studying within-patient effects allows an approach to establishing causal inferences with observational data, limiting the probability that stable differences between people can act as intrusive variables that explain the effects found (Falkenström et al., 2017).

Moreover, these dynamics are only starting to be studied in in-person psychotherapy, so there is no evidence concerning videoconferencing psychotherapy. Given the importance that videoconferencing psychotherapy has since the advent of the COVID-19 pandemic, emerge as an urgent topic to conduct this type of studies. The evidence in videoconferencing psychotherapy shows that there is a dearth of studies exploring mechanisms of change.

Building on previous studies, a study was conducted with the aim of analyzing the effects of ER on treatment outcome using longitudinal models and to disaggregate the between-subject effects and within-subject effects. So far, this is one of the first studies to apply such methods to ER in naturalistic settings, making it a useful addition to previous research in the area.

Accordingly, the research hypotheses were that there was going to be a significant between-patient effect of ER on outcome, with greater levels of ER over the course of treatment being related to lower clinical severity; and there was going to be a significant within-patient effect of ER on outcome, with positive session-by-session variations on ER being associated with reductions on clinical severity. From a conceptual point of view, testing hypotheses #1 and #2 of the study permit to identify potential information regarding the clinical relevance of ER levels and variations during treatment.

The sample in the present study consisted of 225 patients who were treated in a psychotherapeutic outpatient clinic of a Buenos Aires, Argentina. To be eligible, patients had to be at least 18 years old. Diagnoses were established by an expert clinician by means of an unstructured clinical interview, and supported by a comprehensive assessment, including the Dimensional Assessment of Personality Pathology-Basic Questionnaire, Inventory of Interpersonal Problems, The Symptom Checklist-90-R (SCL-90-R) and WHO Disability Assessment Schedule (WHODAS 2.0). Before the intake interview, patients gave their written informed consent.

On average, patients were 34.77 years of age (*SD 13.21*). The majority of participants were female (66,9%). Most of the participants had at least either completed a professional training or a university degree. Patients were treated by 62 therapists who either had completed their postgraduate training in psychotherapy or were currently enrolled in the program. All therapists were Caucasian and 74% were female. 53 of the therapists had already finished the postgraduate therapy training, while 9 were in the last year of the training. As part of their postgraduate training, all the therapists had received courses on integrative CBT. Furthermore, all the therapists had biweekly video-based supervision meetings in small groups, conducted by experts from the respective clinical condition.

Regarding the inclusion and exclusion criteria, all therapists considered which patients could be included in the study. The reasons of inclusion weighted by the therapists revolved around the acceptability of patients to fulfill the questionnaires. Sometimes, and particularly in a psychotherapy

culture like the existing in Argentina, patients may be reluctant to these procedures. Following Practice Oriented Practice principles, clinicians were involved in the whole design of the project and for the whole setup of the study but also, they had the priority regarding who was able to be included. Patients with severe mental disorders were excluded given the existing evidence showing detrimental effects in doing this kind of procedures for these patients (Errázuriz & Zilcha-Mano, 2018).

With regards to the treatment, Aiglé Foundation is a clinical center in which an Integrative Psychotherapy Model is implemented. This model has a cognitive behavioral core but incorporates notions and procedures from psychodynamic, systemic and humanistic-existential therapies. It is therefore based on: 1) a broad information processing framework utilizing an integrated conceptualization of theory of mind (Osbeck, 2009); 2) a biopsychosocial psychopathological model with personality as the core structure that organizes the experience and behaviors and accordingly their dysfunctions (Hopwood, 2018); and 3) principles of change that guide the respective interventions throughout the treatments (Castonguay & Beutler, 2006; Castonguay et al., 2019). Hence, treatments are not manualized, but they rather follow these principles of change as well as phases of treatment. Namely, some treatments may be characterized as a focalized when a symptomatic improvement is pursued; and some treatments may be structured in order to target modulatory or even basic patterns (Livesley, 2012).

Materials - *Emotion regulation*. Difficulties in Emotion regulation will be assessed using the state Difficulties in Emotion Regulation Scale (S-DERS; Lavender et al., 2017). The S-DERS consists of 21 items, and for each of them participants are asked to "indicate how much it applies to your emotions right now," with response options ranging from 1 (not at all) to 5 (completely). It has 4 subscales: Nonacceptance (i.e., nonacceptance of current emotions), Modulate (i.e., difficulties modulating emotional and behavioral responses in the moment), Awareness (i.e., limited awareness of current emotions), and Clarity (i.e., limited clarity about current emotions). We used an adapted version of the original DERS to measure emotional regulation not as a stable trait but as a state. Therefore, it represents a scale that is more sensitive to measure change and useful for evaluating mechanisms of change. The instrument has shown evidence of reliability and validity in its original English version. Currently, the adaptation and validation to the Argentine context is under preparation, which was carried out through a process of translation and back translation, and later the analysis of psychometric properties that has shown adequate levels of reliability and validity.

Outcome - Outcome was assessed at baseline and then every two weeks through the Outcome Questionnaire (OQ-30.2; Ellsworth et al., 2006). The OQ-30.2 consists of 30 items with a range from 0 (never) to 4 (almost always), totaling a maximum score of 120 points. This scale evaluates three independent dimensions: symptomatology, interpersonal relationship and overall functioning. The maximum score for each subscale is 50. The OQ-30.2 has been found to have good internal consistency (alpha .90), good concurrent validity (with the Depression Anxiety Stress Scales: r = 82) and sensitivity

to change. The Spanish version of the OQ 30.2 (Errázuriz et al., 2017) presents good psychometric properties.

Procedure - This study takes place in an integrative cognitive behavioral therapy clinical center where a practice research network functions since many years (Fernández-Alvarez et al., 2015). All the patients provided informed consent before being enrolled in the study. Before the treatments started, they completed a questionnaire package at baseline. Furthermore, they completed both the OQ and DERS after every two therapy sessions. That is, patients answer the questionnaires on a biweekly basis. Although ideal process and outcome research guidelines suggest that the outcome measure should be taken before the session, and the process measure after the session, this was not possible in the context of the routine practice. The therapists did not receive any feedback concerning patients' ratings on the DERS or the OQ-30. The local ethics committee approved the procedures of the study.

The analytical procedure: To test the main hypotheses, hierarchical linear models were used (HLMs; Raudenbush & Bryk, 2002). HLMs deal with the dependency of data due to repeated measures, providing a robust strategy to handle missing data within patients. These models mimic an intent-to-treat approach, allowing the inclusion of all participants with at least one measurement point in a given outcome variable into the analyses. The multiple assessment times of the OQ-30 served as an outcome variable, nested within patients.

Thus, all the analyses were conducted using two-level HLMs (Level 1: within-patient effects; Level 2: between-patient effects). First, for comparison purposes, we ran a two-level fully unconditional model and a two-level unconditional time-as-only predictor model, with the dependent variable being OQ-30 scores in both cases. In the fully unconditional model, we did not include any predictor to explain OQ-30 variance, while in the time-as-only predictor models we incorporated time (defined as session number and centered at posttreatment) as a level-1 predictor. Second, we ran three-level hybrid random effect models (HREMs) with the OQ-30 scores as the dependent variable (Falkenström et al., 2017). These models allow disaggregating between- and within- patients effects of the emotion regulation on therapy outcome, by including the time-varying quality of the emotion regulation as a level-1 predictor, person mean centered (estimating the within-patient effect of the emotion regulation), and the overall level of emotion regulation during the whole treatment as a level-2 predictor of the intercept, grand-mean centered (estimating the between-patient effect of the emotion regulation; Curran & Bauer, 2011). In the literature concerning these methods, there is an important debate regarding how to deal with time effects (see, e.g., Falkenström et al., 2017). When both the time-varying predictor and the outcome variable present a trend over time, some authors recommended controlling for time effects (i.e., detrending; Curran & Bauer, 2011). This procedure could limit the effect of unobserved confounders that are associated with both variable trends explaining the putative association between them (Falkenström et al., 2017).

However, more recent studies have indicated that this will imply a very restrictive and conservative procedure that is not recommended when the natural evolution of the targeted variables

will be consistent with their time trends (Falkenström et al., 2017; L. P. Wang & Maxwell, 2015). For this study, the recommendation of Falkenström et al. (2017) considering a synthesis of these two positions was followed. For testing hypothesis #1, as a first step, we ran the HREMs without controlling for time effect (i.e., not detrending). In the case of significant effects, as a second step, we ran the same models controlling for the time effect (i.e., detrending) to see if the results were maintained. As suggested by Wang and Maxwell (2015) and to control for the time effect, we included time as a level-1 predictor. If after detrending the results remained significant, this would strengthen the possibility of causal inferences based on the findings (Falkenström et al., 2017). All the HLM analyses were conducted on the R software.

Results

Samples Descriptives - Regarding the DERS-S, patients showed an average score of 42.79 (*SD* = 13,24) at the beginning of treatment. With regard to the OQ, patients showed an average value of 41.74 (*SD* = 16.02) at the beginning of treatment.

Primary Analysis

Fully unconditional model. In the DERS-S fully-unconditional model showed an average value of 38.29 across treatment, $\gamma 00 = 38.29$, $SE = 1.06$, $t(223) = 36.01$, $p < .001$.

Emotion Regulation effects on Outcome. This model showed significant between-patient effects on outcome of DERS-S, $\gamma 01 = 1.07$, $SE = 0.04$, $t(227) = 24.17$, $p < .001$. A one-unit greater DERS-S level was associated with an increase in 1.07 units on the OQ score during treatment.

Furthermore, this model presented significant within-patient effect on the OQ score of both Emotion Regulation, $\gamma 10 = 0.72$, $SE = 0.04$, $t(100) = 19.84$, $p < .001$. A one-unit variance in patient's Emotion Regulation from their individual mean was associated with a 0.72 points higher score in the OQ at that session.

When running a detrending model in order to control the effect of time-varying confounders, the model showed significant between-patient effect of Emotion Regulation, $\gamma 01 = 1.07$, $SE = 0.04$, $t(228) = 24.19$, $p < .001$. Moreover, same significant results were observed for the within-patient effect of Emotion Regulation, $\gamma 01 = 0.70$, $SE = 0.02$, $t(1569) = 32.92$, $p < .001$.

Discussion - This study aimed at investigating the effects of difficulties in ER on outcome in naturalistic integrative CBT. First, we analyzed the main effects of ER on outcome. The findings of the study showed both significant BP and WP effects of ER on outcome.

Regarding the first hypothesis of the study, the results display both significant BP and WP effects of ER on outcome, operationalized as the evolution of symptomatic severity. On the one hand, the BP effect of ER means that patients with a greater level of ER during treatment presented a lower

level of symptoms across treatment. On the other hand, the significant WP effect of ER suggests that positive variations in ER from patients' own mean during treatment were associated with lower symptomatic levels in the next two sessions. Although the research design was observational, the significant WP effect provides an approximation to establishing causal effects between emotion regulation and outcome, by adjusting for trait-like confounders (i.e., the BP effects included in the model; Falkenström et al., 2017). Furthermore, when detrending the models (i.e., including time as a covariate), the WP effect remained significant. This replication suggests that the WP effect of ER cannot be explained by confounding variables that are responsible for change in both, symptoms and ER. These findings that are in line with a wide body of research connecting outcome with ER (Kivity et al., 2021; Radkovsky et al., 2014; Strauss et al., 2019), and more specifically with maladaptive or deficient ER, which implies that in integrative CBT for emotional disorders, therapists might benefit from modifying patients' ER capacities.

These findings gain particular importance in a context in which almost all therapists around the world are using VCP. Therapists have been doing a rather intuitive adaptation of their practices to start seeing their patients through remote modalities. This study permits to determine that changes are activated in a similar way than in-person treatment. That is, therapists' interventions promote a better ER by their patients, which in turn result in better outcomes.

Among the principal limitations, although treatment was integrative CBT oriented and therapists received supervision within this orientation, the therapies were provided in a naturalistic setting and no further adherence checks were conducted. Thus, generalizability of results to other psychological treatments should be taken with caution. Besides, despite having a large sample, no previous power analyses were considered before the start of the treatment. Moreover, we acknowledge that although the DERS well established overall measure of ER deficits, and its state version permit to detect changes over time with high sensitivity, it only represents a facet of the complex nature of ER as seen in the first section of this dissertation.

Limitations notwithstanding, this study presents preliminary evidence for significant effects of ER on depression and anxiety severity. Therapists using videoconferencing psychotherapy might be able to improve therapy outcome by enhancing patients' overall ER. In cases in which it is observed a particular difficulty in regulating emotions, therapist might change the course of action of the therapeutic process in order to prevent failure, dropout or inert treatments. Therefore, these results might contribute to personalize therapies for emotional disorders.

2.2 *Self-applied and guided Internet-delivered interventions*

Self-applied and guided internet-delivered interventions entail an heterogenous set of clinical interventions. However, the common and probably defining feature is that they deliver manualized treatments that have gathered scientific evidence through the Internet. A burgeoning body of evidence

has been produced, with dozens of meta-analyses in a vast array of clinical conditions (Andersson, Carlbring, et al., 2019; Carlbring et al., 2018). Doubtlessly, this line of research is the one that has elaborated the more sophisticated and clinically relevant research, with rigorous research on efficacy, effectiveness and efficiency (Andersson et al., 2019), negative effects (Rozental et al., 2017) and adoption in the real world (Titov et al., 2018).

Several advantages of these interventions have been highlighted for patients (i.e. treatment programs), clinicians and researchers (e.g. recruitment and data collection, notifications, and monitoring of psychological treatment; Andersson and Titov, 2014). First and foremost, the possibility of outreaching people who otherwise would not have of access to any kind of psychological treatment, such as people living in rural areas (Griffiths & Christensen, 2007). Besides, there is a number of other advantages that are worth mentioning. First, the possibility of working at the own pace and go through the content the wished number of times (i.e. versatility), the stigma avoidance typically associated with mental disorders (i.e. anonymity), and the ability of interventions shown to be effective in a research setting to be expanded under real world and everyday settings (i.e. scalability) have been reported as the potential of these interventions (Kazdin & Blase, 2011). Besides, in a context in which psychotherapy is threatened by pseudoscientific procedures and clinicians are not always well trained, internet interventions can guarantee that the delivered interventions are empirically supported treatments. Finally, cost-effectiveness (i.e. relatively low cost compared to the usual treatment) has been also identified as a relevant aspect (Andersson & Titov, 2014; Donker et al., 2015).

An important aspect of all these interventions delivered through the Internet is the type and degree of guidance provided to the individuals. Internet-based interventions are generally an adaptation from traditional face-to-face protocols and can be delivered with some type of clinician or therapist support or completely self-guided. Existing literature suggests that guided Internet-based treatments frequently obtain better outcomes than unguided (Shim et al., 2017).

In line with all the other areas of interest in clinical psychology, Internet interventions have also been used to target ER as a key transdiagnostic process. As previously mentioned, the conceptualization of ER is heterogeneous and it has led to the development of Internet interventions that target ER directly, others that directly target ER as one component of a longer or more comprehensive treatment, and those interventions that target ER indirectly.

2.2.1 Direct target of emotion regulation

Dialectic Behavior Therapy (DBT) is an illustrative example that is directly focused on teaching ER skills in individuals with patterns of emotion dysregulation (Neacsiu et al., 2014). Based on behavioral research, DBT incorporate the 5-phases model proposed by Gross along with modules for the improvement of additional processes: Management of emotion vulnerability factors, support of biological, expression and action change, and improvement of emotional processing. ER DBT skills have been used transdiagnostically to improve several disorders, with successful examples has of

adaptation to be applied over the Internet. Notable efforts have been made in order to adapt DBT to computerized treatments (Lungu et al., 2019) with some studies that empirically support the usefulness of this adaptation, for example for suicide and alcohol problems (Wilks et al., 2018).

Different mindfulness-based interventions such as Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 2003), Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2002), or Acceptance and Commitment Therapy (ACT; Hayes et al., 1999) provide strategies to accept internal experiences or improve present-focus awareness, all aspects related to ER (Gratz & Tull, 2010). These interventions can be seen as ER trainings. Indeed, there is ample evidence linking ER and mindfulness. While some studies consider mindfulness as a ER strategy (Brockman et al., 2017; Guendelman et al., 2017), others conceptualize and mindfulness as distinct phenomena (Roemer et al., 2015). Thus, Internet-based mindfulness treatments have been shown to be a valuable treatment option in the ER process, teaching individuals to experience reality without attempting to control, suppress, or avoid experiences (Boettcher et al., 2014; Carlbring et al., 2013). Existing systematic reviews of online mindfulness and acceptance-based interventions have synthesized the evidence of studies evaluating their effectiveness in teaching skills related to ER (Cavanagh et al., 2014; Kelson et al., 2019; Spijkerman et al., 2016).

Besides, within this category is the Unified Protocol (UP) (Barlow et al., 2016). The treatment efficacy of the UP as a transdiagnostic ER based intervention program has been summarized in a recent systematic review and meta-analysis (Sakiris & Berle, 2019). There are adaptations of the UP into the Internet both in adults (Schaeuffele et al., 2020) and adolescents (iUP-A; Sandín et al., 2019). The study by Schaeuffele and colleagues is the first pure adaptation of the UP to the Internet. In a two-arm RCT, the trial yielded significant results in the improvement of all primary and secondary outcomes (against a waitlist).

Based on the UP and integrating other components such as DBT strategies, some transdiagnostic Internet-based interventions have been developed either in adults from specialized care (González-Robles et al., 2020) or community sample (Díaz-García, González-Robles, García-Palacios, Fernández-Álvarez, et al., 2021). González-Robles et al. (2020) tested 214 individuals from the Spanish health care system in a two-arm RCT comparing the experimental arm (EmotionRegulation) with treatment as usual. The authors could determine the effectiveness of the protocol with improvements both on depression and anxiety. Meanwhile, Díaz-García et al. (2021) used the same protocol but incorporating a third arm with additional components of positive affect. Besides, the treatment as usual was not included given that this study involved a community sample. Instead, a waiting list group was included. In total, 216 were randomized in the three conditions, showing the efficacy of both experimental arms compared with the waiting list. Nevertheless, the trial did not yield statistical difference between these two active conditions.

Likewise, modification of attention targets ER as an important aspect and there are some initial attempts to use it in online treatments. The rational of modification of attention is that before the

deployment of maladaptive strategies, different cognitive and psychological processes occur and, accordingly, a systemic bias in one of these mechanisms could potentially affect the overall process. For instance, selective attention plays a key role in ER (Gross, 1998) and, consistently, biased attentional selectivity has been shown to be directly connected to poor regulatory skills (Mathews & MacLeod, 2005). There is an undoubted overlap between ER attentional bias modification (Van Bockstaele et al., 2019). As a potential key factor increasing psychological vulnerability and emotional dysfunction, modification of attention therapy specifically targets selective attentional responses to negative information by means of technologies for the training of attentional skills (MacLeod & Mathews, 2012). Over the Internet, a number of modification of attention trainings have been developed with successful results, such as in social anxiety disorder (Boettcher et al., 2013; Carlbring et al., 2012), depression (Williams et al., 2013, 2015), gambling problems (Boffo et al., 2017), or transdiagnostic programs for adolescents (De Voogd et al., 2017), just to mention a few.

Another treatment that has ER as the therapeutic target is ER Therapy (ERT; Mennin, 2004). ERT has been developed as protocol in order to improve patients' abilities in identifying and elaborating emotions, and to increase the flexibility to cope with daily situations by selecting appropriate strategies according to the context. ERT has also been adapted to be delivered over the Internet, specifically for adolescents with non-suicidal self-injury disorder. In an open trial developed by Bjureberg et al., (2018) and supported by an Internet Web site, an eleven module intervention was delivered over 12 weeks for adolescents.

There are existing internet interventions that have been designed to improve perseverative cognition (worry and rumination), a transdiagnostic process that can be considered a putatively maladaptive cognitive ER strategy (Ehring & Watkins, 2008; Wahl et al., 2019). An example was tested by Newby et al. (2014) in a transdiagnostic Internet CBT intervention for mixed anxiety and depression. They found significant positive effects in the reduction of negative repetitive thinking, which in turn showed to mediate the improvement of depressive symptomatology.

Hoorelbeke and Koster (2017) brought forth an interesting prevention double-blind randomized controlled trial for remitted depressed patients. Undergoing a 10-session intervention that targeted cognitive control over working memory, conceived as a causal process of perseverative negative thinking, individuals achieved significant improvements in cognitive ER.

Finally, Cook et al. (2019) tested RESPOND, whose target to improve repetitive negative thinking in students of risk of developing depression. RESPOND constitutes an illustrative example of how transdiagnostic interventions could be used with prevention purposes.

2.2.2 Indirect improvement of emotion regulation

There are a number of interventions that do not explicitly target ER as a therapeutic process, but still achieved changes on it. An illustrative example is a psychodynamic Internet-based therapy for

adolescent depression, which showed significant improvements in difficulties of ER in comparison to a control group (Lindqvist et al., 2020).

A vast array of interventions, from positive psychology (e.g. gratitude; Heckendorf et al., 2019 that measures repetitive negative thinking) to different kind of CBT interventions have measured ER and found significant improvements. Ebert et al. (2013) conducted a RCT with the aim of fostering long-term effects of inpatient psychotherapy, in which ER skills were measured at pre- and posttreatment. Likewise, Kuosmanen et al. (2017) using a CBT gaming intervention for adolescents revealed significant improvements in ER.

Overall, taking into account the introduction it is reasonable to suggest the reason why ER improves, despite the fact that it was not explicitly targeted. ER can be conceived a higher-order factor that involves numerous factors of lower-order that statistically may strongly correlate. For example, as described before, practically all forms of CBT bring forth cognitive reappraisal and therefore it can be expected improvements if a variety of ER questionnaires are measured in a certain treatment. The same can be stated for exposure or behavioral activation, two well-established components of CBT.

2.2.3 ER as a mechanism of change in internet interventions

However, in order to establish that ER operates as a mechanism of change in internet interventions it is not sufficient to develop a protocol and detect significant improvements in pre- post assessments. A mechanism of change should be identified in well-designed studies in which longitudinal measurements of the candidate mechanism are taken (Falkenström et al., 2020).

As described, several studies were conducted considering ER as a main component. However, these interventions have the pitfall of failing to demonstrate how they work. In line with all clinical research, there is a dearth of studies that focus on mechanisms of change in internet interventions. A recent systematic review showed that although some studies have studied the mediation of variables, including ER, only few have explored it with methodological rigor (Domhardt et al., 2021).

In this review, the authors identified 13 clinical studies that fulfilled the inclusion criteria. From these, no one explicitly targeted ER. Nevertheless, considering a broader understanding of ER, several studies can be identified. Two explored the mediational role of repetitive negative thinking (Lamers et al., 2015; Newby et al., 2014), one study analyzed worry and problem orientation (Warmerdam et al., 2010), one psychological flexibility (Pots et al., 2016), and also two behavioral activation (Forand et al., 2018; Seeley et al., 2019). This last study of Seeley and colleagues also explored the mediational role of savoring. All these analyses yielded significant mediational results.

Recently, Enrique and colleagues (2021) performed secondary analyses of 358 individuals who underwent an internet-delivered cognitive behavior therapy. They found that reappraisal, measured by the subscale of the ER questionnaire, mediated the improvements both in depression and anxiety. Another recent example showed that mindfulness is a robust mechanism of change of in a transdiagnostic treatment of patients with depression or anxiety (Schaeuffele et al., 2021).

As can be seen in table 3, from the sum of studies that explored ER as a mechanism of change in internet interventions, a great majority used a linear mediational strategy based on the classic approach originally defined by Baron and Kenny (1986) and extensively disseminated due to the contribution of Hayes (2009). However, the complex interaction of variables requires to rely on more novel statistical methods (Hofmann et al., 2020).

For example, none of these studies have disentangled between and within effects, which as previously described, it may give relevant clues concerning how treatments work. The only one that addresses this question was a psychodynamic intervention for adolescents that assessed the effect of within-person changes in ER on depression. It revealed that ER operated as a mechanism of change (Mechler et al., 2020).

Table 3. Evidence for emotion regulation as a mechanism of change in internet interventions.

Study	Clinical condition	ER measure	Design	Analysis
(Enrique et al., 2021)	Depression & anxiety	Cognitive reappraisal	RCT	Mediation analysis
(Forand et al., 2018)	Depression	Behavioral activation	RCT	Mediation analysis
(Lamers et al., 2015)	Depression	Repetitive negative thinking	RCT	Mediation analysis
(Mechler et al., 2020)	Depression	Overall ER measure	RCT	Between- / within analysis
(Newby et al., 2014)	Depression & anxiety	Repetitive negative thinking	RCT	Mediation analysis
(Pots et al., 2016)	Depression	Behavioral activation	RCT	Mediation analysis
(Schaeuffele et al., 2021)	Depression & anxiety	Mindfulness	RCT	Mediation analysis
(Williams et al. 2013)	Depression	Interpretation bias	RCT	Mediation analysis

Taken together, while there is preliminary evidence for some transdiagnostic mechanisms of change in internet-based psychological interventions, no studies have focused on the relevance of affect and ER as transdiagnostic processes. Using evidence from a previously reported RCT (Díaz-García et al., 2021), the aim of this analysis was to explore whether positive and negative affect may be used as a pathway for symptomatic progress (i.e., depression and anxiety). As a result, we hypothesized that prior increases in positive affect, as well as decreases in negative affect, would account for decreases in anxiety and depression over the course of transdiagnostic treatment. To our knowledge, no previous study has looked at positive and negative affect over the course (i.e., with multiple measurement points) of a transdiagnostic internet-based treatment for emotional disorders, nor has it looked into the potential role of affect as a change mechanism from a transdiagnostic standpoint.

Data were gathered as part of a major RCT that looked at the effectiveness of an internet-based transdiagnostic therapy for ED (Díaz-García et al., 2021). A total of 216 individuals were randomly assigned to one of three conditions: the Transdiagnostic Internet-based protocol (TIBP; n = 71), the Transdiagnostic Internet-based protocol + Positive Affect variable (TIBP+PA; n = 73), or the Waiting List monitoring condition (WL; n = 72). We just looked at the TIBP and TIBP + PA conditions for the purposes of this analysis. Information about the study's nature, participants, procedures, and results are published elsewhere (Díaz-García et al., 2021), so only a brief overview will be given here.

The interventions consisted of 12 (TIBP condition) and 16 (TIBP+PA condition) consecutive modules. The protocol content is adapted from the UP (Barlow et al., 2004), incorporating strategies for ER from Dialectical Behavior Therapy (DBT) (Linehan, 1993). It includes core components, mainly designed to down-regulate NA (present-focused emotional awareness and acceptance, cognitive flexibility, behavioral and emotional avoidance patterns, and interoceptive and situational exposure). Besides, to up-regulate the PA dimension the treatment included a module of behavioral activation, strategies to encourage pleasant and significant activities linked to value and life goals, and strategies to improve personal strengths, positive feelings, positive cognitions, and positive behavior. The protocol also includes strategies derived from the Well-being Therapy (WBT) and from Fredickson's Broaden-and-Build (Díaz-Garcia et al., 2017). Traditional therapy components of evidence-based ED treatment are also included in the program (Psychoeducation, Motivation for change, and Relapse prevention).

The participants had up to 18 weeks to complete the 12 or 16 modules. The modules contained multimedia elements (videos, images, texts) to be completely self-applied via the Internet through a PC or a tablet. To enhance adherence, the program offered feedback on completed tasks and asynchronous text-based messages were provided twice per week. Furthermore, the program also sent automatic emails with reminders to access the modules when participants had not entered in the past 15 days. In addition, human support was also provided through weekly phone calls during the treatment period to solve possible questions and to reinforce the importance of completing the modules and do the homeworks between them. Figure 2 displays the modules, the core therapeutic components, the measurement points, and outcome.

MODULES	M1 Emotional disorders and emotion regulation	M2 Motivation for change	M3 Understanding the role of emotions	M4 The acceptance of emotional experiences	M5 Practicing acceptance	M6 Learning to be flexible	M7 Practicing cognitive flexibility	M8 Emotional avoidance	M9 Emotion Driven Behaviors	M10 Accepting and facing physical sensations	M11 Facing emotions in the contexts where they occur	M12 Leraning to move on	M13 Learning to enjoy	M14 Learining to live	M15 Living and learning	M16 Relapse prevention
CORE THERAPEUTIC COMPONENTS	Psychoeducation and Motivation for change			Present-focused emotional awareness and acceptance		Cognitive flexibility		Behavioral and Emotional avoidance patterns		Interoceptive and situational exposure		Specific component to up-regulate positive affect				Relapse prevention
POST-MODULE ASSESSMENTE	POST-M1 PANAS-E OASIS ODSIS	POST-M2 PANAS-E OASIS ODSIS	POST-M3 PANAS-E OASIS ODSIS	POST-M4 PANAS-E OASIS ODSIS	POST-M5 PANAS-E OASIS ODSIS	POST-M6 PANAS-E OASIS ODSIS	POST-M7 PANAS-E OASIS ODSIS	POST-M8 PANAS-E OASIS ODSIS	POST-M9 PANAS-E OASIS ODSIS	POST-M10 PANAS-E OASIS ODSIS	POST-M11 PANAS-E OASIS ODSIS	POST-M12 PANAS-E OASIS ODSIS	POST-M13 PANAS-E OASIS ODSIS	POST-M14 PANAS-E OASIS ODSIS	POST-M15 PANAS-E OASIS ODSIS	POST-M16 PANAS-E OASIS ODSIS

Figure 2. Treatment modules, core therapeutic components and measurement points

Adult volunteers who had a primary diagnosis of anxiety problems confirmed by the Mini-International Neuropsychiatric Interview took part in the study (MINI 5.0; Ferrando et al., 2000). Being at least 18 years old, being able to understand and read Spanish, getting access to the Internet and an email address, and giving online informed consent were also requirements. Participants of dementia,

bipolar disorder, or alcohol and/or drug dependency disorder, as well as those with a high risk of suicide, were removed from the sample, as were others that had a medical diagnosis or disability that prevented them from receiving therapeutic therapy. Receiving another psychiatric therapy after the research was also an exclusion criterion. Receiving pharmacological therapy was not an exclusion requirement, although any rise and/or improvement in dosage (in the case of receiving) during the research duration automatically excluded the subject from further studies. The TIBP and TIBP + PA treatments were completed by 144 participants (71 percent of whom were female). The participants' ages ranged from 19 to 72, with a mean of 34.44 years (SD = 11.53). Furthermore, 59% of the participants were single, 35% were married, 6% were divorced or widowed, 4% had simple studies, 19% had medium studies, and 77% had higher studies. The trial was authorised by the Ethics Committee of the Universitat Jaume I in Spain, and it was reported on ClinicalTrials.gov as (NCT02578758).

All assessments were self-rated on the online platform. Figure 2 shows an overview of measurement time points. All participants filled out the pre-treatment evaluation, after completing each of the 16 modules (i.e., post-module evaluation), and at the end of the treatment (i.e., post-treatment evaluation).

Positive and Negative Affect Scale (PANAS) (Watson et al., 1988). The PANAS consists of 20 items with a range from 1 (very slightly or not at all) to 5 (extremely). Respondents have to indicate the extent to which they experienced the feeling or emotion during the past few weeks. This scale evaluates two independent dimensions: PA and NA. The maximum score for each subscale is 50. The scale showed excellent internal consistency (α between .84 and .90) and convergent and discriminant validity. The Spanish version has demonstrated high internal consistency (α = 0.89 and 0.91 for PA and NA in women, respectively, and α = 0.87 and 0.89 for PA and NA in men, respectively) in college students (Sandín et al., 1999) and in a clinical sample with emotional disorders ((α = 0.91 for PA and α = 0.87 for NA) (Díaz-García et al., 2020).

Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills et al., 2009; Norman et al., 2011). The OASIS consists of a 5-item questionnaire with a scale ranging from 0 to 4, which measures the frequency and severity of anxiety, as well as the level of avoidance, work/academic/home interference, and social and everyday life impairment related to anxiety symptoms. A psychometric analysis of the OASIS scale found good internal consistency (α = .80), test-retest reliability (k = .82) and convergent validity for this instrument. The Spanish version of the OASIS confirmed the factorial structure and reliability and validity data obtained by the original authors (internal consistency in both populations, general and clinical (α = .0.86) and test-retest reliability (k = .84) (González-Robles et al., 2018).

Overall Depression Severity and Impairment Scale (ODSIS) (Bentley et al., 2014). The ODSIS is a self-report measure made up of 5 items. Individuals select among five different response options ranging from 0 to 4 for each item, and scores can range between 0 and 20 points. This scale evaluates experiences related to depression. The ODSIS measures the frequency and severity of depression, as well as the level of avoidance, work/academic/home interference, and social and everyday life impairment related to depression symptoms. The ODSIS can also be used to assess severity and impairment associated with low mood during the previous week. In the Spanish version of the ODSIS, the internal consistency has been shown to be excellent, with a Cronbach's alpha of .93 and good convergent and discriminant validity (Mira et al., 2019).

Data Analytic plan. To test the hypothesis of the study, we used hierarchical linear modeling (HLM, Raudenbush & Bryk, 2002). These analysis accounts for the nested structure of the data (repeated measures nested within patients) including an error term for each level of hierarchy in the data and providing a more reliable estimation of the parameters. It also allows to study different levels of mechanisms of change by disaggregating within and between effects (nested structure of data). Furthermore, HLM provides a sound approach to handle missing data, allowing to include in the analyses all the participants that have at least one measurement completed.

Using HLM, for comparison purposes, we first ran separate fully-unconditional two-level models (Level-1: repeated measures, Level-2: within patients) for each outcome variable (i.e., either OASIS or ODSIS).

Where at Level 1, OASIS/ODSIS scores at time i for patient j were predicted by patient j's estimated OASIS/ODSIS average score across treatment (β_{0j}). The random effect r_{ij} allow the patient j to vary at time i from its estimated average score in OASIS/ODSIS during treatment. At Level 2, β_{0j} was predicted by the sample's average OASIS/ODSIS across treatment (γ_{00}). The random effects u_{0j} allowed the patients j to varied from the sample's average OASIS/ODSIS across treatment.

Then, we conducted two-level conditional models analyzing the effect of Positive and Negative Affect in each of the outcome variables. Because these predictors vary over the course of treatment, two components of the effects needed to be disentangled (Curran & Bauer, 2011). First, the effects of the over level of Negative Affect and Positive Affect (as separate predictors) over the outcome variables (between-patient). Second, the effects of fluctuations in Negative Affect and Positive Affect (as separate predictors) over the outcome variables (within-patient).These two effects occur at different level of analysis and generalizing the between-patient effect to the individual (i.e.: within-patient) would be an inference error (for a better understanding, see Curran y Bauer, 2011). Therefore, we disaggregated both between- and within patient effects of the predictor variables following the centering strategy recommended by Falkenström and colleagues (2017). Regarding the between-patient effects, patient's average levels of Positive and Negative Affect during treatment were included as level-2 predictors of

the intercept (grand-mean centered). While to compute the within-patient effects, we included the session-by-session deviation from their individual mean on Positive and Negative Affect as level-1 predictors (i.e., patient-mean centered).

Where at Level 1, *OASIS/ODSIS* scores at time *i* for patient *j* were predicted by patient *j*'s estimated *OASIS/ODSIS* in a session with an average PA and NA score (β_{0j}), by the effect of the patient's deviation in PA from his/her own mean (β_{1j}) and by the effect of the patient's deviation in NA from his/her own mean (β_{2j}). The random effect r_{ij} allow the patient *j* to vary from its estimated score in *OASIS/ODSIS* at time *i*. At Level 2, β_{0j} was predicted by the sample's average *OASIS/ODSIS* in patients with an average PA and NA across treatment (γ_{00}), the effect of PA level across treatment (γ_{01}), and the effect of NA level across treatment (γ_{02}). β_{1j} was predicted by the sample's average effect of the patient's deviation in PA(γ_{10}), while β_{2j} was predicted by the sample's average effect of the patient's deviation in NA (γ_{20}). The random effects u_{0j}, u_{1j}, and u_{2j} allowed the patients *j* to varied from the sample's average estimated *OASIS/ODSIS* score, the sample's average effect of the patient's deviation in PA, and the sample's average effect of the patient's deviation in NA, respectively.

When doing longitudinal process-outcome research, our analysis may suffer from omitted variable bias. Omitted variable bias is a term concerning those "third" variables not measured in the study which may be influencing both independent and outcome variable. If not controlled, these omitted variables threaten the confidence of potential causal conclusions. Especially in longitudinal studies, temporary variables and the mere effect of time can imply a causal effect on the studied phenomenon (e.g., spontaneous recovery). One way to remove these variables is by running a "detrending model", as recommended by Falkenström and colleagues (2017), by including time as a further level 1 predictor in the conditional model, adjusting for its effects. Therefore, we conducted a final detrending model by adding a linear time variable in the models. All analyses conducted were run using *R* version 3.5.3 (R Core Team, 2018) and specifically packages lme4 and lmerTest (Bates et al., 2015).

Results

Sample Descriptives - Regarding Positive Affect, patients showed an average score of 20.01 (*SD* = 6.39) at the beginning of treatment, while at the end of treatment, Positive Affect increased up to 26.27 with greater variability (*SD* = 8.25). Respecting Negative Affect, patients showed an average value of 31.33 (*SD* = 8.28) at the beginning of treatment, while at post-treatment was 20.75 (*SD* = 7.59).

Primary Analysis

Fully unconditional model. For OASIS, the unconditional model showed an average value of 7.15 across treatment, γ00 = 7.15, *SE* = 0.30, 95% CI [6.56, 7.74], $t(143) = 23.8$, $p < .001$. In the ODSIS fully-unconditional model, patients presented a mean value of 6.4 during treatment, γ00 = 6.40, *SE* = 0.34, 95% CI [5.72, 7.07], $t(143) = 18.62$, $p < .001$.

Positive and Negative Affect effects on Anxiety. This model yielded significant between-patient effects on Anxiety symptoms (i.e., OASIS) of both Positive Affect, γ01 = -0.10, *SE* = 0.02, 95% CI [-0.15, -0.05], *t*(132) = -3.71, *p* < .001, and Negative Affect, γ02 = 0.4, *SE* = 0.03, 95% CI [0.35, 0.45], *t*(145) = 15.13, *p* < .001. These results can be read as follows: A one-unit greater Positive Affect level was associated with a decrease in 0.10 units on the OASIS score during treatment; and a one-unit greater Negative Affect level was associated with an increase in 0.40 units on the OASIS score during treatment.

Furthermore, the results showed significant within-patient effect on the OASIS score of both Positive Affect, γ10 = -0.12, *SE* = 0.02, 95% CI [-0.16, -0.09], *t*(96) = -6.90, *p* < .001, and Negative Affect, γ20 = 0.30, *SE* = 0.02, 95% CI [0.27, 0.34], *t*(119) = 17.90, *p* < .001. That is, a one-unit variance in patient's Positive Affect from their individual mean was associated with a 0.12 points lower score in the OASIS at that session. On the other hand, a one-unit variance in patient's Negative Affect from their individual mean associated with an increase of 0.30 points on the OASIS (i.e., with a higher anxiety severity) during treatment.

Furthermore, the detrending model showed significant between-patient effect of Positive Affect, γ01 = -0.10, *SE* = 0.03, 95% CI [-0.15, -0.04], *t*(140) = -3.61, *p* < .001, and Negative affect, γ02 = 0.38, *SE* = 0.03, 95% CI [0.33, 0.44], *t*(152) = 14.25, *p* < .001. These significant results were observed for the within-patient effect of Positive Affect as well, γ01 = -0.10, *SE* = 0.02, 95% CI [-0.13, -0.06], *t*(105) = -5.83, *p* < .001, and Negative affect, γ02 = 0.27, *SE* = 0.02, 95% CI [0.23, 0.30], *t*(130) = 15.22, *p* < .001.

Positive and Negative Affect effects on Depression. With regard to depression, significant between-patient effects on Depression symptoms of both Positive Affect, γ01 = -0.20, *SE* = 0.03, 95% CI [-0.26, -0.13], *t*(136) = -5.91, *p* < .001, and Negative Affect, γ02 = 0.37, *SE* = 0.03, 95% CI [0.31, 0.43], *t*(151) = 11.57, *p* < .001. First, a one-unit greater Positive Affect level was associated with a decrease in 0.20 units on the ODSIS score during treatment. Secondly, a one-unit greater Negative Affect level was associated with a decrease in 0.37 units on the ODSIS score during treatment.

Moreover, this model showed significant within-patient effect on the ODSIS score of both Positive Affect, γ10 = -0.23, *SE* = 0.02, 95% CI [-0.27, -0.18], *t*(115) = -10.07, *p* < .001, and Negative Affect, γ20 = 0.18, *SE* = 0.02, 95% CI [0.15, 0.21], *t*(103) = 11.09, *p* < .001. A one-unit variance in patient's Positive Affect from their individual mean was associated with a 0.23 points lower score in the ODSIS at that session. Conversely, a one-unit variance in patient's Negative Affect from their own mean was associated with an increase of 0.18 points on the ODSIS (i.e., with a higher anxiety severity) during treatment. When comparing this conditional models with both Positive and Negative Affect as random predictors of ODSIS, this model significantly improved the model fit compared with the fully unconditional model, x^2 (5) = 139, *p* < .001.

As well as for effects on anxiety, the detrending model for ODSIS also showed significant effects, both for Positive and Negative Affect. The model showed significant between-patient effects

on Positive Affect, γ01 = -0.20, *SE* = 0.03, 95% CI [-0.26, -0.13], *t*(136) = -5.77, *p* < .001, and Negative Affect, γ02 = 0.36, *SE* = 0.03, 95% CI [0.30, 0.43], *t*(151) = 11.13, *p* < .001. Regarding within-patient effects on ODSIS, both Positive Affect, γ10 = -0.22, *SE* = 0.02, 95% CI [-0.26, -0.17], *t*(118) = -9.73, *p* < .001, and Negative Affect, γ20 = 0.16, *SE* = 0.02, 95% CI [0.13, -0.20], *t*(116) = -9.63, *p* < .001, remained significant when adjusting for time effects.

Discussion - Mechanisms of change in longitudinal studies with multiple measurement points have been scarcely studied. The goal of this study was to examine the influence of affectivity on depression and anxiety symptomatology in a transdiagnostic Internet-based treatment for individuals with emotional disorders. We wanted to look at the impacts of NA and PA on the outcomes of a transdiagnostic Internet-based treatment using longitudinal models and disaggregate the impacts of this proposed mechanism of change within and across patients.

The findings revealed a significant between-patient influence on symptoms, which was linked to decreased depression and anxiety levels. A significant between-patient effect was observed in the case of depression. Throughout the intervention, higher PA levels and lower NA levels were linked with reduced depressed symptoms, as predicted. This trend was also seen in the case of anxiety, with a significant between-patient effect on anxiety symptoms. In other words, during treatment, higher PA levels and lower NA levels were associated with reduced anxiety symptoms. Furthermore, within-patient effects of affectivity on depression and anxiety were found, implying that increases in PA and decreases in NA throughout treatment were associated with lower depression and anxiety symptoms. In this regard, the effects remained significant after running a detrending model (i.e., including time as a covariate in the model), revealing that the within effect of affectivity cannot be explained by confounding factors that may explain change (Falkenström et al., 2017). They also indicate that affectivity plays a key role in recovery from anxiety and/or depression, demonstrating that NA and PA are changeable constructs that may be modified by transdiagnostic treatment.

This can be read in terms of the literature of mechanisms of change, and how affectivity may play an important role in that regard. As seen in the introduction, affect and emotion generation and regulation are intimately related and are organized at different levels of a hierarchy along with personality traits that are the higher order factor (Naragon-Gainey et al. 2018). The results of this study indicate that affectivity can be a trans-theoretical and transdiagnostic construct and, therefore, a mechanism of change of emotional disorders. The findings of this study indicate that it may be particularly relevant to focus on higher order factors that link emotional disorders together (i.e., NA; Barlow, Sauer-Zavala, Carl, Bullis, & Ellard; 2014 and PA; Carl, Fairholme, Gallagher, Thompson-Hollands, & Barlow, 2014). Additionally, the knowledge about affectivity as a mechanism of change in emotional disorders may contribute to a better understanding of the patients' psychological functioning and potentially increment the efficacy and effectiveness of future interventions.

These findings should be analyzed in light of the following limitations. First, the patients study were diagnosed with emotional disorders from a community sample, which limits the generalizability of the study. Future research should therefore be conducted in inpatient settings or specialized care to determine whether results are replicated. Besides, this design did not consider the relationship between affect and other important factors in psychotherapy, such as personality pathology, comorbid diagnoses, or recovery. A third important point is that the present study includes a number of strategies that were used to reduce NA and increase PA; however, future research will be needed to determine which of these strategies are more effective for whom, given that the various diagnoses were lumped together under the same label of emotional disorders. It would also be required to investigate the function of each of the treatment protocol's therapeutic components. Finally, individuals were assessed during therapy using the study's web platform; however, a more ecological survey method from the vast array of methods pertaining to the family of Ambulatory Assessment (AA) methods, would be useful to evaluate therapeutic processes in the patients' everyday lives.

Notwithstanding these limitations, the present study has important strength to highlight. To the best of our knowledge, it constitutes one of the very first studies that explores positive and negative affect throughout a transdiagnostic internet-based treatment for emotional disorders, disentangling the within effects. Having scores of every module completed by the patients permits to study association between mechanisms of change and outcomes. Specifically, this study shows how it is possible to account for the variability of affect, estimating the effects for each individual patient.

This study builds upon the growing evidence showing that guided interventions can help to disseminate psychological treatments for emotional disorders, showing how

the assessment and treatment of emotional disorders, incrementing the dissemination of transdiagnostic treatments Therefore, it is responding to an essential challenge in the field of emotional disorders, that is, to help to disseminate and increase the access to evidence-based interventions, improving the field of psychological treatments.

2.3 *Blended treatments*

Blended treatments have emerged as an alternative to enhance the dissemination and implementation of evidence-based treatments and reduce the costs associated with traditional psychotherapy (Schuster et al., 2018). The principal feature is that they merge in-person and a remote modality such as videoconferencing psychotherapy, guided or unguided interventions, chats or other interventions (Kleiboer et al., 2016; Kooistra et al., 2014). They may provide the strengths of both approaches (Erbe et al., 2017; Wentzel et al., 2016). For example, in terms of therapeutic alliance there are promising results revealing that it can be successfully established in blended formats of intervention (Kooistra et al., 2020; Vernmark et al., 2019).

One of the most representative research programs on blended therapy in Europe is E-COMPARED, a multicenter study that is currently being undertaken in eight countries and investigates

the clinical and cost-effectiveness of blended treatment for depression compared to treatment-as-usual in routine care (Kleiboer et al., 2016). Previously, in an attempt to test blended treatments, an Internet-based cognitive behavioral therapy was alternated with face-to-face sessions for the treatment of patients with mild to moderate anxiety or depression (Månsson et al., 2013). This study showed that Internet-based support can be useful as a vehicle for communication and for the structure in therapy without negatively impacting the effects of cognitive behavioral therapy.

Over the last years, a growing body of evidence has been produced showing not only the efficacy of blended treatments, but also the pursuit of implementation in real world contexts (Baumeister et al., 2021; Lungu et al., 2020). Despite the good results, it is also challenging mainly because many therapists do not perceive the incorporation of technology as a way of saving time (Cerga-Pashoja et al., 2020; Mol et al., 2019).

Additionally, other blended treatments have been developed in the Acceptance and Commitment Therapy (ACT) framework (Levin et al., 2017; Vaessen et al., 2019; van Aubel et al., 2020). All these studies incorporate ER strategies from traditional cognitive behavioral therapy (e.g., psychoeducation, cognitive restructuring, behavioral activation) and acceptance-based components (e.g., acceptance, values and committed action, psychological flexibility).

The first transdiagnostic intervention that will be provided as an add-on of in-person psychotherapy is REMOTION, which has been developed to target specifically ER (Bielinski et al., 2020). The training presents different modules according to each stage of the extended model of Gross (2015). REMOTION is currently being tested in a two-arm RCT that compares the active condition with treatment as usual.

Moreover, a very promising research line seeks to integrate a transdiagnostic internet intervention with group therapy for emotional disorders (Díaz-García et al., 2021). This study is designed on the basis of a previous validated protocol, which has the principal aim of regulating emotions (Díaz-García et al., 2017; Díaz-García et al., 2021).

3. New perspectives in the intervention of ER with digital technologies

3.1 Digital technologies to improve existing interventions

So far, technology has principally been harnessed to disseminate existing interventions. Internet interventions as well as videoconference constitute clear manifestations of this endeavor. Psychological treatments have still much room for improvement, and technologies can foster their development beyond their dissemination. Should digital technologies be combined with presential modalities or even integrated into them, it would be possible to greatly improve the existing procedures in clinical practice. Hence, this section delves into interventions that improve, augment or enhance the traditional delivery of existing interventions (e.g. virtual reality for exposure therapy) as well as interventions that without

the technological input would not be possible to be delivered (e.g. biofeedback or ecological momentary interventions).

3.1.1 Mixed realities: Virtual and Augmented Reality

The possibility of creating new worlds is a defining feature of our mind. Indeed, the mind can be considered as a virtual reality (VR) system. Imagining alternative past events or visualizing potential future scenarios have demonstrated to be very powerful emotionally wise (Hirsch et al., 2003; E. A. Holmes & Mathews, 2010). That is the principle in which mixed realities are based on. Ample evidence has shown that VR environments are capable of eliciting emotional reactions as strong as real stimuli (Baños et al., 2008; Riva et al., 2007), as well as to experience the sense of "being there" (i.e., presence) (Riva, 2009). Doubtlessly, VR is the most researched and well-known of the mixed realities, although augmented reality (AR) and augmented virtuality are part of this continuum.

In line with all intervention research, the literature of virtual reality has been conducted taking into account the classical perspective of specific disorders. Therefore, the described body evidence did not explicitly mention ER as a treatment target. However, it is possible to examine the results in VR through the lens of ER.

3.1.1.1 Exposure treatments: Tackling avoidance

The tendency to avoid potentially threatening situations has been shown to intensify anxious responding patterns and to prevent patients from implementing adaptive strategies (Salters-Pedneault et al., 2004). When confronting feared stimuli, exposure therapy is therefore supporting individuals to better regulate emotions by reducing avoidance behaviours.

In the last 25 years, VR has gained its place among the technological interventions in clinical psychology. From the initial works by in the early 90's to these days there have been naturally many changes, although VR has principally been used as an exposure tool. That is, VR has emerged and is still considered an appealing alternative to *in vivo* exposure given the possibility of providing exposure in controllable and safe ways, which enhance the acceptance to a usually rejected treatment (Garcia-Palacios et al., 2007). Besides, VR may help to reduce the logistical problems of *in vivo* exposure (McAleavey et al., 2014) and thus permitting to tackle the reluctance of therapists to apply exposure (Schumacher et al., 2018).

Besides, the use of VR gives the possibility to manipulate a feared stimulus and thereby change context exposure, which is a way of maximizing exposure through the inhibitory learning principle (Craske et al., 2014), and specifically in patients with spider phobia revealed to be more effective than extinction in a single context to reduce renewal rates (Shiban et al., 2013, 2015). The use of AR also constitutes an important tool to enhance traditional exposure therapy, permitting the incorporation of virtual elements into reality (i.e., feared stimuli) and bring relevant and salient information to the scene (Botella et al., 2010, 2016; Wrzesien et al., 2013).

Over more than two decades, several meta-analytical studies have shown the effectiveness of VR as an exposure tool, primarily for anxiety and stress related disorders (Botella et al., 2017; Carl et al., 2019; Opriş et al., 2012), and at a lesser extent for eating disorders and addictive behaviors (Maples-Keller et al., 2017). Overall, there is a sustained trend that shows the equal efficacy of *in virtuo* exposure to other active treatments. The vast literature that has been produced in this field permitted to show that VR gains are transferable to real life (Morina et al., 2015) and attrition rates are equivalent to face-to-face interventions (Benbow & Anderson, 2019).

One of the major pending point in the VR literature, was the extent to which VR exposure therapy is iatrogenic. In order to answer this question, an individual patient meta-analysis was conducted to determine both the overall rates of deterioration of patients receiving VR therapy.

The primary goal of this study was to look at the rates of deterioration of all the randomized control trials for anxiety disorders that used VR. Deterioration rates have been suggested as the most concise way to capture iatrogenic effects among the various possible options. Although other means of measuring negative outcomes, such as the subjects' subjective experience or a reduction in interpersonal functioning, may be of considerable therapeutic benefit, a thorough quatitative analysis is problematic due to the lack of standardized scales suited to VR and the complex nature of the intervening variables (Rozental et al., 2017). Deterioration is characterized as an increase in symptomatology, and since treatment results are often studied in randomized control trials, the method for determining the number of patients who are worse off is relatively simple in clinical psychology.

Adults with anxiety disorders receiving a VR treatment in an RCT design were considered for this study. Following Meyerbröker and Emmelkamp's (2010) suggestion, the VR condition had to have at least 10 patients. Besides, the inclusion criteria were designed following the PICOS acronym. P: adult population with anxiety disorders or stress related disorders*;* I: psychological intervention with VR; C: non-VR active condition or waiting list*;* O: symptomatology*;* and S: randomized control trials. Two independent reviewers looked at two of the most important databases (Pubmed and Web of Science), identifying potentially significant papers. The year of publishing was not a constraint. Relevant keywords and mesh terminology were used for each database consultation (see appendix 1 for the string used for Pubmed). The strings comprised of two parts: (1) virtual reality and all synonyms, and (2) anxiety disorders and all associated terms.

All the papers were exported to software of reference management (Mendeley) during the research selection period. After deleting duplicates, the cumulative search yielded 1272 documents, of which 646 were recovered for further study. The next step was for the two reviewers to read all of the titles separately, excluding those that were not important to the systematic review's goal (e.g. did not mention VR or related terms, or were not based on psychological interventions). There were no differences in the final selection of the two reviewers. Following this, 124 full-text papers were listed as potentially important research. Finally, according to the qualifying requirements, 36 studies were considered to be eligible.

Unlike conventional meta-analyses, all of the datasets were requested after a comprehensive analysis of the current literature on VR-based trials. A new dataset was developed from the collected datasets with the aim of evaluating the raw scores for each patient in order to ensure a more reliable analysis than one based on group means and standard deviations. In the case of deterioration rates, the best way to assess their prevalence is considering the individual patient level, and these effects were meta-analyzed.

All the corresponding authors of the 36 papers included in the systematic review were contacted. This e-mail contained the aim of the study, and corresponding authors were invited to co-author the future papers. Finally, 15 datasets were obtained, while 21 datasets could not be retrieved from the authors for different reasons, including irretrievable data, impossibility of sharing the material due to legal constraints, or no answer from the corresponding authors (after 3 attempts). Appendix 1 presents a flow chart of the systematic review.

For the quality Assessment of included studies an assessment of risk of bias was performed., using the *Cochrane Handbook for Systematic Review Interventions* (J. P. T. Higgins et al., 2011). The following domains were assessed: (1) Random sequence generation and allocation concealment (selection bias); (2) Therapist and researcher allegiance, treatment fidelity (performance bias); (3) Blinding of outcome assessor (detection bias); (4) Incomplete outcome data reporting (attrition bias); and (5) Selective outcome reporting (reporting bias). We assessed and categorized the risk of bias following the *Cochrane* guidelines: (1) low risk of bias, plausible bias unlikely to seriously alter the results; (2) high risk of bias, plausible bias that seriously weakens confidence in the results; and (3) unclear risk of bias, plausible bias that raises some doubt about the results. Two independent reviewers assessed the studies, reaching a 92.22% of agreement. Discrepancies were resolved by consensus between reviewers.

Statistical analysis. Deterioration were determined using the Reliable Change Index (RCI), following the recommendations given by Jacobson and colleagues (Jacobson et al., 1984). The RCI represents a measure of change between two measurement points, establishing if a potential difference between those two scores is reliable and not caused merely by measurement error. In the present IPD meta-analysis, an RCI of 0.84 was selected (p = .20). Patients whose RCI was equal or superior to 0.84 were dummy coded as being reliably deteriorated (1 = yes, 0 = no). This information was utilized to explore if there were clinical or sociodemographic variable predict the worsening of the patients, using deterioration as the dependent variable in a logistic regression. The independent variables, i.e., predictors, were chosen a priori: 1) clinical severity at pre-treatment assessment, 2) marital status, 3) educational level, 4) age, and 5) gender. The results of the logistic regression are presented as odds ratios (OR), which refers to an increase or decrease in the odds of deterioration, compared to a predetermined reference category. For nominal variables, e.g., gender, the OR indicates an increase in the odds of worsening when going from female (0) to male (1). For the continuous variables, i.e., clinical severity at pre-treatment assessment and age, the OR stands for an increase of 1 SD above the mean.

Predictors with an OR where the 95% Confidence Interval (CI) does not contain 1 are considered significant, which implies that they might predict deterioration. However, as with all analyses of predictors, the results should be considered tentative, requiring further research before any firm conclusions can be drawn about their importance (Clarke, 2005). Finally, given that there is a risk of ceiling effects when calculating deterioration during treatment using self-report measures, scoring near the instrument's maximum at pretreatment assessment was assessed by dummy coding of patients who were within the RCI's upper boundary on each respective clinical trial (1 = yes, 0 = no). All statistical analyses were conducted in SPSS 24.

Deterioration rates from the VR group and a composite of deterioration rates from both control groups were utilized to compute Odds Ratios to summarize the data gathered from the included trials (ORs). The summary statistic is shown as an OR with a 95% confidence interval. The Q statistic and the I2 index were used to calculate heterogeneity (Higgins et al., 2003). The I^2 index is defined as the fraction of between-study variance that is not explained by main study random sampling error. The percentages are used to discriminate low (25%), middle (50%), and high heterogeneity (75%). However, it must be taken into account that the I^2 statistic can be biased when it is calculated based on small sample sizes (Von Hippel, 2015). A forest plot with the ORs was obtained using Comprehensive Meta-analysis software. The OR comparing the likelihood of deterioration between VR and waitlist was calculated using the Mantel–Haenszel method. The MH is a recommended strategy for smaller samples as is the case of the present study (Bradburn et al., 2007)

Results - Table 4 shows the 36 studies that fulfilled all of the inclusion criteria. In total, 15 datasets out of the 36 studies identified in the systematic review were retrieved for the IPD meta-analysis. The raw data from these studies was merged into a single dataset, which overall resulted in a sample of 810 patients. From this total number, 348 (42.96%) received VR, 282 (34.81%) received other active intervention, and 180 (22.22%) were in a waiting list group. Regarding the clinical conditions, 230 patients presented a diagnosis of social anxiety disorder (4 studies), 60 of agoraphobia (4 studies), 17 of panic disorder (1 study), 225 of specific phobias including small animal phobias (2 studies) and fear of flying (4 studies), and 80 of post-traumatic stress disorder (3 studies).

Representativeness of the included studies in relation to the 36 papers that met the criteria in the systematic review - A total of 1956 patients with anxiety disorders receiving a VR treatment met the inclusion criteria specified for this study, which means that the sample included for the IPD analysis represents 41.10% of the overall sample.

Table 4. Characteristics and Deterioration Rates for the Clinical Trials.

Study	Primary diagnosis	Virtual reality *n* (%)	Other treatment *n* (%)	Wait-list control *n* (%)	Deterioration virtual reality *n* (%)	Deterioration other treatment *n* (%)	Deterioration waiting-list *n* (%)	OR (VR vs. All controls)
Andersson et al. (2013)	SAD	36 (37.5)	49 (51.0)	11 (11.5)	5 (13.9)[a]	2 (4.1)	1 (9.1)	2.77
Botella et al. (2016)	SP	32 (50.8)	31 (49.2)	-	1 (3.1)	1 (3.2)	-	0.97
Bouchard et al. (2017)	SAD	17 (28.8)	22 (37.7)	20 (33.9)	0 (0.0)	0 (0.0)	5 (25.0)	-
Baños et al. (2011)	TEPT PG AD	20 (51.3)	19 (48.7)	-	0 (0.0)	0 (0.0)	-	-
Kampmann et al. (2016)	SAD	20 (33.3)	20 (33.3)	20 (33.3)	1 (5.0)	0 (0.0)	2 (10.)	1.00
North et al. (1996)	AG	30 (50.0)	-	30 (50.0)	0 (0.0)	-	2 (6.7)	-
De la Rosa et al. (2012)	TEPT	10 (50.0)	10 (50.0)	7 (35.0)	0 (0.0)	0 (0.0)	-	-
Difede et al. (2007)	TEPT	13 (61.9)	-	8 (38.1)	0 (0.0)	-	4 (50.0)	-
Botella et al. (2007)	PD	12 (32.4)	12 (32.4)	13 (35.1)	0 (0.0)	0 (0.0)	1 (7.7)	-
Peñate et al. (2014)	AG	23 (26.0)	14 (48.0)	13 (26.0)	1 (4.3)	0 (0.0)	2 (15.4)	0.82
Pitti et al. (2015)	AG	49 (38.3)	38 (29.7)	41 (32.0)	1 (2.0)	0 (0.0)	7 (17.1)	0.16
Mühlberger et al. (2001)	SP	15 (50.0)	12 (50.0)	-	0 (0.0)	0 (0.0)	-	-
Mühlberger et al. (2003)	SP	26 (55.3)	11 (23.4)	10 (21.3)	2 (7.7)	1 (9.1)	3 (30.0)	0.4
Moldovan et al. (2014)	SP SAD AG	26 (65.0)	-	14 (35.0)[b]	2 (7.7)	0 (0.0)	0 (0.0)	-
Tortella et al. (2011)	SP	19 (31.7)	41 (68.3)	-	1 (5.3)	4 (9.8)	0 (0.0)	0.54
					14 (4.0)	**8 (2.8)**	**27 (15.0)**	

Risk of bias in the included studies. The quality of the papers included differed. Although the studies' average methodological consistency was poor in terms of randomization and blinding, they were high in terms of attrition and reporting biases. The poor methodological consistency of the VR studies is revealed by the fact that only 46.66% of them presented a low risk of bias in terms of random sequence

generation and participant and staff blinding, and only 20% of them were conducted with an appropriate allocation concealment. More concerning, though, is the generation of spontaneous sequences, which is often difficult to achieve in psychotherapeutic treatments. Since the selection bias is mostly unknown, it is conceivable that proper randomizations were not carried out and that instead a reporting bias exists.

Table 5. Socio-demographic Characteristics of the Patients

Baseline characteristic	Virtual reality (n = 348)	Other treatment (n = 282)	Wait-list control (n = 180)	Full sample (n = 810)	Missing data
Gender: *n* (% female)	248 (71.3)	203 (72.0)	99 (55.0)	550 (67.9)	0 (0.0)
Age (years): *M* (*SD*)	35.6 (11.2)	36.6 (11.7)	36.9 (11.2)	36.2 (11.4)	19 (2.4)
Marital status: *n* (%)					165 (20.4)
Single	135 (38.8)	125 (44.3)	65 (36.1)	325 (40.1)	
Relationship	138 (39.7)	115 (40.8)	67 (37.2)	320 (39.5)	
Highest educational level: *n* (%)					93 (11.5)
Primary school	20 (5.7)	8 (2.8)	7 (3.9)	35 (4.3)	
Secondary school	142 (40.8)	108 (38.3)	58 (32.2)	308 (38.0)	
University	149 (42.8)	134 (47.5)	91 (50.6)	374 (46.1)	
Employment: *n* (%)					359 (44.3)
Unemployed	18 (5.2)	28 (9.9)	15 (8.3)	61 (7.5)	
Student	35 (10.1)	28 (9.9)	13 (7.2)	76 (9.4)	
Employed	134 (38.5)	104 (36.9)	70 (38.9)	308 (38.0)	
Retired	2 (0.6)	3 (1.1)	1 (0.6)	6 (0.7)	
Primary diagnosis: *n* (%)					2 (0.2)
Social anxiety disorder	98 (28.2)	90 (31.9)	42 (23.3)	230 (28.4)	
Specific phobia	87 (25.0)	79 (28.0)	59 (32.8)	225 (27.8)	
Agoraphobia	33 (9.5)	23 (8.2)	4 (2.2)	60 (7.4)	
Posttraumatic stress disorder	33 (9.5)	25 (8.9)	22 (12.2)	80 (9.9)	
Panic disorder	3 (0.9)	1 (0.4)	2 (1.1)	6 (0.7)	
Panic disorder with agoraphobia	92 (26.4)	64 (22.7)	51 (28.3)	207 (25.6)	

Deterioration rates - 734 (90.6%) were included in the analysis of deterioration, from which 49 (6.0%) were identified as reliably deteriorated. Taking into consideration the three conditions, 14 (4.0%) for patients receiving VR, 8 (2.8%) for other active treatment, and 27 (15.0%) in wait-list control (see Table 5). The two active conditions were merged and compared only to the waiting list, obtaining an OR =

4.87, 95% CI [2.69, 8.80]. This means that the odds for deterioration were significantly higher for patients that were waiting for a treatment rather than receiving an active intervention.

In addition, MH ORs were run for VR vs all controls, all active treatments versus waiting, and lastly VR versus active therapies to ensure that there were no changes in the chances of deterioration between these two situations. 12 of the 15 studies were included in the comparison of VR with all controls since three studies (R. M. Baños et al., 2011; de la Rosa Gómez & Cárdenas, 2012; Mühlberger et al., 2001) did not provide deteriorating patients in any of the conditions, making the MH OR impossible to determine. As shown in Figure 3, the pooled OR in favor of VR was 0.61 [95 percent CI 0.31–1.23], indicating that VR-based therapies were 39 percent less likely than all control circumstances to generate a worsened effect. Despite this, the 95 percent confidence interval (z=1.17, p=0.17) did not approach statistical significance. Heterogeneity between studies is low (Q(11) = 11.402, p = 0.410, I2 = 3.525). While the OR is not significant, it implies that the chances of worsening in VR are lower than on the waitlist. Finally, the trim and fill technique of Duval and Tweedie (2000) was utilized to find any possibly missing studies and their influence on the summary MH odds ratio. With an adjusted MH odds ratio of 0.98 [0.46–2.11], four possibly missing studies were found.

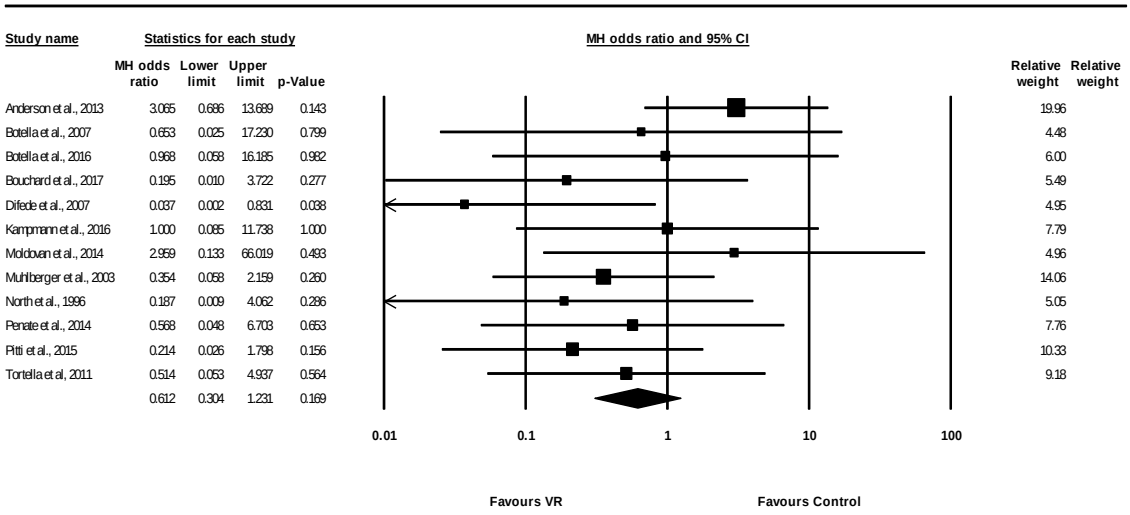

Figure 3. Forest plot of included studies for the comparison VR versus all controls.

Besides, the comparison of all active conditions versus waiting list resulted in an OR of 0.165 [-3.879 – 0.411], $p < 0.001$ indicating that the odds of deterioration are significantly higher in waitlist compared to treatment (VR or other treatment). Although a higher variability between studies is noticeable in comparison to VR versus all controls, following the standards suggested in the literature (Higgins et al., 2003) the detected is also low (Q(9)=11.343, p= 0.253, I2=20.658). One potentially missing study was identified and imputed based on the Duval and Tweedie trim and fill method. The adjusted OR was 0.129 [0.049 – 0.346].

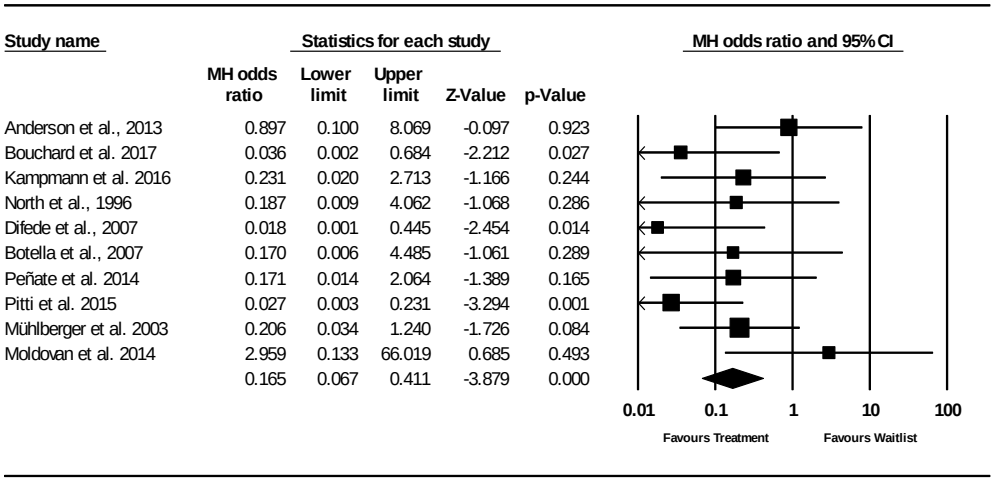

Figure 4. Forest plot of studies for the comparison all active conditions versus WL.

Finally, a comparison of VR and active conditions was performed with the aim of confirming that no significant difference was present between these two conditions. The MH odds ratio comparing the odds of deterioration from VR to other treatment was 1.68 [0.65 – 4.33], $p = 0.287$. Variability between studies was low ($Q(6) = 2.64$, $p = 0.853$, $I^2 = 0.00$). By doing this, the previous comparison of VR and other treatments versus WL is consistent.

Regarding the predictors of deterioration, given the large difference in deterioration rates, the analyses of potential predictors using logistic regressions were carried out separately for the three conditions. None of the predictors chosen a priori were related to deterioration in any of the cases; 1) clinical severity at pre-treatment assessment, 2) marital status, 3) educational level, 4) age, and 5) gender. The only exception was marital status in patients waiting for treatment, OR = 0.19, 95% CI [0.05, 0.67], suggesting that being in a relationship lowered the odds of deterioration somewhat. The current study examined the deterioration rates of VR-based treatments for anxiety disorders. The dataset consisted of 15 studies, which, overall, were representative of the whole sample of 36 RCTs conducted within the field of VR for anxiety disorders and stress related disorders; each study had a sample of at least 10 patients in the VR condition. Raw scores from 810 patients were entered into an aggregated dataset, and the RCI was utilized to detect the deteriorated cases.

Table 6. Odds Ratios for Each Predictor Variable Using the Full Imputed Model and Divided by VR, Other Treatments, and WL Control

	Virtual Reality				Other treatments				Wait-list control			
Predictor (*reference*)	OR	Lower CI	Upper CI	*p*	OR	Lower CI	Upper CI	*p*	OR	Lower CI	Upper CI	*p*

Clinical severity at pre treatment assessment (*lower severity*)	1.00	0.99	1.02	0.90	0.92	0.84	1.01	0.09	1.00	0.98	1.02	0.74
Marital status, single/relationship (*single*)	1.19	0.37	3.86	0.77	n.a.	n.a.	n.a.	n.a.	0.19	0.05	0.67	0.01*
Educational level, less than/at least university (*less than university*)	0.64	0.18	2.26	0.49	n.a.	n.a.	n.a.	n.a.	1.11	0.31	4.02	0.87
Age (*lower age*)	1.01	0.96	1.07	0.63	1.25	0.98	1.60	0.08	1.04	0.98	1.10	0.16
Gender (*female*)	2.13	0.63	7.17	0.22	n.a.	n.a.	n.a.	n.a.	0.87	0.21	3.56	0.84

Note. OR odds ratio; CI 95% confidence interval. **p* .05. n.a. = not applicable, i.e., too few cases for the logistic regression to converge

In light of the obtained results, it can be said that VR seems to represent a non-iatrogenic intervention for individuals suffering from anxiety disorders. Besides, none of the predictors were associated with higher or lower odds of deterioration, but marital status in the wait-list control. Nonetheless, due to the low rates of deterioration, it was not possible to examine this issue in depth.

In the same vein, when ORs are compared, aggregated groups should be created due to the low frequencies. First, all the active conditions were compared to waiting list groups. This difference was statistically significant, showing that exposure, no matter which modality of the type of treatment, is less likely to induce a deteriorated effect compared to patients assigned to waiting list controls. Nevertheless, when comparing VR versus all controls, no significant differences were found, although the tendency was in favor of VR.

It must be mentioned that the low frequencies of deterioration rates made it difficult to arrive at more conclusive statements. In fact, the pitfall of small samples within VR research has been previously described in the literature (Page & Coxon, 2016), and it is a major issue to overcome in attempting to increase the quality of research in the field and, thus, better determine the extent to which VR can be useful in clinical practice.

Limitations and Future Research – First, given the availability of the raw data of the single studies, it could have been applied multilevel individual patient data meta-analysis. This kind of

advanced method is aligned with the hierarchical analyses that were used in the first two empirical contributions of the present dissertation. The implementation of multilevel analysis would have permitted to deal with the nested structured of the data. Besides, this strategy is appropriate in handling missing data. As no imputation analyses were performed for missing values and this could have led to some biased results, the incorporation of multilevel analysis would have been beneficial.

Another aspect that is worth mentioning is that deterioration rates is a straightforward way to obtain a negative effect, but negative effects may be present in many other ways that should also be examined. Furthermore, despite the results obtained, it cannot be concluded that patients undergoing VR-based treatments will not experience any negative effects.

Implications of these results in light of the ER literature - When confronting feared stimuli, exposure therapy is aiding individuals to better regulate emotions. Considering for example the temporal model of Gross (2015), behavioral avoidance can be understood as an antecedent strategy, specifically as a situation selection and modification. In this sense, exposure helps to change expectations and emotional responses associated with feared stimuli (Papa et al., 2012). However, ER has been rarely considered as a mechanism of change or as outcome measure. This lack of empirical data does not imply that ER did not improve throughout the numerous VRET treatments, and future VRET treatments could include some ER measure to explore the extent to which VRET fosters changes in this regard.

Over the last years, a growing body of evidence emerged on the role of VR beyond exposure for clinical interventions. Although it is still a nascent area, there are interesting illustrative examples that shed light on how the field of VR is expanding its frontiers (Fernández-Álvarez et al., 2020). Many of these developments are important to grasp deeper layers of intervention, such as regulatory and modulatory problems.

3.1.1.2 Virtual Attention focused interventions

VR has been also used to target attentional resources, which is a relevant process of many psychological interventions. Over the last years, mindfulness-based interventions are the most illustrative example of attentional focused interventions. Despite differences among mindfulness interventions, all of them train patient's attention to be focused on the present moment in order to pursue the deployment of putatively adaptive ER strategies such as acceptance and decentering.

In VR, however, there are only few examples. Navarro-Haro et al. (2019) have conducted a study in a naturalistic setting for generalized anxiety disorder individuals, which showed that although the mindfulness intervention is not superior conducted with VR, the technology may help to reduce dropout rates. The same research group used a similar approach in order to test the applicability of mindfulness through VR in a more severe clinical condition, such as borderline personality disorder

(Navarro-Haro et al., 2016). Although the study suggests that it is feasible, it was only a non-experimental single case, reason for which no conclusive statements can be drawn.

Finally, although not directly designed to target ER, findings of utmost interest were obtained by Cebolla et al. (2019), who developed a VR-based self-compassion intervention in which participants could see themselves from a third-person perspective while listening to audios that promoted their self-compassion. After two weeks, those individuals who receive the VR-based self-compassion intervention showed larger levels of awareness and attention to the present for mental events and bodily sensations, thus demonstrating the usefulness of VR to incorporate mindfulness skills.

Another research line that is worth mentioning is the study of cognitive bias modification of interpretations in VR. Initial evidence suggests that VR could enhance the already strong effects due to the immersive nature of virtual environments and thus facilitate participants' engagement with the training and arguably amplify the targeted anxiety-relevant schemas (Otkhmezuri et al., 2019). Similarly, a study focused on the feasibility of VR-based attention bias modification, using a dot-probe training paradigm, which was designed to facilitate attentional disengagement from threatening stimuli in socially anxiety individuals (Urech et al., 2015). However, these two examples were just proof-of-concepts, and more conclusive evidence should be produced. Indeed, the first controlled study, which also used a dot-probe training paradigm with four conditions (mock vs. active; 2D vs. 3D) for social anxiety, did not yield significant interaction effects (Ma et al., 2019).

3.1.1.3 Virtual reality for positive affect augmentation

First, and an already developed is the use of VR as a tool for the induction of emotions (Diniz Bernardo et al., 2021). When applied to clinical interventions, virtual environments can result in a useful tool in order to active patients' emotional states (e.g., in trauma related disorders or dissociative disorders). A pioneering development in this regard has been the platform called "Engaging Media for Mental Health Application" (EMMA), which permitted to select images sounds and scenarios depending on patient's preferences and needs (Baños et al., 2009). In this example, VR is not just a platform to provide patients with exposure, but to foster the elaboration of traumas through personalized virtual environments (Baños et al., 2009, 2011; Botella, García-Palacios, et al., 2010; Guillén et al., 2018). The world of EMMA has also been tested combined to structured CBT in a patient reporting complicated grief (Botella et al., 2008).

Mounting body of evidence reveal that strategies like listening to relaxing music (Linnemann et al., 2015) or watching videos of natural environments (Bielinis et al., 2020; Freeman et al., 2004; Wang et al., 2020) can help to reduce stress levels, which in turn has shown to be a maintaining factor of maladaptive emotion regulation (Myruski et al., 2020). In this sense, VR constitutes a powerful tool to foster these strategies, given that it allows to provide users with the possibility to experience the virtual world in which pleasant from a first-person perspective, peaceful and non-arousing audio and visual stimuli are integrated.

As a result, VR-based treatments that immerse users in a virtual calm environment to practice relaxing methods and reduce physiological arousal have been created (Pizzoli et al., 2019). There is data that shows the effectiveness of exposure to VR-based natural settings for stress recovery on both physiological and self-reported measures (Anderson et al., 2017; Annerstedt et al., 2013) and for increasing ER (Ip et al., 2018).

Baños et al. (2004) developed a mood induction technique based on a virtual reality scenario to induce calm and three more emotional states (sadness, joy, anxiety). Participants were invited to stroll around a virtual park (The Park of Well-Being) with light settings that could be adjusted to create a certain emotional state using an open immersive display and a wireless pad (e.g., the environment turned grey and cloudy to induce sadness). Furthermore, depending on the emotion to be induced, the surroundings may be altered by selecting Velten statements, music, videos, autobiographical memories, storylines, and photographs. The environment demonstrated to create a growing subjective sensation of presence throughout the virtual experience, despite being non-immersive (Baños et al., 2005). Furthermore, the virtual environment was found to be effective in inducing a state of relaxation (Baños et al., 2004) as well as changing the produced mood to the opposite emotion (Baños et al., 2006).

Relaxation Island, an immersive virtual environment in which participants can wander freely while listening to calming tales based on progressive muscle relaxation, autogenic training, and deep breathing methods, is another remarkable effort in this subject (Villani & Riva, 2008). A sample of 60 undergraduate students reported decreased anxiety symptoms, decreased sorrow levels, and increased relaxation rates after two sessions. Besides, Villani et al. (2012) developed a VR stress management protocol based on a virtual wilderness park in which participants may practice gradual muscle relaxation and guided imagery, based on these promising results. The authors confirmed earlier findings by demonstrating the efficacy of a VR-based intervention for enhancing emotional well-being in those who are under highly stressful situations.

In clinical populations, a number of studies have looked into the efficacy of VR-based relaxing therapies. A group of individuals with MDD or bipolar illness were exposed to practice various relaxation techniques at a serene virtual beach (Shah et al., 2015). Patients reported lower stress levels, less depression and anxiety symptoms, and a greater sense of relaxation after therapy. Similarly, a virtual reality self-management relaxation protocol using immersive 360° nature films was recently created and evaluated in a group of individuals diagnosed with anxiety, psychotic, depressive, or bipolar disorders (Veling et al., 2020). VR resulted in a much higher reduction in negative affect, such as momentary anxiety and sadness, when compared to a normal relaxing method. These findings are especially important since they show the effectiveness of providing VR-based treatments using off-the-shelf devices like smartphones.

The elicitation of emotions through VR environments has a great potential to target regulatory problems, far beyond the already scant examples. A potential development consists of creating scenarios to implement the so-called *opposite action* technique in the framework of DBT, which

undoubtedly helps individuals suffering from borderline personality disorder and other conditions. This would be highly recommended to be implemented in the context of clinical practice, both in individual and group formats, in order to provide patients with safe and highly controlled exercises to put in practice the strategies that are useful for moments of high impulsivity outside the consultation.

Interestingly, one study also explored the efficacy of a three-session VR-based stress management program in a clinical sample (Shah et al., 2015). After attending psychoeducational sessions, a group of patients diagnosed with MDD or bipolar disorder were encouraged to practice different relaxation techniques while walking on a peaceful virtual beach. At the end of the treatment, patients reported decreased stress levels, depressive and anxiety symptoms, as well as enhanced perceived relaxation.

A further category of VR-based interventions to lower physiological arousal includes stress inoculation training (Meichenbaum & Deffenbacher, 1988), which entails the gradual and repeated exposure to stressful situations in order to foster coping skills and decrease the emotional impact of stressors on an individual's affective state (i.e., "mental readiness"). In line with the fundamentals discussed for exposure therapy, VR has been shown to be an adequate tool to be used in this type of interventions (Serino et al., 2014).

Undoubtedly, there is a predominance of studies that focused on the withdrawal or avoidance system described in the introduction. However, emotional disorders have demonstrated to present also a core impairment in the approach system and VR has been proposed as a useful tool to bridge this gap. Behavioral activation is based on the principles of positive reinforcement, and accordingly hinges on the motivation to engage in rewarding activities. As described by Syzdek et al. (2010) the whole ER process can be seen through the lens of behavioral activation. In that sense, there are already some developments to promote this process that may help to overcome low positive affect conditions. For example, Paul et al. (2020) developed a VR-based intervention to foster behavioral activation. The incorporation of 360° videos reproducing different activities (e.g., travels, nature, animals) was integrated into a broader protocol of behavioral activation and administered to a patient suffering from depression. Between each session, individuals were instructed to experience enjoyable activities through four virtual scenarios. Preliminary results from this single-case study revealed the feasibility and acceptability of the intervention, which is now being tested in a broader depressive sample. Moreover, the participant also showed significantly reduced depressive symptoms, which suggests the great of this tool. Similarly, the use of VR has been recently tested as a tool to expose depressed patients to positively valenced reinforcing stimuli (Chen et al., 2021). The 13-session protocol, which included VR positive induction and imaginal recounting, significantly reduced patients' levels of anhedonia, depression, anxiety, and negative affect, despite the mechanisms of change remaining unknown.

As described by humanistic-existential therapies, the elaboration of meaning and the capacity to rewrite the narratives is a way of modifying the autobiographical memory and that can also be grasped as a way of regulating emotions (Pascual-Leone et al., 2016; Pascuzzi & Smorti, 2017).

Autobiographical memory training could be achieved through VR environments that permit to stimulate the evocation of specific memories. Some initial evidence in this regard was achieved by Baños and colleagues (2011) who used a system that used symbolic information for the re-elaboration of traumatic events in PTSD patients.

For this dissertation, a VR-based technique to train positive autobiographical memory for depressive individuals has been developed using *Google Earth VR*, an app that permits to travel to different places around the world from a first-person perspective. Positive reminiscence is a commonly used technique for boosting present levels of positive emotions (Bryant et al., 2005; Quoidbach et al., 2010) by re-experiencing prior positive memories' thoughts, feelings, and desires (Klein, 2015). The goal of this VR-based intervention was to facilitate the retrieval of positive memories, which is consistent with evidence that depressed patients tend to recall more negative than positive memories (Gaddy & Ingram, 2014; Matt et al., 1992) and to underestimate previous positive experiences (Colombo et al., 2020). As a result, a geographical reference is supplied for recalling good experiences from the past.

A growing body of research suggested the significant association between depression and autobiographical memory (AM) impairments. AM is described as a collection of personal experiences that individuals recall from their own lives (Conway, 1987). Brewer (1994) claims that memories constitute a basic structure of an individual's identity, as well as a major source of information for giving the self a sense of unity and coherence (Romano et al., 2020). Recalling autobiographical memories has also been shown to aid some self-related activities such as problem solving, future planning, and openness to the future (Pascuzzi & Smorti, 2017). Above all, AM recall includes reliving previous mental states, such as beliefs, emotions, thoughts, and desires (Klein, 2015). The recall of such events (e.g., positive reminiscence) is considered an effective positive emotion regulation strategy (Bryant et al., 2005; Quoidbach et al., 2010), that is, a strategy that allows to enhance positive emotions in the present (Bryant et al., 2005; Quoidbach et al., 2010), that is, a strategy that allows to enhance positive emotions in the current situation.

To date, several aspects of AM have been shown to be impaired in individuals showing depressive symptoms. As a consequence of a negative bias (Gotlib & Joormann, 2010; Neshat-Doost et al., 1998), depressed patients tend to retrieve negative memories to a greater extent than positive ones (Gaddy & Ingram, 2014; Matt et al., 1992) and to underestimate the positivity of past positive experiences (Colombo et al., 2020). Furthermore, depression has been associated with overgeneral memories, i.e. the tendency to retrieve routine actions rather than specific events, as well as memories that lack in specificity and details (Dalgleish & Werner-Seidler, 2014; Sumner et al., 2010; Williams et al., 2007). Finally, depressed individuals have been found to retrieve memories from a third-person perspective, as if the events were unrelated to them (Lemogne et al., 2006; Siedlecki, 2015). Especially in the case of positive memories, the use of the third-person perspective might be considered maladaptive, as it increases the emotional distancing from past positive episodes and thus prevents

people from using them to enhance positive affect (PA) in the present (Wallace-Hadrill & Kamboj, 2016).

AM impairments might be important to understand some of the key features underlying depressive symptoms. For example, poor AM retrieval seems to be intimately related to ruminative style thinking (Dalgleish & Werner-Seidler, 2014; E. Watkins & Teasdale, 2001), which constitutes a hallmark of depression (Aldao et al., 2014). In this sense, a reduction in rumination has been associated with a decrease in overgeneral memories (E. Watkins & Teasdale, 2001). Additionally, a maladaptive use of AM is likely to affect the use of positive reminiscence as a mood-repair mechanism (Burt et al., 1995; Matt et al., 1992), which in turn might explain the difficulties of depressed patients in using pleasant memories to augment PA. Interestingly, recent studies have demonstrated the feasibility and efficacy of AM interventions (Ahmadi Forooshani et al., 2020; Dalgleish and Werner-Seidler, 2014), which further confirms the potential role of memory in the maintenance of depressive symptoms. Consequently, addressing AM impairments might represent a useful therapeutic tool to be used in individuals with depressive symptoms, potentially fostering positive emotion regulation and, more generally, enhancing PA levels. Because AM recall has been found to be more effective than other mood induction techniques for the elicitation of positive emotions (Jallais & Gilet, 2010; Strack et al., 1985; Zhang et al., 2014), the development of innovative therapeutic strategies that target the ability to recall positive memories seems promising.

First, virtual reality (VR) can provide a spatial reference for recalling previous experiences by exposing users to realistic and personally meaningful settings (Baños et al., 2004; Baños et al., 2008; Botella et al., 2004), thereby acting as a memory projector. Second, there is evidence that using virtual reality to evoke emotions is effective (Jallais & Gilet, 2010; Strack et al., 1985; Zhang et al., 2014). This implies that combining AM memory with VR might increase the strength of the emotions produced, perhaps improving the vividness and/or specificity of the recalled memories. Finally, the immersive nature of VR allows users to relive an event through their own eyes, pushing them to recollect the event from a first-person viewpoint. In particular, the off-the-shelf, freely released Google Earth VR program gives up hitherto unimagined possibilities in the field of AM. Google Earth VR allows users to travel to many locations around the world and experience a "feeling of being there" from a first-person perspective, allowing them to virtually visit the location where an event occurred. As a result, using this VR-based application together may improve the recall of happy experiences, perhaps increasing the specificity and vividness of such recollections.

18 individuals with moderate-to-moderately severe depressive symptoms were included in the present study. The main objective of the study was to examine the effects of a brief intervention consisting of 2 sessions of a VR-based AM recall task. Consistent with the previous literature, we expected that the AM intervention would lead to increased PA (Jallais & Gilet, 2010; Strack et al., 1985; Zhang et al., 2014) and reduced depressive symptoms (Dalgleish & Werner-Seidler, 2014). Furthermore, we hypothesized that the intervention would also improve patients' emotion regulation

skills. First, we hypothesized that the VR-based AM intervention would enhance patients' positive reminiscence and, more specifically, the frequency of use of this strategy and the vividness of the recalled past positive memories. Second, because positive reminiscence is considered to be a positive emotion regulation strategy to upregulate momentary positive emotions (Bryant et al., 2005; Quoidbach et al., 2015), we also hypothesized that the brief intervention would enhance daily savoring levels (i.e., enjoyment of positive experiences). Finally, and consistent with previous studies, we expected to observe decreased rumination levels after the intervention (Watkins & Teasdale, 2001).

Methods

Inclusion and exclusion criteria - To be eligible for the study, individuals had to meet the following criteria: Being aged between 18 and 65 years, being able to read and understand Spanish, and scoring between 10 and 19 at the Patient Health Questionnaire-9 (PHQ-9) (i.e., moderate-to-moderately severe depressive symptoms) (Kroenke et al., 2001). Individuals scoring more than 19 (i.e., severe depressive symptoms) were offered a psychological treatment at the Psychological Care Centre of the University.

Individuals that were suffering from a severe mental disorder as assessed with the Mini International Neuropsychiatric Interview Version 5.0 (MINI) (Ferrando et al., 2000), such as alcohol and/or substance dependence disorder, bipolar disorder, psychotic disorder or dementia were excluded. In case individuals were already receiving a psychological treatment, they were also excluded. The procedure that was done for the present study was approved by the ethics committee of the Jaume I University (number: 17/2018). Informed consent was obtained from all participants.

Sample - The sample consisted of 16 females and 2 males (n=18), with a mean age of 21.61 years (SD=3.24). More details are reported in Table 7. Group 1 included 8 days of baseline (phase A) and 10 days of treatment monitoring (phase B); Group 2 corresponds to 9 days of baseline (phase A) and 9 days of treatment monitoring (phase B); Group 3 had 10 days of baseline (phase A) and 8 days of treatment monitoring (phase B). (PHQ-9 = Patient Health Questionnaire – 9 items).

Table 7. Sociodemographic and clinical characteristics of the recruited sample

ID	Age	Sex	Group	PHQ-9
1	23	f	3	11
2	19	f	2	10
3	20	m	3	14
4	25	f	2	13
5	26	f	1	11
6	20	m	1	15
7	20	f	1	15
8	18	f	1	13

9	21	f	2	16
10	20	f	3	10
11	21	f	3	10
12	20	f	2	10
13	19	f	3	15
14	19	f	2	10
15	23	f	1	10
16	31	f	3	10
17	24	f	1	11
18	20	f	2	12

Study design - Traditionally, RCTs have dominated the evaluation of intervention efficacy, with the effect of the proposed treatment being assessed using average group ratings. Despite the undisputable valuable information that provide RCTs, they also present significant pitfalls, such as the need for control or waiting list conditions and the need to recruit large samples (Kratochwill et al., 2010). SCEDs are gaining popularity in clinical research given that it is not needed a control condition (each participant's baseline is used as a control). SCEDs were more difficult in the past due to the need of continuous assessment, but currently this is not a drawback anymore due to the availability of remote ways of doing assessment, such as technologically assisted ambulatory assessment.

The current implements a multiple baseline SCED. The design entails three baseline lengths, following the established guidelines for these designs (Kratochwill et al., 2013). Participants were randomly assigned to one of the three groups: Group 1, which included 8 days of baseline (phase A) and 10 days of treatment monitoring (phase B); group 2, which included 9 days of baseline (phase A) and 9 days of treatment monitoring (phase B); and group 3, which included 10 days of baseline (phase A) and 8 days of treatment monitoring (phase B). Regarding treatment (B phase), all participants received two intervention sessions on two consecutive days. Thus, group 1 received the treatment on days 9 and 10, group 2 received the treatment on days 10 and 11, and group 3 received the treatment on days 11 and 12. Considering the potential presence of missing data, the duration of the baseline and follow-up periods was chosen in order to ensure that 5 assessments per subjects could be obtained, which is the minimum needed to perform analyses (Kratochwill et al., 2010).

Daily assessments were collected using Qualtrics. Participants were prompted once a day (08:30 pm) in order to complete a set of daily psychological measures about depressive symptoms, positive and negative affect and emotion regulation skills. Participants were given two hours and a half to access the survey (until 11.00 pm); after that period of time, the assessment was marked as missing. The mean delay between prompt time and assessment completion was 24 minutes (SD=31.63). The

study was conducted in accordance with the Single-Case Reporting Guidelines in Behavioral Interventions (SCRIBE) checklist for SCDs (Tate et al., 2016).

Every participant underwent two VR-based sessions on consecutive days (of 30 to 45 minutes). In each session was used Google Earth VR, which permits to the users to place themselves anywhere in the world and to experience the feeling of "being there" thanks to the immersiveness of VR. Participants entered the virtual scenario by means of a head-mounted display (Oculus Rift DK2) connected to a laptop (Alienware 17 R5 with NVIDIA GTX1070 graphics card and Intel i7 CPU) on which the application was run. The setup also included two sensors and two hand-controllers, which enabled participants to explore the virtual environment.

In each session, participants were asked to recall a positive memory of their life. Before beginning the activity, participants were given some examples that defined what the term "specific event" meant. They were then given as much time as they needed to think about a happy memory and write down the spatial details. This task was completed in less than 5 minutes by the participants. Participants were then instructed to keep their eyes closed while wearing the VR head-mounted display until the researcher could identify the exact location where the recalled incident occurred. Participants were instructed to open their eyes and begin explaining their recollection whenever they were ready. During the recall phase, there was no time constraint; participants were allowed to discuss and explain their recollection for as long as they desired. Each memory recall lasted between 5 and 15 minutes on average. The identical procedure was carried out twice, yielding two positive memories for each session.

Experimental check - In order to explore the short-term efficacy of the VR-based AM task to induce positive emotions (i.e., experimental check), participants were instructed to complete the PANAS and to rate the intensity of seven low- and high-arousal positive emotions (happiness, diversion, gratitude, hope, pride, serenity, and excitement) on a 0-100 scale ("To what extent are you currently experiencing the following emotions?" 0= not at all, 100= extremely) at the beginning of the session and after each of the two memory recall procedures. In both cases, the instructions referred to the *momentary* experience of emotions. As the procedure had not been tested before, the experimental check analyses allowed to control for the efficacy of the procedure in inducing positive emotional states.

Study outcomes

Affect: Based on previous studies (Colombo et al., 2020; Colombo et al., 2020), we used two 0-100 single items (0=not at all; 100=extremely) evaluating daily PA ("To what extent have you experienced positive emotions today?") and NA levels ("To what extent have you experienced negative emotions today?").

Depressive symptoms: Daily depressive symptoms were assessed using the Patient Health Questionnaire–2 (PHQ-2) (Kroenke et al., 2003), the short version of the PHQ-9 (Diez-Quevedo et al., 2001; Kroenke et al., 2001), a self-report questionnaire for the assessment of depressive symptoms. The

PHQ-2 has been shown to have good psychometric properties (Kroenke et al., 2003) and to be an adequate tool to capture daily depressive symptoms through mobile assessments (Bauer et al., 2018). The original instructions were modified in order to make them more suitable for daily administration ("*Today, how often have you been bothered by any of the following problems?*").

Emotion regulation: In order to create *ad hoc* single items assessing daily emotion regulation, we conducted a focus group with five experts in the field. Disagreements were resolved through consensus and, when needed, the opinion from a further researcher with expertise in emotion regulation was obtained. The following items rated on a 0-100 scale (0=not at all; 100=extremely) were finally created: Daily rumination ("Today, I have been rehashing in my mind the things I've said or done"), daily positive reminiscence (frequency: "Today, I have recalled positive memories of my life"; vividness: "Today, it has been easy to retrieve positive memories in a vivid and clear way"), and daily savoring levels ("Today, I have been able to concentrate and savour/took the most of the things I have done").

Procedure - Participants were recruited through poster advertisements at the Jaume I University and different social media platforms. Individuals willing to participate in the study contacted our laboratory by email. One week before the beginning of the study, the potential participants were sent a link to complete the PHQ-9 online. Those meeting the inclusion criteria on the PHQ-9 scores were invited to attend the laboratory during the following days in order to receive more detailed information about the study, as well as to further investigate their eligibility through the administration of the MINI. If the criteria for study participation were satisfied, individuals were asked to sign the informed consent.

Participants might contact the researchers at any time during the trial if they had any questions or concerns regarding the procedure. Participants were notified by email when missing data was discovered in the daily assessments (at least two consecutive missing data entries), and they were reminded to follow the assessment procedure. Participants returned to the lab for a final debriefing session at the conclusion of the study. Each participant that fulfilled the complete protocol received a remuneration of 20 euros.

Data analysis - First, repeated measure ANOVAs were conducted. Since many comparisons were performed, the Holm-Bonferroni Method was applied to correct for familywise error rates for multiple hypothesis tests, obtaining a p-value of 0.002. By doing this, we explored whether there was a significant change in positive and negative emotions after the VR-based AM recall procedure at the group level (i.e., experimental check).

To test the main study hypotheses for every individual, baseline-to-posttreatment changes in daily measures were calculated by means of a non-overlap of all pairs (NAP) analysis. In the NAP, every single point in the baseline phase (A) is compared against every point in the treatment phase (B). This measure of overlap is recommended over other overlap measures that use partial data only, such as the percent of non-overlapping data and percent of data points exceeding the median (Parker et al., 2014).

The NAP provides a percentage of non-overlap (i.e., improvement) when comparing the baseline and the treatment phase. This non-overlap index ranges from 0 to 100 and higher scores indicate less overlap (greater treatment effectiveness).

In terms of NAP interpretation, the median non-overlap of past treatment studies has been proposed as a good comparison measure for interpretation (Gómez-Pérez et al., 2020; Parker et al., 2011). NAP scores greater than 96% should be interpreted as very large intervention effects (i.e., corresponding to the median effects of investigations above the 75th percentile of previously published effects in different studies). NAP indices between 66% and 96% would represent moderate-to-large effects (median NAP effects of investigations between percentile 50 and 75). Mild-to-moderate treatment effects would correspond to NAPs between 38% and 66% (median effects of studies between the 25th and 50th percentile of published effects). Finally, a NAP below 38% corresponds to poor treatment effect (i.e., the 25th percentile of smallest NAP scores reported across studies).

Results

Experimental check - Table 8 shows the results of the repeated measures ANOVAs that explored the effects of the VR-based AM task on momentary affect. In both sessions, participants showed significant higher levels of PA and positive emotions as well as decreased NA rates following the AM procedure. Interestingly, while in the first session no significant difference was observed between the two VR tasks, in the second session participants also showed increased levels of PA between the first and the second recalls.

Table 8. Results of the repeated measures ANOVA.

		SESSION 1				**SESSION 2**			
Outcome variable	***Condition***	***M***	***SD***	*T0*	*T1*	***M***	***SD***	*T0*	*T1*
PANAS-PA	*T0*	26.83	4.99			23.83	8.06		
	T1	34.39	7.82	*		31.89	8.71	*	
	T2	36.06	8.35	*		35.28	9.47	*	*
PANAS-NA	*T0*	15.61	3.52			14.67	4.68		
	T1	11.56	2.12	*		11.78	2.34		
	T2	10.89	1.49	*		11.39	1.69		
HAPPINESS	*T0*	55.17	18.2			47.22	20.6		
	T1	84.11	15.9	*		76.89	19.9	*	
	T2	89.78	10.9	*		85.06	12.5	*	
DIVERSION	*T0*	40.56	19.9			36.89	21.6		
	T1	76.72	18.9	*		67.39	26.2	*	
	T2	82.39	16.1	*		77.72	19.3	*	
GRATITUDE	*T0*	47.33	20.5			39.5	22.2		
	T1	80.28	16.2	*		75	21.1	*	
	T2	82.61	14.9	*		84.28	15.6	*	
HOPE	*T0*	55.67	23.3			46.39	22.9		
	T1	73.39	22.2			71.61	23.9	*	
	T2	74.83	19.7			78.11	18.1	*	
PRIDE	*T0*	38.67	24.4			36.94	22.4		
	T1	68.22	29.9	*		65.5	27.3	*	
	T2	74.72	25.4	*		74.89	24.9	*	

	T0	47.61	20.4		50.94	26.3		
SERENITY	*T1*	72.89	24.6		70.67	25.6		
	T2	75.33	23.9		75.39	27.4	*	
	T0	55.17	18.7		43.61	22.5		
ENTHUSIASM	*T1*	81.33	18.1	*	68.33	27.3	*	
	T2	82	17.7	*	82.67	17.7	*	

**p<.002*

Results of the repeated measures ANOVA analyses to compare PA, NA and positive emotions among the three time points (T0=baseline; T1=first recall, T2=second recall). PA and NA measures were assessed through the PANAS, whereas positive emotions were measured through 0-100 items. PA: positive affect; NA: negative affect. In the ANOVAs, the baseline score was the reference in the comparison with first and second recalls. The Holm-Bonferroni Method was used to correct for familywise error rates for multiple hypothesis tests.

Overall, our results suggest that the VR-based AM procedure successfully elicited positive emotions and reduced negative ones at the group level.

3.2 Effects of the AM VR-based task: Changes at the individual level

According to the NAP analyses, the majority of participants did not show a significant improvement on most variables of interest (Table 9).

Table 9: Results of the NAP analyses. PA: positive affect; NA: negative affect; PHQ2: Patient Health Questionnaire – 2.

ID	Group	Phase A Assessments	Phase B Assessments	PA	NA	PHQ2	Rumination	Reminiscence Frequency	Reminiscence Vividness	Savoring
1	3	5/10	7/8	**68.6***	0	50	11.4	**80***	58.9	37.1
2	2	8/9	9/9	61.8	**72.9***	**70.8***	**70.8***	60.4	**74.3***	**69.4***
3	3	10/10	8/8	30	21.5	15	6.9	43.8	59.4	46.9
4	2	9/9	8/9	52.8	57.6	43.8	**66***	31.9	56.8	28.5
5	1	8/8	10/10	35	43.1	53.8	**85***	22.5	41.2	51.2
6	1	8/8	10/10	63.1	63.7	60	25	52.5	41.2	55.6
7	1	7/8	10/10	39.3	46.4	57.1	**67.1***	55.7	42.9	**67.1***
8	1	7/8	9/10	**78.6***	29.4	56.3	43.7	**76.2***	**77***	**69.3***
9	2	8/9	9/9	43.1	54.9	52.8	40.3	63.9	41.2	50.7
10	3	9/10	7/8	49.1	58.7	61.1	55.6	57.1	55	47.6
11	3	9/9	9/9	61.8	46.3	**77.2***	**87***	59.9	57.4	**80.9***
12	2	9/9	9/9	**87.7***	54.3	63	29.6	**74.1***	**68.5***	**90.1***
13	3	8/10	8/8	59.4	53.1	**66***	52.6	54.7	**66.1***	49.2
14	2	8/9	9/9	61.8	30.5	45.1	62.5	56.9	41.2	39.6
15	1	8/8	10/10	**90***	55.0	**71.2***	**66.9**	48.1	55	**81.3***
16	3	10/10	8/8	51.3	58.8	60	28.1	50	58.9	65

17	1	8/8	10/10	45.6	60.6	47.5	**68.1***	34.4	15.6	46.3
18	2	6/9	9/9	50	63	**68.5***	65.7	29.6	22.2	55.3
	Moderate-to-large effect			4/18	1/18	5/18	7/18	3/18	4/18	6/18

**=NAP indices over 66% (moderate-to-large effect)*

However, it is of particular relevance to highlight that those participants who did present improvements in one outcome were likely to improve in several outcomes (i.e., generalization of effects).

After a visual inspection of the graphical representations used to conduct the NAP analyses presented in Table 10, a secondary analysis was conducted. Specifically, we noticed that many variables were likely to improve immediately after the intervention (e.g., a couple of days later), although these improvements were not maintained in time (see two examples in Figure 5).

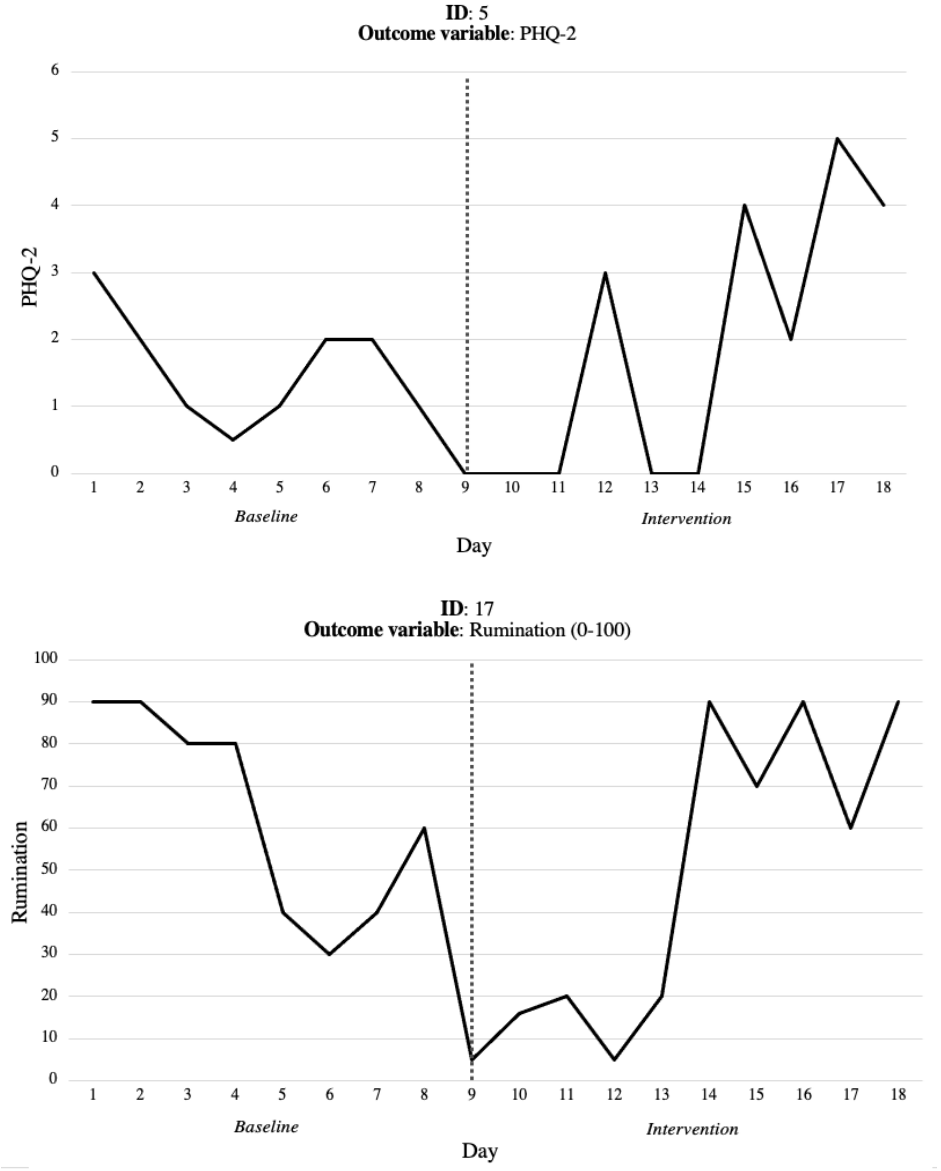

Figure 5: Graphical representation of the evolution in daily depressive symptoms and rumination in two participants. The dotted line represents the beginning of the intervention. In both cases, significant short-term improvements were observed, which were not maintained over time.

We performed the NAP analyses to determine the extent to which the therapy was successful in the short term. Concretely, the post-intervention phase was divided into three time-intervals: 0-3 days, 4-6 days and 7-10 days. As a result, each time interval was compared to the baseline (Table 10). Compared to 4-6 days and 7-10 days phases, results showed that immediately after the intervention (i.e., 0-3 days) almost all participants (17 out of 18) presented a significant improvement in at least one of the outcomes, and a vast majority showed significant gains in many variables. The percentage of participants that reported a moderate-to-large improvement was: 72% for PA; 61% for positive reminiscence – vividness; 67% for positive reminiscence – frequency; 67% for savoring; 50% for NA, 39% for rumination and 44% for depressive symptoms.

Table 10. Results of the NAP analyses comparing the baseline (phase A) to three time-intervals of the post-intervention phase: 0-3 days (phase B^{I}), 4-6 days (phase B^{II}) and 7-10 days (phase B^{III}). PA: positive affect; NA: negative affect; PHQ2: Patient Health Questionnaire – 2.

		A-B^{I}							A-B^{II}							A-B^{III}						
ID	Group	PA	NA	PHQ2	Rumination	Frequency Reminiscence	Vividness Reminiscence	Reminiscence	Savoring	PA	NA	PHQ2	Rumination	Frequency Reminiscence	Vividness Reminiscence	Reminiscence	Savoring	PA	NA	PHQ2	Rumination	Frequency Reminiscence	Vividness Reminiscence	Reminiscence	Savoring
1	3	40	0	35	10	**90***	**75***	40	**66.7***	0	46.7	20	**66.7***	43.3	33.3	60	0	**70**	10	**90***	60	40
2	2	**83.3***	**79.2***	**75***	56.3	60.42	**70.8***	**95.8***	52.1	**77.1***	**75***	56.3	37.5	37.5	62.5	50	58.3	62.5	45.8	50	56.3	37.5
3	3	50	26.7	30	10	**70***	**75***	60	16.7	23.3	3.3	5	6.7	30	38.3	20	10	10	30	10	52.5	40
4	2	**87***	**90.7***	**66.7***	**66.7***	**72.22***	**81.5***	61.1	42.6	37	46.3	63	13	50	14.8	5.6	11.1	5.6	**69.4***	0	5.6	11.1
5	1	**68.8***	**91.7***	**1***	**75***	25	**79.2***	**87.5***	43.8	37.5	**68.8***	**91.7***	50	45.8	45.8	3.1	10.9	7.8	**84.4***	0	9,4	18.8
6	1	**89.6***	**91.7***	**83. 3***	56.3	**72.92***	65	**89.6***	33.3	58.3	50	4.2	43.8	31.3	33.3	53.1	46.9	50	12.5	43.8	31.3	46.9
7	1	28.6	2.4	35.7	47.6	19.05	26.2	23.8	33.3	61.9	47.6	52.4	26.2	31	47.6	50	**67.9***	**69.6***	**67.9***	**69.6***	64.3	**71.4***
8	1	**95.2***	33.3	42.9	42.9	**80.95***	**85.7***	42.9	**78.6***	28.6	53.6	64.3	**85.7***	**100***	**78.6***	**66.1***	26.8	**67.9***	33.9	**67.9***	58.9	**73.2***
9	2	**68.8***	**89.6***	59.3	14.8	**93.75***	**83.3***	**77.1***	27.1	35.4	27.8	59.3	33.3	**83.3***	35.4	33.3	43.8	55.6	38.9	64.6	52.1	35.4
10	3	**80.6***	**75***	44.4	**100***	**88.89***	**75***	**83.3***	50	**79.6***	55.6	27.8	51.9	33.3	44.4	11.1	16.7	2.8	52.8	33.3	25	13.9
11	3	**90***	61.7	**78.3***	**70***	60	61.7	**73.3***	33.3	53.3	43.4	**95***	51.7	55	**75***	35	35	55	55	32.5	15	**70***
12	2	**85.2***	27.8	**66.7***	44.4	**75.93***	**70.4***	**77.8***	**88.9***	**74.1***	**77.8***	0	**85.2***	64.8	**81.5***	**88.9***	24.1	44.4	16.7	61.1	59.3	**77.8***
13	3	**81.3***	**66.7***	**85.4***	53.3	**79.17***	**93.8***	**72.9***	43.8	47.9	56.3	60	39.6	41.7	50	9.4	40.6	37.5	22.5	40.6	21.9	6.3
14	2	**66.7***	41.7	56.3	**66.7***	**89.58***	**81.3 ***	45.8	52.1	43.8	47.9	57.4	52.1	45.8	47.9	37.5	8.3	31.3	35.2	29.2	45.8	25
15	1	**87.5***	58.3	56.3	**75***	54.17	50	**77.1***	**1***	54.2	**79.2***	58.3	64.6	**79.2***	**75***	**84.4***	53.1	**76.6***	64.1	31.3	39.1	**82.8***
16	3	46.7	**71.7***	60	43.3	65	**76.7***	**76.7***	63.3	65	60	11.7	55	63.3	**70***	30	30	60	0	20	50	37.5
17	1	**93.8***	**81.3***	**87.5***	**100***	**70.83***	35.4	**81.3***	37.5	50	45.8	**70.8***	18.8	6.3	29.2	15.6	40.6	18.8	32.8	18.8	6.3	20.3
18	2	50	50	61.1	55.6	41.67	22.2	**66.7***	50	**77.8***	**77.8***	**97.2***	16.7	8.3	**66.7***	50	61.1	**66.7***	41.7	30.6	22.2	61.1
Moderate-to-large effect		13/18	9/18	8/18	7/18	11/18	12/18	12/18	4/18	4/18	5/18	4/18	3/18	3/18	6/18	3/18	1/18	5/18	3/18	3/18	0/18	5/18

**= Moderate-to-large effect (NAP indices > 66)*

In the current study, the effects of a brief intervention combining VR with a positive AM recall task were explored. The goal was to test the efficacy of this intervention on affect, depressive symptoms, and emotion regulation skills in a sample of individuals with subclinical depression.

To confirm the VR-based AM task's effectiveness, we first looked into whether the technique might cause a substantial shift in participants' affective state. Participants exhibited higher levels of PA and pleasant emotions and lower levels of NA when compared to the baseline, demonstrating the VR-based AM task's effectiveness in eliciting positive affective states in the short term. Surprisingly, the experimental check also indicated that a single AM recollection would have been enough to enhance mood in the first session. In the second session, however, this was not the case. It's possible that when the novelty of the VR-based experience wore off in the first session, participants lost their naiveness to the task, resulting in a lower efficacy at producing happy feelings, necessitating a more intense intervention (i.e., two AM recalls). While these findings are intriguing, more research is needed to clarify this issue and determine if each session of this VR-based AM intervention requires one or two recall tasks.

Although some AM training has been established (Ahmadi Forooshani et al., 2020), the originality of our intervention was the use of virtual reality (VR) to further increase the retrieval of prior happy memories. We anticipated that the VR-based AM intervention would improve daily reminiscence, PA, and savoring while reducing daily rumination. Our assumptions were not confirmed by the primary NAP analysis, which did not yield the predicted findings. Only a few people improved significantly on the factors that were studied. As a consequence, our findings do not support the AM intervention's effectiveness as a stand-alone treatment for individuals with moderate depression symptoms. Despite prior research pointing to positive effects, our findings are consistent with a recent meta-analysis that concluded that the existing trials do not support the use of autobiographical memory-based treatments as standalone therapy for mental health issues (Ahmadi Forooshani et al., 2020).

Nevertheless, our hypotheses were partially confirmed by the secondary analyses. Indeed, the results observed in the short term (i.e., 0-3 days after the intervention) revealed significant improvements in at least one outcome measure in almost all participants (17 out of 18).

It is of particular interest that participants who improved in one variable were also likely to get better in other outcome measures, including mechanisms that are argued to underlie depressive symptoms like emotion regulation skills (Sloan et al., 2017), confirming the intimate link among memory, affect, and emotion regulation (Dalgleish & Werner-Seidler, 2014). Moreover, while variables associated with positive emotional states and their regulation (i.e., PA, memory vividness, frequency of positive reminiscence, and savoring) showed a moderate-to-large moderate-to-large improvement in more than half of the participants, the number of individuals showing significant gains on negatively valence measures (i.e., NA, rumination, and depressive symptomatology) showed a moderate-to-large improvement in less than half of the participants. In essence, positive and negative affect do not fall on opposite ends of a bipolar scale (Berrios et al., 2015; Larsen & McGraw, 2011),, and this smaller effect

could be due to the VR intervention's inherent nature, which was designed to target the recall of positive memories and, as a result, the enhancement of positive emotions. Despite the fact that just a few individuals had a moderate to large percent change, the consistent minor change should not be overlooked. While it is true that both positive and negative induction techniques have been found to activate the other dimension (Joseph et al., 2020), our findings imply that encouraging positive AM may have a favorable impact on depressive symptoms and the experience of negative emotional states. Furthermore, we did not see the predicted reduction in daily rumination levels, with just 7 out of 18 subjects reporting a moderate-to-large significant effect. One reason might be based on the study's design. The intervention consisted of two sessions delivered on consecutive days, which may have hampered the consolidation and practice of the skills learned. Because the procedure was not meant to explicitly target ruminative type thinking, it is indeed possible that additional sessions over a longer length of time would have been required to considerably improve the processes that the therapy did not explicitly address, such as rumination.

Overall, our results could not find a strong evidence regarding the efficacy of the VR intervention to reduce key clinical outcomes neither in the short- nor in the long-terms in moderate-to-moderately severe depressed individuals, such as symptoms severity and rumination rates. However, the moderate-to-large effect observed in relation to positively valenced variables supports the idea that the VR-based AM recall task may be a suitable procedure to obtain immediate and/or brief-term improvements, as well as a therapeutic component that could potentially be integrated in a broader treatment protocol for mild depression. Notably, our sample was composed of individuals with mild depressive symptoms. The extent to which this intervention might be beneficial for MDD patients remains an open question. Furthermore, it is important to note that the extent to which the short-term effects of the current treatment can be maintained or even improved with repeated practice over time is still unclear.

According to a recently published meta-analysis, AM treatments generally last between 4 and 8 sessions (Ahmadi Forooshani et al., 2020). This meta-analysis confirmed the efficacy of such brief interventions on memory specificity, but also showed that these interventions should not be used as stand-alone treatments, similar to the findings of the current investigation. Drawing upon these findings, it is not surprising that our results could only reveal short-term effects. While this may be seen as a drawback of the study, the fact that short-term improvements were observed after only two sessions may be viewed as an encouraging result, indicating that this simple method could be a viable treatment option for short-term positive mood induction.

These results permit to describe a number of limitations. First, because the VR procedure was only implemented twice, the sustainability of the intervention in terms of effectiveness if this was repeated on a routine basis is unclear. Additionally, usability and acceptability rating for this technology use were not explored, which would be important for implementation purposes. Moreover, recruiting a bigger sample would enable to study moderators of treatment response (i.e., communalities between

responders and non-responders to the intervention), the mechanisms explaining why individuals change with the treatment, and how the variables investigated in this study reciprocally influenced each other in order to produce a change. Besides, it would be of utmost importance to consider how this intervention could be integrated in a broader protocol of intervention for patients with clinical depression, or the benefits of using this procedure as a just-on time intervention. Finally, the findings of the present study might have been influenced by the specific design of the protocol. For instance, the manipulation-check mood ratings administered during the VR sessions might have affected the scores of daily PA and NA collected at the end of the same day. Furthermore, although moderate improvements were observed in emotion regulation measures such as savoring and positive reminiscence, these results might have been affected by the significant enhancement of daily PA: In other words, a more positive mood throughout the day might have produced higher scores on these items. More research is needed in order to understand the mechanisms of change underlying this intervention and to disentangle whether the VR procedure presented in this study can also address and enhance emotion regulation skills, besides producing a significant improvement of mood.

Overall, the VR-based technique reported in this study appears to be a viable short-term tool for inducing positive mood and improving emotion regulation strategies. The proposed procedure could potentially be included as a clinically relevant component within a broader intervention protocol, even though our study only included subjects with moderate-to-moderately severe depressive symptoms and more research is needed to confirm its efficacy in clinically depressed patients. Importantly, despite the fact that our study used a more advanced head-mounted display (the Oculus Rift), Google Earth has recently is available for all operative systems. That means that the VR-based AM exercise described in this study can be rapidly implemented as a complement for traditional in-person or videoconference psychotherapy, allowing patients to employ it as a quick self-help process in everyday life. Despite the fact that some lessons have been learned, additional studies are needed to fully understand the potential of this and other comparable interventions in regular care.

3.1.1.4 Virtual Embodied interventions

Virtual reality is a multisensory computer-generated interface. VR-simulated worlds enable to feel immerse in an undistinguishable way compared to non-virtual or “real” environments. Therefore, VR constitutes a powerful tool to create alternative realities. Indeed, from a classical cognitive perspective, our supposedly real world is the intrapersonal brain-centered activity. However, latest advancements in cognitive sciences have refuted this stance (Bailey et al., 2016). Embodied, situated, embedded, and enactive perspectives consider that cognitions are not only determined by internal representational contents but by the whole body of the individuals and the actions that they deploy in a specific situational context (Newen et al., 2018).

The integration of a broad information-processing approach is essential, permitting us to move from exposure to more complex facets as recently reviewed by Riva, Wiederhold, and Mantovani

(2019). Hence, VR has the potential of representing, simulating, and also modifying the internal representations of the body and accordingly to fool the so-called "body matrix" (Riva, 2018).

Among the functions of body representation, the encoding and integration of visual, visceral, somatosensory, auditory, vestibular, and motor signals is one of the most important ones. Bodily self-consciousness emerges from those functions and is controlled by the "body matrix," which is defined as a complex network of multisensory and homeostatic brain areas that has the purpose of protecting the organism when a threat alters the body and the space around it (Riva et al., 2017). The multisensory integration is built with the continuous prediction of expected sensory inputs. Considering the mind as a probabilistic system, the experience that an individual has of the body is the result of a predictive process in which the different properties from the different sensory systems are integrated. That is, *exteroception* (e.g., vision and touch), *proprioception* (the sense of the position of the body/body segments), *vestibular input* (the sense of motion and position of the body), and *interoception* (the afferent signaling of internal bodily signals) (Riva et al., 2018).

Regulating emotions is influenced by the individual's overall capacity of integrating multisensory information. There is evidence that demonstrates the strong association between interoception and ER in clinical population, indicating that interoceptive difficulties, principally interoceptive awareness, may be relevant in the explanation of difficulties in regulating emotions (Jakubczyk et al., 2020). Having a healthy interoceptive awareness functioning is considered to be a protective factor, just as a flexible use of ER strategies. An illustrative example is the evidence that ineffective interoceptive awareness has direct consequences, for example, in the deployment of cognitive reappraisal (Füstös et al., 2013).

The perception of reality is generated by a bidirectional process of prediction in which the brain constantly regulates the stimuli in a heuristic way with the aim of minimizing the discrepancy between the information and the inner models created as a consequence of the accumulation of experience. That is, the predictive coding is related to the mental representation that the person can create of their own body and internal physiological functioning, something that could be referred to as "material me" (Seth & Friston, 2016). The interoceptive inference is in this respect key to understand the generation of the subjective experience as a consequence of the pursuit of integrating the content coming from the predictive representations (Strigo & Bud Craig, 2016).

In this sense, VR opens up unprecedent opportunities to generate associations between bodily stimuli that were not associated before, enabling therapeutic changes. For example, VR may augment the bodily experience through the awareness of internal bodily information or the exchange of sensory channels, such as vision to touch or to hearing. In that vein, it is essential that a new network of representations can be generated in order to let the internal system to update the predictive model of the body matrix. The ultimate goal is to correct the prediction errors that disrupt the homeostatic balance of the organisms. That is, VR can fool the perception of the self-representation in order to help to re-elaborate the dysfunctional associations. VR permits a positive update of self-

representations, by means of modifying the appearance of one's avatars. As an illustrative example, body-swapping illusion permits to induce an illusory experience of owning a virtual body. The illusion can be achieved through the observation of a virtual body from a first-person perspective, which in turn can be synchronized or asynchronized with the real body of the observer (Riva et al., 2019).

For example, Aymerich-Franch, Kizilcec, and Bailenson (2014) suggested that the use of *doppelgängers* enables vicarious learning, given that the avatar is one's own body and the learning model at the same time. This study explored if a dissimilar virtual-self decreased anxiety in a public speaking setting, finding that more anxious individuals preferred dissimilar virtual self-representations and embodying a dissimilar avatar helped them reduce their anxiety. Likewise, Guterstam, Abdulkarim, and Ehrsson (2015) showed that having an invisible body may reduce the social anxiety levels during a task of public speaking in front of others.

Embodied interventions have also been suggested to increment empathy levels, which is a constitutive aspect of interpersonal ER (Zaki, 2020). For instance, Falconer and colleagues (2016) revealed that using this approach it is possible to increment levels of self-compassion in depressed patients.

Overall, in the VR realm, a wide range of interventions are being developed. Currently, VR not only permits to conduct exposure in more ecological and controlled ways, but also it has permitted to open up numerous avenues. An illustrative example is the embodied medicine paradigm (Riva et al., 2019) and the possibility of using it as an embodied and extended mind tool. In other words, VR is fostering the materialization of exploring other ways of cognition that from a philosophical and theoretical have gain a lot of importance but its translation to applied and empirical fields, in particular the clinical one, has been scarcely researched yet.

Unlike initial developments in VR, current standalone VR equipment is massively consumed, much beyond health issues. Furthermore, novel 360° cameras can easily create immersive 360° videos that can be explored from all angles of recording. These videos can be integrated and manipulated by means of open-source software and toolkit creators in order to elaborate *ad hoc* scenarios in which to simulate eliciting situations and improve, for example, ER strategies.

Finally, the incorporation of gamified features in the context of treatments is demonstrating to be helpful, not only for the increase of engagement (Looyestyn et al., 2017) but also for the use of the technology. For example, a systematic review has synthesized the evidence of studies exploring the connection between videogames and ER (Villani et al., 2018). With a broad conceptualization of ER, this review permits to understand how gamified features may be incorporated in the design of technology-based ER interventions.

3.1.2 Sensing-based interventions: Biofeedback

Historically, most psychological interventions have mainly focused on explicit facets of communication, specifically the verbal language. Despite the undoubted importance of this dimension, sometimes it is not possible either due to difficulties in the capacity of the patient to process the emotional experience or the reluctance of individuals to start a psychotherapeutic process (Fiskum, 2019). For example, Gevirtz (2007) stated that biofeedback may be used as Trojan horse. That is, providing the patient a model that is seen as a medical procedure, and slightly introduce the psychological factors which may be perceived negatively. This negative consideration might occur due to the not uncommon stigma that is linked with psychological treatments, or due to the stage of change of the patient that hinder them to accept the problem (precontemplation stage).

Many possibilities are enabled by the incorporation of ubiquitous sensors that could record ongoing physiological data in ecological settings for clinical psychology. With regard to the treatment, when people have feedback from their own psychophysiological processes by means of a visual, auditive, tactile or other signals, it is usually denominated biofeedback. The defining feature of biofeedback techniques is the ability to provide individuals with insight of their psychophysiological processes in order to increase the regulation of a certain physical process.

Heart Rate Variability Biofeedback (HRVB) has been researched in the context of stress management, anxiety disorders, substance use disorder and depression, among the most researched psychological conditions. Given the previously described evidence regarding the transdiagnostic nature of diminished HRV across the whole psychopathological spectrum, HRVB is suggested as a useful procedure not only in high arousing conditions (Goessl et al., 2017) but also in low arousing conditions such as depression (Schoenberg & David, 2014). Meanwhile, neurofeedback has also proven to be useful for a range of conditions, including anxiety and depression (Trambaiolli et al., 2021). However, given that no study had explored the quantitative effect of bio- and neurofeedback on depression, we conducted a meta-analysis to test it.

Main research questions: (1) What is the effectiveness of bio- and neurofeedback for MDD?; (2) What is the effectiveness of bio- and neurofeedback for depressive symptoms in both medical and mental/psychiatric conditions other than MDD?; (3) Are there any moderators that explain possible sources of heterogeneity among the effect sizes?

Materials and Methods. The systematic review has been developed in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (see appendix 2; Moher et al., 2009). Regarding the search strategy, papers were identified by doing systematic searches of the databases PubMed, Scopus, Web of Science, and Embase. Grey literature was also searched, as well as the reference lists of review papers of bio- and neurofeedback and psychiatric disorders.

Eligibility **criteria**: Given that the study had two different purposes, two eligibility criteria were established for each of those two aims. For the first goal, original papers written in English presenting data on the efficacy of bio- and neurofeedback of diagnoses depressed individuals were selected. For the second goal, studies that included a measure of depressive symptomatology, but the diagnosis was

other than depression, were included for the meta-analysis. In both searches, unpublished research, conference papers and proceedings, dissertations, and publications published in non-peer-reviewed journals were not included.

Study selection procedure: One researcher conducted all searches in the databases for both objectives. Duplicates were removed from the results once they were exported to EndNote. Following that, two reviewers separately reviewed all titles and abstracts for possibly relevant articles for each of the two aims. The two independent reviewers reviewed entire texts from the total number of papers that were considered for additional assessment to see if the qualifying criteria were met. A third reviewer was consulted in cases of disagreements.

Quality assessment of studies: Cochrane Collaboration Risk of Bias tool was utilized to assess sources of bias in RCTs. The criteria taken into consideration were lack of allocation/concealment, lack of blinding, incomplete accounting of outcome or patient events, and selective outcome reporting.

Effect size Calculation and Coding of Studies: We estimated the effect size of both the difference in change between the groups as well as the pre-post change within the biofeedback groups by using Hedges' g, a variation of Cohen's d which takes into account for biases associated with small sample sizes. When the group mean, standard deviation (SD), variance or standard error of the mean, and number of subjects were available for each group, these data were preferably used to calculate the effect size. When some of these data were missing, we looked for other data allowing for the effect size computation, such as unstandardized mean differences, t and p-values. If multiple measurements for depression were used in the same study, a pooled effect size was calculated in order to include in the meta-analyses only a single effect size for each study. Pooled estimate of the effect size was calculated as the average of the different effect sizes of each measure. Variance of the pooled estimate was also calculated as the average of the different variances of the effect sizes; as the correlations among the measures is often not reported in the papers, such approach represents the most conservative way to calculate the pooled effect size variance (i.e. the strategy that leads to the largest variances of the estimate of the pool effect size, assuming a perfect correlation among measures). Similarly, a pooled effect size was calculated and included in the meta-analysis if either multiple biofeedback or control groups were used in the study.

Furthermore, gender, age, length of treatment, type of biofeedback intervention (heart rate variability biofeedback or neurofeedback), year of publication, experimental design (randomized-control trial), and methodological quality of studies were included in the analyses as moderators. Two of the authors performed independently the computation of effect sizes and any discrepancy was resolved before analysis.

Meta-Analytic Statistics - The inverse variance (the sum of the within-study variance plus an estimate of the between-studies variance) was used to weight each study effect size, giving studies with large sample sizes a higher weighting than studies with small sample sizes. In cases in which the available

data in the paper was insufficient to calculate the effect size, we tried to contact the corresponding author.

The pooled effect sizes were computed using random-effects models (Restricted Maximum-Likelihood Estimation, with confidence intervals and statistical tests derived using the Knapp–Hartung technique (Knapp & Hartung, 2003), which assumes considerable heterogeneity among studies. The significance threshold was set at 0.05.

The Q statistic and the I^2 index were utilized to look at the effect size heterogeneity between studies. To compensate for the test's weak statistical power, the Q statistic's significance threshold was set at 0.1. (Petitti, 2001). I^2 is understood as the amount of overall variability in a collection of effect sizes that cannot be attributable only to sampling error. We evaluated whether the cause of the heterogeneity could be traced to one single effect size outlying all others if the Q statistic was significant or I^2 showed heterogeneity. In this scenario, we performed the meta-analytic studies one at a time, eliminating each effect size as we went. When an effect size's deletion from studies resulted in the resolution of heterogeneity, but its inclusion during the removal of other effect sizes did not, it was termed outlier.

Finally, in order to try to understand probable causes of heterogeneity across effect sizes, moderators were included in the meta-analysis. Moderators were only considered if they appeared in at least four separate studies. Because the number of papers predicted to be included in the present meta-analyses is likely to be restricted, each moderator will be examined independently.

Visual examination of the funnel plots and the Egger's regression test (one-tailed p of 0.05 was deemed to show the presence of the bias; Egger et al., 1997) were used to assess publication bias. To assess the type of possible publication bias and compute an estimated impact size that compensates for it, we utilized the trim-and-fill technique developed by Duval and Tweedie (Peters et al., 2007).

Results

Included Studies

As illustrated in the PRISMA flow chart (appendix 2), a total of 11786 records have been retrieved from the initial database searches. After removing all duplicated articles, the first screening step (examination of titles and abstracts) identified 7235 references that were of potential interest for our meta-analysis. Such process was independently carried out by two of the authors and yielded 18 and 24 references, for each of the respective steps of our study. A total number of 22 papers fulfilled the inclusion criteria and were finally included in the study. 24 papers were excluded because they did not satisfy the inclusion criteria.

Efficacy of bio- and neurofeedback for Major Depressive Disorder (level 1)

Pre-post between-group effect sizes

For the pre-post between-group analysis comparing the bio- and neurofeedback and control groups, the random-effects analyses yielded an overall effect size of Hedges' g = 0.717 (95% CI 0.2121–1.1224, *t* = 3.357, *p* = .0121) (Figure 5), indicating a greater efficacy of bio- and neurofeedback compared to control treatments in the treatment of MDD. No evidence of significant heterogeneity was found considering the Q statistics (*Q* = 8.193, p = 0.316), while I^2 resulted of 29%, indicating a small potential heterogeneity among the effect sizes of the single studies (J. P T Higgins, 2003).

Table 11. Between effect sizes of Neuro- and biofeedback for depressive symptomatology level 1

	Country	Type of BF	Control group	Design	Mean age BF	Mean age CG	Sample size (BF/CG)	% of female BF	% of female CG	Instrument	Nr. of sessions	Risk of bias
Young 2017	USA	fMRI	Placebo	RCT/Double-Blind, placebo-controlled	32	31	36 (19/17)	66%	75%	Composite of 3 scales	2	+/+/+/+
Choi 2011	South Korea	EEG	Psychotherapy Placebo	RCT/Single-blind	28.46	28.54	23 (12/11)	20%	57%	Composite of 2 scales	5	+/U/+/+
Li 2015	China / USA	fMRI	Regular rehabilitation[1]	RCT	54.38	59.64	24 (13/11)	62%	27%	Hamilton Depression Rating Scale	3 times/w. for 4–6 w.	U/U/U/+
Caldwell 2018	USA	HRV	Psychotherapy active	RCT	20.09	20.64	20 (10/10)	100%	100%	Beck Depression Inventory-II	5	U/U/U/+
Linden 2012	UK / Netherlands	fMIR & EEG	Healthy subjects / imagery procedure	Experimental design	48.37	48.5	16 (8/8)	0%	37%	HDRS-17	4	U/U/U/+
Mehler 2018	Netherlands	fMRI	Activation of higher visual processes	RCT	47.19	46.94	32 (16/16)	69%	62,5%	HDRS-17	5	+/+/+/+

[1]Hamilton Depression Rating Scale (17-items)

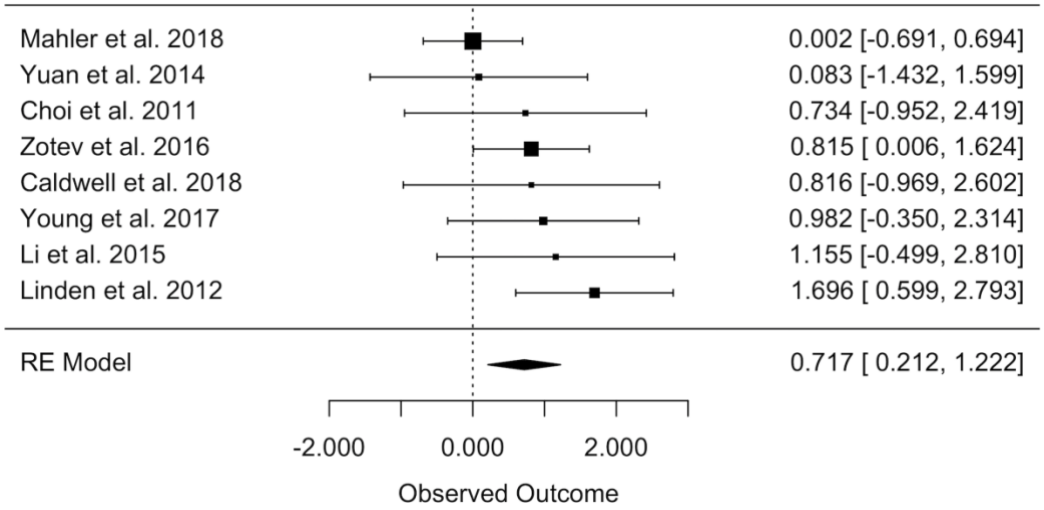

Figure 7. Pre-post between-group effect sizes in level 1.

Moderator analyses and publication bias

The effect of all moderators resulted statistically non-significant (see Table 12). The occurrence of publication bias was not suggested by any of the tests used (Trim and Fill analysis suggests that no studies needed to fall to the right or left of the mean to make the plot symmetrical, and Egger's test resulted not significant (p = 0.4365) as well as by visual inspection of the funnel plot (Figure 8).

Table 12. Moderators between analysis level 1.

	INTERCEPT							MODERATOR						
MODERATOR	Interpretation of the estimate	estimate	se	t	p	95% CI lower bound	95% CI higher bound	Interpretation of the estimate	estimate	se	tval	pval	95% CI lower bound	95% CI higher bound
Type of feedback	Estimated effect size of hrv biofeedback	0,996	0,591	1,686	0,143	-0,450	2,443	Estimated effect size difference between neurofeedback and hrv biofeedback	-0,321	0,640	-0,503	0,633	-1,886	1,243
Randomized control trial	Estimated effect size of non-randomized control trials	0,958	0,322	2,973	0,025	0,170	1,747	Estimated effect size difference between randomized and non-randomized control trials	-0,452	0,430	-1,051	0,334	-1,503	0,600
Year of publication	Estimated effect size for studies published in 2011	1,459	0,406	3,593	0,011	0,465	2,452	Estimated change of the effect size for every year of publication after 2011	-0,167	0,076	-2,214	0,069	-0,352	0,018
Number of sessions	Estimated effect size with 4 sessions	0,717	0,228	3,144	0,020	0,159	1,276	Estimated change effect size change for every additional session	0,025	0,066	0,379	0,718	-0,136	0,186
Average age of biofeedback group	Estimated effect size at average age of 40 years	0,724	0,230	3,144	0,020	0,161	1,288	Estimated effect size cahnge for every additional year of the mean age	0,003	0,025	0,109	0,917	-0,059	0,064
Pecentage of female subjects in the biofeedback group	Estimated effect size with only male subjects	1,473	0,419	3,518	0,013	0,448	2,498	Estimated effect size difference between only female and only male subjects	-1,362	0,651	-2,092	0,081	-2,954	0,231
Quality of the study	Estimated effect size with low risk of bias	0,210	0,284	0,741	0,487	-0,485	0,906	Estimated effect size difference effect size between unknown/high and low risk of bias	0,738	0,369	1,997	0,093	-0,166	1,642

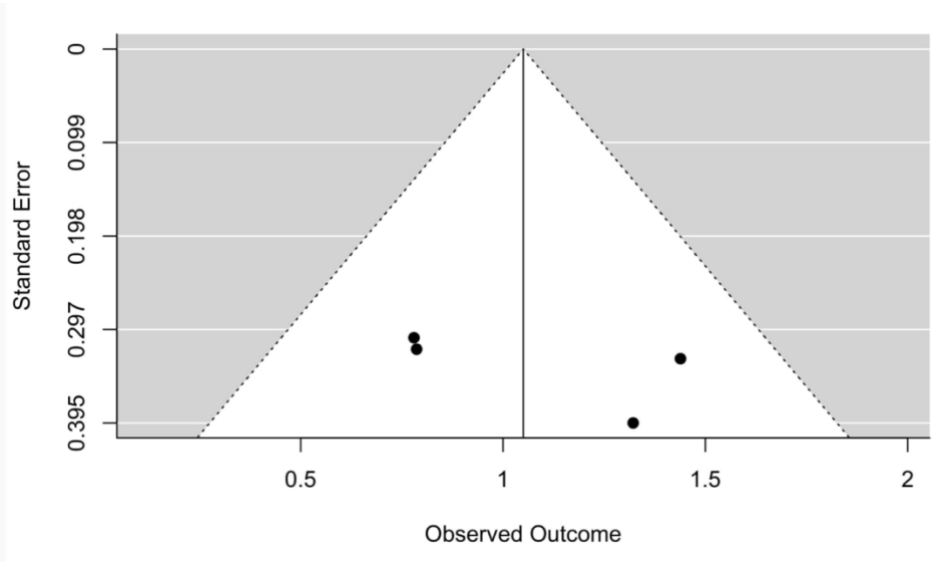

Figure 8. Funnel plot between analyses in level 1.

Pre-post within-group effect sizes

For the pre-post within-group analysis of the sole biofeedback treatment, the random effects meta-analysis yielded an overall within-group effect size of Hedges' g = 1.050 (95% CI .492-1.608, t = 5.991, p = .001) (Figure 7), which indicates a significant efficacy of bio- and neurofeedback in improving MDD symptomatology. No evidence of significant heterogeneity was found considering the Q statistics (Q = 3.353, p = 0.340), and also I^2 (13%) suggest a very limited heterogeneity among the effect sizes of the single studies.

Table 13. Within effect sizes of Neuro- and biofeedback for depressive symptomatology in all conditions

	Country	Type of BF	Design	Mean age AC	Mean age CG	Sample size	Percent of female	Instrument	Number of sessions	Risk of bias
Young 2017	USA	fMRI	RANDOMIZED/Double-Blind, placebo-controlled	32	31	36 (19/17)	66% / 75%	¿?	2	+/+/+/+
Choi 2011	South Korea	NEURO	RANDOMIZED/Single-blind	28.46	28.54	23 (12/11)	20% / 57%	¿?	5	+/U/+/+
Yuan 2014		fMRI	Case control	38	35	27 (13/14)	79% / 85%	Hamilton Depression Rating Scale	1	+/U/+/+
Zotev 2016	USA	fMRI	RANDOMIZED/Double-Blind, placebo-controlled	41	34	24 (13/11)	69% / 85%	Profile of Mood States	2	+/U/+/+

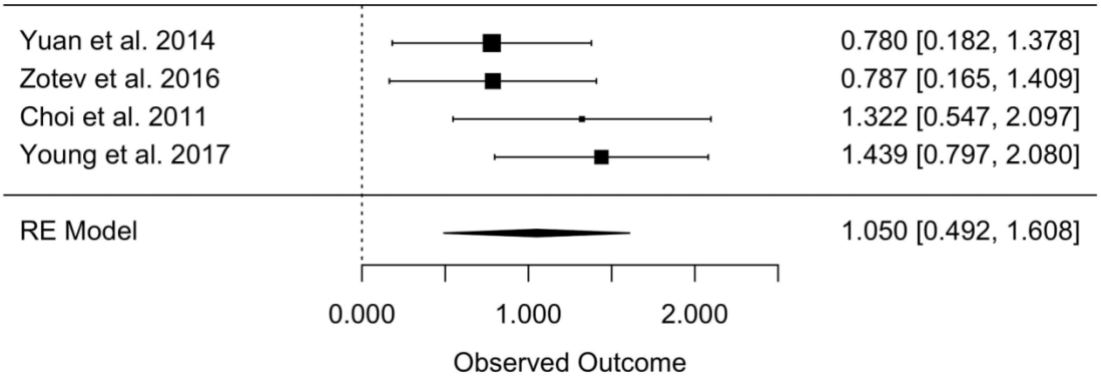

Figure 9. Pre-post within-group effect sizes in level 1.

Moderator analyses

Among the moderators (see Table 14), only the experimental design resulted in having a significant effect in moderating the overall within-group effect size (F = 126.582, p = .008). The within-group effect size of biofeedback treatments resulted significant both in randomized-control studies (Hedges' g = 1.391, 95% CI 1.216–1.566, t=34.164, p < .001) and in non-randomized studies (Hedges' g = 0.783, 95% CI 0.630–1.566, t=22.045, p = .002), with the latter resulting significantly greater than the former.

Table 14. Moderators within analysis level 1.

	INTERCEPT							MODERATOR					
MODERATOR	Interpretation of the estimate	estimate	se	t	p	95% CI lower bound	95% CI higher bound	Interpretation of the estimate	estimate	se	tval	pval	95% CI lower bound	95% CI higher bound
Type of neurofeedback	*all studies investigated neurofeedback efficacy*													
Randomized control trial	Estimated effect size of non-randomized control trials	0,783	0,036	22,045	0,002	0,630	0,936	Estimated effect size difference between randomized and non-randomized control trials	0,608	0,054	11,251	0,008	0,375	0,840
Year of publication	Estimated effect size for studies published in 2011	1,067	0,425	2,511	0,129	-0,761	2,896	Estimated change of the effect size for every year of publication after 2011	-0,002	0,099	-0,023	0,984	-0,429	0,424
Number of sessions	Estimated effect size with 4 sessions	1,262	0,290	4,343	0,049	0,012	2,511	Estimated change effect size change for every additional session	0,122	0,131	0,926	0,452	-0,443	0,686
Average age of biofeedback group	Estimated effect size at average age of 40 years	0,790	0,129	6,142	0,025	0,236	1,343	Estimated effect size cahnge for every additional year of the mean age	-0,058	0,020	-2,914	0,100	-0,144	0,028

Pecentage of female subjects in the biofeedback group	Estimated effect size with only male subjects	1,567	0,566	2,766	0,110	-0,870	4,004	Estimated effect size difference between only female and only male subjects	-0,832	0,864	-0,963	0,437	-4,551	2,887
Quality of the study	Estimated effect size with low risk of bias	1,439	0,276	5,221	0,035	0,253	2,624	Estimated effect size difference effect size between unknown/high and low risk of bias	-0,528	0,320	-1,653	0,240	-1,903	0,847

Publication bias

Trim and Fill analysis indicated that one study would need to fall to the left of the mean to make the plot symmetrical, while no studies on the other side. This suggests that the overall effect size calculated in the within-group analysis may be inflated by the lack of inclusion in the meta-analysis of some unreported study, as it is also evidenced by visual inspection of the funnel plot (Figure 10). However, the random-effects meta-analysis performed adjusting for missing studies still yielded a significant overall effect size (Hedges' g= 1.196, 95% CI 0.985-1.407, t = 11.102, p < .0001), with only a very small reduction of its previous magnitude. Instead, no evidence of publication bias was suggested by the Egger's test (p = .281)

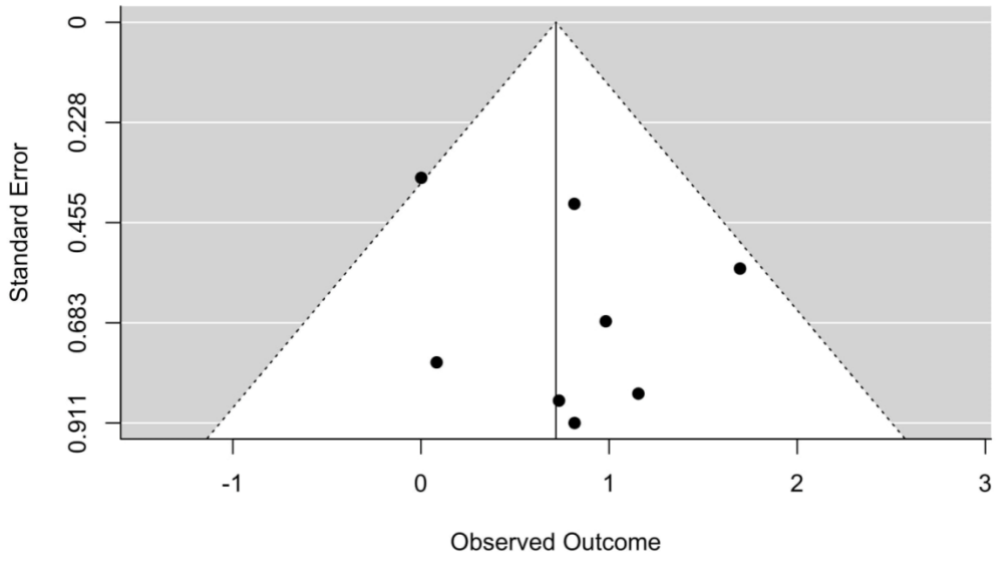

Figure 10. Funnel plot within analyses in level 1.

Efficacy of biofeedback for depressive symptoms in other conditions (level 2)

Pre-post between-group effect sizes

For the pre-post between-groups analysis comparing the bio- and neurofeedback and control groups, the random-effects analyses yielded a significant overall effect size of Hedges' g = 0.303 (95% CI 0.121–0.484, t =2.217, p = 0.003) (Figure 8), indicating a greater efficacy of bio- and neurofeedback compared to control treatments for depressive symptoms. No evidence of significant heterogeneity was found considering the Q statistics (Q = 4.350, p = 0.993), and also I^2 (0%) suggest a lack of heterogeneity among the effect sizes of the single studies.

Table 15. Between effect sizes of Neuro- and biofeedback for depressive symptomatology in all conditions

	Country	Type of BF	Comparison condition	Population	Sample size	Percent of female	Instrument	Number of sessions	Risk of bias
Hallman et al. 2011	Sweden	HRV	Control (check if WL)	Chronic neck pain	23 (HRV 12; CG 11)	91%	HAD	10	U/U/+/+
Patron 2013	Italy	HRV	Daily counseling sessions	After cardiac surgery patients	26 (HRV 13; CG 13)	22.5%	CES-D	5 (45')	U/U/U/+
Penzlin 2015	Germany / USA	HRV	CBT	Addiction (alcohol)	43 (HRV 24; CG 19)	¿?¿?	BDI-II	6 (20')	+/+/+/+
Ratanasiripong 2015	USA / Thailand	HRV	WL	Healthy population	60 (HRV 30; CG 30)	97%	CES-D	1[2]	+/U/U/+
Swanson 2009	USA	HRV	Quasi-false alpha-theta biofeedback	Heart Failure	29 (HRV 15; CG 14)	80%	CES-D	6 (45')	+/U/+/+
Zucker 2009	USA	HRV	Progressive muscle relaxation	PTSD	38 (HRV 19; CG 19)	44.7%	BDI-II	4 weeks once a day for 20' at home	+/+/U/+
Schönberg 2017	Germany	Neuro	Sham neurofeedback	ADHD	75 (NBF 37; CG 38)	44%	BDI-II		+/+/+/+
Schönberg 2017	Germany	Neuro	Meta-cognitive group therapy group	ADHD	75 (NBF 37; CG 38)	44%	BDI-II	30	+/+/+/+
Hsueh 2016	Taiwan	Neuro	Sham neurofeedback	Memory enhancem.	25; 25	60%	BDI-II	12	+/+/U/+
Lackner 2016	Austria / UK	Neuro	Training sessions (different psychotherapeutic aspects)	Addiction (alcohol)	25 (NF 13; CG 12)	0%	BDI-V (modified version of BDI)	12	+/+/U/+
Menella 2017	Italy	Neuro	Active control training	Healthy population	32 (NF 16; CG 16)	100%	BDI-II	7 (45')	+/+/U/+
Dehgahani-Arani 2013	Iran	Neuro	TAU (medication)	Addiction (opiate)	20 (NF 10; CG 10)	No info	GHQ-28 (General Health Quest.)	30	+/+/U/+
Choobforoushzadeh 2015	Iran	Neuro	TAU (medication)	Multiple schlerosis	24 (NF 12; CG 12)	50%	HADS	16	+/+/U/+
Li-Ching 2018	Taiwan	HRV	Medicine	Coronary Artery Disease	210 (105 HRV; 105 CG)	12% HRV 10.20%CG	BDI-II	6 (60')	+/U/+/+

1. One session with therapists and then four weeks to use at home three times a day

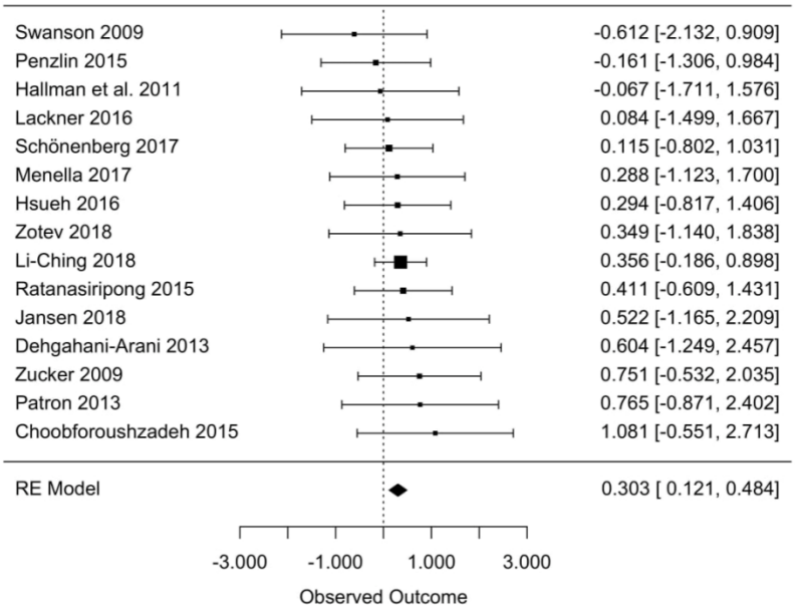

Figure 11. Pre-post between-group effect sizes in level 2.

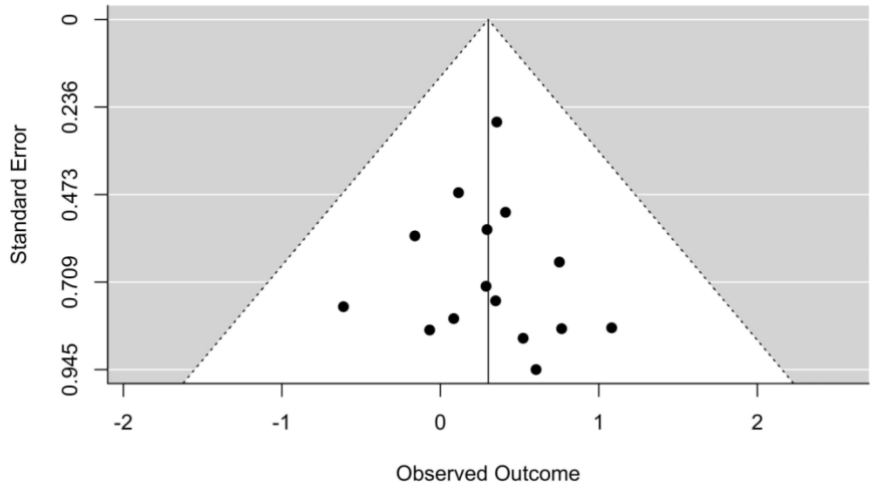

Figure 12. Funnel plot between analyses in level 2.

Moderator analyses* and *Publication bias

The effect of all moderators resulted statistically non-significant (Table 16) and no occurrence of publication bias was suggested by any of the tests used (Trim and Fill analysis suggests that no studies needed to fall to the right or left of the mean to make the plot symmetrical, and Egger's test resulted not significant with a p = .911) as well as by visual inspection of the funnel plot (Figure 12).

Table 16. Moderators level 2.

Moderator	INTERCEPT	MODERATOR

	Interpretation of the estimate	estimate	se	t	p	95% CI lower bound	95% CI higher bound	Interpretation of the estimate	estimate	se	tval	pval	95% CI lower bound	95% CI higher bound
Type of neurofeedback	Estimated effect size of hrv biofeedback	0,280	0,112	2,506	0,026	0,039	0,522	Estimated effect size difference between neurofeedback and hrv biofeedback	0,057	0,180	0,320	0,754	-0,331	0,446
Randomized control trial	*all studies are randomized contoled trials*													
Year of publication	Estimated effect size for studies published in 2011	0,245	0,173	1,413	0,181	-0,129	0,619	Estimated change of the effect size for every year of publication after 2011	0,012	0,032	0,387	0,705	-0,056	0,081
Number of sessions	Estimated effect size with 4 sessions	0,263	0,122	2,144	0,055	-0,007	0,532	Estimated change effect size change for every additional session	0,000	0,011	0,015	0,988	-0,024	0,025
Average age of biofeedback group	Estimated effect size at average age of 40 years	0,289	0,108	2,683	0,023	0,049	0,530	Estimated effect size cahnge for every additional year of the mean age	0,000	0,007	-0,017	0,986	-0,015	0,015
Pecentage of female subjects in the biofeedback group	Estimated effect size with only male subjects	0,203	0,122	1,657	0,128	-0,070	0,475	Estimated effect size difference between only female and only male subjects	0,013	0,017	0,725	0,485	-0,026	0,052
Quality of the study	Estimated effect size with low risk of bias	0,007	0,198	0,036	0,972	-0,424	0,438	Estimated effect size difference effect size between unknown/high and low risk of bias	0,351	0,218	1,609	0,134	-0,124	0,827

Pre-post within-group effect sizes - Pre-post within-group analysis of the sole biofeedback treatments could not be performed because only one study (Kayiran et al., 2010) satisfied all the inclusion criteria for this part of the meta-analysis.

This is the first meta-analysis of biofeedback and neurofeedback for the treatment of depressed symptoms that we are aware of. These data imply that bio- and neurofeedback are effective therapies for those suffering from clinical depression as well as secondary depressive symptomatology. Furthermore, the findings are consistent with earlier qualitative reviews (Hammond, 2005; Linden et al., 2012; Sacchet & Gotlib, 2016).

The effect size found in the within-group analyses were of Hedges' g = 0.717, whereas in the

between-group studies Hedges' g = 1.050. The moderator analyses show that treatment efficacy is only significant when experimental design is taken into consideration, favoring RCTs over non-RCTs. The lack of significance for all other moderators suggests that the findings may be applied to a wide variety of social and clinical factors.

Nonetheless, just one RCT for MDD utilizing HRVB has been undertaken (Caldwell & Steffen, 2018), making it difficult to infer that this strategy is useful for MDD, despite the fact that it has a strong theoretical foundation (Lehrer & Gevirtz, 2014). Furthermore, several of the studies that targeted clinical depression with HRVB were unable to be included owing to a variety of factors, including the lack of a control group or the fact that patients were on antidepressants. So far, a large number of studies have suggested that HRVB is useful for depression, with many citing Karavidas and colleagues (2007) or Siepmann and colleagues (2008) as examples. While both studies were effective, neither included a control group, patients were undergoing psychopharmacological therapy in both cases, and both studies were underpowered.

Neurofeedback, on the other hand, acquired greater data. The existing neurofeedback studies included both EEG (Cheon et al., 2016; S. W. Choi et al., 2011) and fMRI (Li et al., 2015; Linden et al., 2012; Mehler et al., 2018; Young et al., 2014, 2017). The goal of the EEG investigations is to alleviate depressed symptomatology by regulating frontal asymmetry activation and boosting relative left frontal activity. Some fMRI studies focused on the amygdala (Young et al., 2014; Young et al., 2017), while others focused on the insula and lateral prefrontal regions (Mahler et al., 2018), which are all regions implicated in the regulation of emotions (Sebastian & Ahmed, 2018).

As has been seen throughout the whole dissertation, emotion regulation is a well-established transdiagnostic process that explains the emergence and maintenance of a wide range of affective disorders (Aldao et al., 2010). In line with the conceptualization provided in the introduction, future treatments should be based on processes of change such as emotion regulation instead of syndromes that are not necessarily valid. When evidence from various theoretical frameworks is combined, it is reasonable to expect that regulating the major physiological substrates associated with emotion regulation will improve the functionality of brain regions involved in a variety of affective disorders, thereby reducing symptomatology.

Aside from RCTs, there are a number of single-case investigations in the literature, all of which used EEG biofeedback (Baehr, 1998; Baehr, 2001; Earnest, 1999; Grin-Yastenko et al., 2018; Hammond, 2000; Rosenfeld, 2000). Furthermore, there are a number of studies that have focused on cognitive, emotional, or physiological characteristics without assessing depressive symptomatology but still are relevant as long as they also showed that neurofeedback can be a helpful tool for depressed people. For example, the study brought forth by Escolano et al. (2014) that demonstrates that neurofeedback can promote the regulation of cognitive deficits through the regulation of alpha activity. Likewise, Hamilton et al. (2016) showed the efficacy of neurofeedback for the decrease of the activity

in the salience network. Finally, it is very relevant the studies that are conducted in the United States revealing the role of fMRI neurofeedback for the increase of amygdala functional connectivity (Young et al., 2018) or the correlation between amygdala activity and EEG asymmetry when participants are doing instructed tasks of emotion regulation (Zotev et al., 2016).

This meta-analyisis shows that MDD can be successfully treated with HRVB or neurofeedback, but not with other commonly used biofeedback modalities. This is in line with existing ideas that explain the processes underlying affective disorders' psychophysiological dysfunction. Several theoretical frameworks have investigated the connection between visceral signals, afferent systems, and brain activity, including the Polyvagal theory (Porges, 2007), the Neurovisceral integration model (Thayer & Lane, 2009), and the baroreflex theory (Lehrer & Gevirtz, 2014). Although there are variations between these theories, there is a general notion that parasympathetic activity (particularly HF-HRV) and brain activity are determined in a reciprocal manner (in particular cortical regions like the prefrontal cortex and subcortical regions like the amygdala). In accordance with this, there is mounting evidence that HRV and certain breathing patterns may have a causal role in the ER regulating brain networks (e.g. Mather & Thayer 2018).

Indeed, research has shown that real time fMRI neurofeedback (rt-fMRI-NF) is potentially although not conclusively effective for different emotional disorders, particularly by improving areas such as amygdala reactivity, anterior insula and anterior cingulate cortex (Thibault et al., 2018). Interestingly, biobehavioral markers that are key in the process of ER were targeted via neurofeedback procedures. A systematic review has synthetized the existing evidence, revealing that rt-fMRI-NF increases positive emotions and decreases in anxiety in clinically depressive and anxious individuals, respectively (Linhartová et al., 2019).

Regarding this second group of studies, the effect size was small in magnitude, albeit significant, and smaller than the pre-post between-groups effect size found for MDD. However, it can be stated for the first time that bio- and neurofeedback techniques are efficacious for the reduction of depressive symptomatology. Given the fact that many of the included studies presented heterogeneous conditions, different baseline levels of depressive symptoms and types of biofeedback, the conclusions should be taken with caution. Moreover, even if many of the included studies presented heterogeneous conditions, no evidence of significant heterogeneity among the effect sizes of the different studies was found. This suggests a quite stable efficacy of bio- and neurofeedback on depressive symptoms independently from the condition.

Risk of bias was high or unclear in the majority of the studies, which represents an undoubted necessity of enhancing the quality of research in this field. Besides, regarding the design some flaws were identified. First, a great part of the studies was underpowered. Given the increasing availability of low cost but reliable psychophysiological devices, bigger samples will be possible to be recruited in the near future. This would represent an important step in order to more clearly determine the extent to which bio- and neurofeedback are effective interventions. In this direction, our results suggest the need

for rigorous RCTs. Due to the high costs of conducting RCTs, SCEDs appear as a good alternative (Kazdin, 2018). Furthermore, future studies should also consider the inclusion of follow-up assessments. Given that depression usually has a high risk of recurrence (Burcusa & Iacono, 2007), the stability of the therapeutic gains in the mid and long term is of paramount importance.

A third important aspect regarding the design of the studies revolves around control groups. Only few studies presented active conditions as comparators and even less studies included both an active and a wait-list condition. Bio- and neurofeedback techniques permit to easily implement sham conditions. This may allow to increase the experimental rigor and thus to more accurately determine the specific contribution of the active aspects in the final outcome.

A fourth aspect to mention in the primary studies, also identified by Goessl and colleagues (2017), is the necessity to better specify the amount of time spent with the professional or practicing bio- or neurofeedback and the therapeutic protocols that were used. The dose-response relationship may provide clues to explain mechanisms of change, something that has been scarcely researched in bio- and neurofeedback yet.

All of the research included in this meta-analysis used standard bio- and neurofeedback techniques. That is, visualizing the physiological process without converting the sensing into a specific actuation output that could be more meaningful or engaging for the participants (Kitson et al., 2018). Furthermore, if various technologies are integrated into traditional processes, the field of bio- and neurofeedback offers a lot of promise. Multimodal biofeedback systems that take into account auditory, visual, and tactile feedbacks may be aided by new technical and design advances (Bergstrom et al., 2014; Jones & Sarter, 2008). In this regard, a novel example conducted in depressed individuals showed how music neurofeedback (EEG) can be developed (Ramirez et al., 2015). Cross-integration of biofeedback, virtual reality, and serious gaming is also becoming more common (Schoeller et al., 2019). Some current ER examples are gamified biofeedback on mobile devices for stress management (Dillon et al., 2016) and VR-based biofeedback for generalized anxiety disorder (Repetto et al., 2013). Innovative developments, such as the integration of biofeedback with mobile and wearable technologies, are also important. That is, to integrate bio- and neurofeedback techniques with dissemination technologies to facilitate their escalation, and with understanding technologies that will be explained in the next chapter. Also, the cross-integration of biofeedback, VR, and serious games is emerging. Some ongoing examples for ER are already available, such as gamified biofeedback in mobile devices for stress management or VR-based biofeedback for generalized anxiety disorder. Novel advancements are also very relevant, such as the integration of biofeedback to mobile and wearable devices.

3.2 Understanding ER interventions: Harnessing the possibilities of digital phenotyping

There is a wide range of possibilities that enable the use of digital technologies for expanding our understanding of ER in the therapeutic context. As aforementioned, they can be incorporated into

research with the aim of enhancing our understanding of the process and outcome of interventions. As explained by Imel et al. (2017), current research focused on the exploration of change mechanisms suffers from an overreliance on human judgment as the main assessment tool. Instead, digital technologies, including sensors, automated speech recognition, natural language processing algorithms, and machine learning models open a whole new avenue of opportunities to complement the indispensable but fallible evaluation of humans.

This field has been denominated personal sensing, digital phenotyping, reality mining, or personal informatics, meaning the "moment-by-moment quantification of the individual-level human phenotype in situ using data from personal digital devices" (Torous et al., 2016) makes use of this potential. By combining data from smartphones, sensors and biosensors, it is possible to obtain a digital index of an individual's experiences and behaviors (Huckvale et al., 2019).

The incorporation of sensors and biosensors can be of utmost importance research and clinicians to identify treatment courses, evaluation of treatment outcome, giving feedback on a patient's state, and in the most complex forms inform personalized interventions.

Precisely, sensors have become essential in the last years given their capacity to measure physiological and behavioral processes that otherwise would not be possible to gauge. In the case of emotion generation and regulation physiological and behavioral processes are of utmost importance despite the fact that the great majority of the evidence has been produced based on self-report measures.

3.2.1. Behavioral markers

The study of behaviors in general, and through passive sensing in particular, constitutes one of the most promising avenues to expand our knowledge in the upcoming years. ER is not the exception to the rule given that behaviors constitute an indispensable dimension of how people regulate their emotions (Kraaij & Garnefski, 2019).

Specifically, in the field of emotional disorders, a wealth of research has been produced over the last years trying to reflect on the potentialities of using sensors and summarizing the preliminary evidence on this topic. A comprehensive detailed enumeration of these developments can be found in several reviews (e.g. Elgendi and Menon, 2019; Gosling et al., 2016; Harari et al., 2016), but the one conducted by Mohr, Zhang and Schueller (2017) provides the most comprehensive critical overview of sensing research in mental health, including smartphones and all types of wearable, social media and computers. In particular, a hierarchical sensemaking framework is outlined, in which four different layers are structured: From sensors (including location, movement, phone screen, phone apps, ambient light, microphone and in-phone communication) through low-level features (like activity type, bedtime / wake time, paralinguistic information, etcetera) and high-level behavioral markers (like depressed mood, stress or social avoidance, among many others) to finally the clinical state (e.g. depression, anxiety, and all other clinical constructs). The myriad of possibilities that arise from exploring the

combinations of these layers has started to be translated into research programs seeking to better understand and predict clinical states.

One of the most relevant behavioral markers are sleep patterns, which have shown to play an instrumental role in the appearance and maintenance of emotional disorders, and this relation is suggested to be largely explained by an impairment in ER (O'Leary et al., 2017). Thus, by means of built-in sensors, a range of smartphone-based sensing systems enables to monitor sleep periods in a passive way. Furthermore, wearable instruments based on accelerometers were created to track a range of processes like physical activity (Choudhury et al., 2008). Indeed, higher levels of accelerometer-based physical activity were significantly correlated with lower rates of depression (Vallance et al., 2011). Other key domains are the social context and social support. By means of different features like social media activity, voice pitch or level activation, depressive symptoms can be predicted, and preventative actions can be implemented. In that sense, GPS features have shown to enable the prediction of depression many weeks before the onset (Saeb et al., 2016).

However, while sensing has the capacity to detect behaviors that are already identified as markers of a specific clinical condition, it also has the ability to uncover new data that shed light into unknown processes related to pathological states. Precisely the evolving work on the connection between GPS information and depression constitutes an illustrative example. The strong association between activity and depression is intuitively explained by the number of visited places or by the covered distance. However, the location entropy (variability of time spent between visited places) is actually what explains the appearance of depressive symptoms.

Over the past years, the growth of social media use is indisputable. Social media platforms constitute a huge source of information in order to gauge online behavior, which in turn could be paramount to detect people in risk or experiencing possible clinical disorders. In particular, an increasing number of studies have been developed in the field of depression, for example for its detection (Choudhury, Gamon, Counts, & Horvitz, 2013). Social media datasets, including e-mail records, very often comprise significant personal datastores that span multiple years. These datasets offer considerable potential for retrospective analyses that explore linguistic content and temporal factors in order to characterize mental health. However, as stated by a recent review (Guntuku et al., 2017), the findings in this field are still inconclusive.

Smart-home devices also entail an enormous source of possibilities in order to impel the continuous and unobtrusive acquisition of relevant multimodal data. Important aspects of ER could be determined by means of smart-home devices, such as emotion dynamics, risk of suicide, interpersonal relationships, sleep patterns, among others (Nelson & Allen, 2018). The most outstanding aspect of smart-home devices is that not only individuals do not have to be aware of the reported answers (like in active assessment) but also, they do not have even to remember to wear or to regularly charge any device.

Other sensors may also be of importance in order to study the process and outcome of clinical interventions, although they have not been extensively implemented yet. For example, location, movement, phone screen, ambient light, microphones or in-phone communication are some of the many sensors that may be used in order to better understand how, under what circumstances and for whom clinical interventions may work (Mohr et al., 2017).

However, these developments have been scarcely applied to explore the therapeutic process. Behavioral and context/environmental information has principally been used to explore their utility as diagnostic markers or their correlation to subjective data (Dogan et al., 2017). Sensors could be implemented before, during and after treatments in order to have behavioral and contextual information to assess how, for whom and the extent to which certain treatments may work. That is, sensors could be implemented in treatments in order to complement self-report assessments. These examples are only a small part of the enormous potential that sensors have in order to study the process and outcome of therapeutic processes.

3.2.2. Central nervous system markers

Just like any mental phenomena, when an individual is in the process of regulating emotions, certain areas of the brain are activated. The most relevant subcortical areas are the bed nucleus of the stria terminalis, the habenula, the striatum and the amygdala. Meanwhile, the prefrontal cortex (PFC), in particular dorsolateral PFC, ventrolateral PFC and ventromedial regions (vmPFC) and the anterior cingulate cortex are the key subcortical regions (for a general overview see Sebastian & Ahmed, 2018, and for specific works Buhle et al., 2017; Goldin et al., 2008; Morawetz et al., 2017; Picó-Pérez et al., 2017). However, as aforementioned, the process of ER is vast, and depending on which aspect is considered, there are relevant distinctions regarding the neurobiological underpinnings.

The implications for the research and practice of these studies are principally in the psychopathological realm, but over the last years there has been an upsurge of interest in the utility of the neurobiological models of the mechanisms of action of psychotherapy (Messina et al., 2016). In particular, there have been numerous studies that identified the brain-behavior circuits that change from pretreatment to posttreatment. Overall, there is ample evidence showing that all psychotherapies reach to modify brain-behavior circuits, revealing that psychotherapeutic change, regardless the specific technique, may help improve the efficacy of control processes in the inhibition of regulation and modulation processes, such as emotional reactivity (Messina et al., 2016).

Moreover, certain regions of the brain have been shown to be predictive of CBT psychotherapy, suggesting the importance of including this kind of assessment to the usual self-reports that have prevailed. There are two examples of particular relevance, because they not only considered regions of interest for the circuit of ER, but they also include an experimental task to upregulate ER at baseline. Based on the results of that ER task, Rubin-Falcone et al. (2020) showed that pre-treatment emotional reactivity Blood Oxygen Level-Dependent (BOLD) signal within hippocampus predicted less favorable

treatment results of depressed patients receiving CBT. Likewise, Walsh et al. (2017) demonstrated that frontostriatal both global connectivity as well as connectivity attenuation are predictors of behavioral activation treatment response in depressed individuals.

3.2.3. Autonomous nervous system markers

The autonomic nerve system's function in emotion generation has been researched for over a century (Kreibig, 2010). Electromyography was used in some of the early advances in psychophysiology. Face electromyography reactions of the corrugator supercilii and zygomaticus major muscles, in particular, have been linked to emotions (Mauss & Robinson, 2009), and as a result, this measure has been used in a number of studies examining the processing and regulation of negative and positive stimuli (Conzelmann et al., 2015). Similarly, electrodermal activity has been taken into account because it is a measure of sympathetic activity and hence arousal level (Urry, 2010). Electromyography and electrodermal activity have not been proposed as indices of the ER process itself, despite their use in detecting the production of emotions and therefore measuring ER at certain times.

Meanwhile, vagal tone constitutes a fundamental component of the parasympathetic activity of the autonomic nervous system. The parasympathetic activity plays an instrumental role in the regulation of numerous parts of the body. For example, vagal tone has been identified as a reliable marker of ER in healthy population (Balzarotti et al., 2017) and some indexes of vagal activity, like heart rate variability or respiratory synyus arrhythmia have gathered ample evidence as central processes in a wide range of physical and mental disorders (Beauchaine & Bell, 2020; Beauchaine & Thayer, 2015). Specifically, ample evidence indicates a strong link between emotional disorders and heart rate variability, with meta-analytical evidence for depression (Kemp et al., 2010), anxiety disorders (Chalmers et al., 2014), borderline personality disorders (Carr et al., 2018) or PTSD (Minassian et al., 2016) among others.

This empirical association has been conceptually explained by two main theories: neurovisceral integration model (Thayer & Lane, 2009) and Polivagal Theory (Porges, 2007). The first of the theories principally describes the connection between the neural areas implicated in the inhibitory processes that are related to the autonomic functioning, in particular the heart rate variability. The second of the theories illustrates the parasympathetic activity with a brake, a vagal brake, which at resting periods should be working and therefore activated. Meanwhile the process should be released in periods of fear or flight response, that is, when the sympathetic process is activated.

Lower levels of heart rate variability are associated with autonomic inflexibility, increased activity of the amygdala and decreased activity of the prefrontal cortex regions responsible for amygdala down-regulation. In turn, all this physiological architecture is linked to inflexible patterns of ER, being this pattern particularly strong people presenting emotional dysfunctions such as depression (Stange et al., 2017). Indeed, ER brain networks not only affect but is also affected by heart rate variability (Mather & Thayer, 2018).

The role of heart rate variability to index parasympathetic flexibility has derived in the incorporation as a complementary measure for psychological treatments. In recent years, growing studies have been conducted showing that heart rate variability predicts outcome in a wide range of disorders, specially emotional disorders (Petrocchi & Cheli, 2019). A high frequency of heart rate variability has also revealed to predict the establishment of therapeutic alliance (Blanck et al., 2019). Besides, psychotherapy treatments have shown to have a positive impact on the regulation of parasympathetic flexibility. That is, numerous studies indicate that cardiac vagal tone improve from pre- to post-treatment assessments (Petrocchi & Cheli, 2019).

To identify studies for potential inclusion, a comprehensive systematic search of electronic databases 'Pubmed', 'Scopus' and 'Web of Science' was conducted. Articles considered eligible for this work were original interventional studies, which investigated cardiac vagal control reporting at least a measure of change both at pre- and post- intervention in emotional disorders.

Thus, studies were selected using the following eligibility criteria: The study was written in English, participants were adults between 18 and 65 years old and the study included a psychotherapy intervention for emotional disorders based on evidence-based treatments (according to the Division 12 Task Force of the American Psychological Association), the psychotherapeutic intervention had to be well described in order to know the characteristics that may be influencing the results (e.g. describe the specific protocol, the length in weeks, or other characteristics). the study included a measure of vagal control at pre- and post-treatment. Meanwhile, exclusion criteria were that participants were under psychopharmacological treatment, bipolar disorder was not considered. Despite being an affective disorder, it is a severe mental illness that is qualitatively different from other affective syndromes like depression, anxiety and stress-related disorders, case reports and pilots with less than 10 patients per condition and abstracts from conferences published in peer-reviewed journals.

The systematic review was conducted according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Two independent reviewers conducted the initial screening and select the studies independently entailed removal of studies based on inclusion/exclusion criteria, through evaluation of titles and abstracts. The remaining studies were analyzed in detail the following variables: a) authors and year of publication; b) country; c) aims of the study; d) groups and sample size; e) affective disorder diagnosed; f) type of therapy; g) type of cardiac vagal tone index; h) design of original study; i) Principal results. All these variables were extracted and coded by two reviewers. Disagreements were solved by discussion before reaching the final number of studies. The electronic search yielded a total of 1814 studies, which were identified through the systematic search of three databases (Pubmed=368; Web of Science=418; Cochrane=404). After removing duplicates, 79 studies were screened based on title and abstract for check the inclusion criteria. Table 17 and 18 resume the studies included for HRV as a treatment outcome and predictor of psychological treatment.

Table 17. Characteristics of studies that assessed HRV as a treatment outcome

Authors	Patient group	Number sessions	Groups	Physiological measure	Principal results
Busscher et al. 2015	Flight phobia	2	CBGT	RSA	Within-flight habituation of RSA reactivity was associated with lower flight anxiety directly after the flight, but not in the follow-up measures.
Carney 2000	MDD w/CHD	16	CBT	RMSSD	No pre post differences were found for RMSSD in 24-hour and daytime measurement, in none of the depressive groups. Instead, daytime RMSSD significantly increased in the severe group from time 1 to time 2.
Carney 2016	MDD w/CHD	12	CBT	Log very low frequency HRV	Prior to treatment, non-remitters had lower nighttime HRV than remitters.
Chien 2015	MDD	12	CBT+breathing	HF-HRV, LF-HRV, LF/HF, SDNN	All indexes of HRV improve in the experimental group, presenting a statistical significance with respect to the control group.
D'Andrea 2012	Complex Trauma	12	ET SIT PT	RSA	Therapists that use more PT and SIT techniques were significantly associated with improved RSA while viewing trauma cues. On the other hand, greater PE process was slightly related to worse RSA while viewing the trauma cues.
Diveky et al. 2013	Panic Disorder	Unclear	CBT	HRV by spectral (frequency) analysis: HF, LF, VLF band and VLF + LF / HF ratio	Statistically significant differences in the VLF band of HRV from pre to post assessment. Given that the actual indexation of VLF in the regulation system is not clear, the findings are difficult to interpret.
Faucher et al. 2016	SAD	12	CBGT MBSR	HRV	Analyses derived from the speech tasks indicate that only the LF levels varied from baseline
Garakani et al. 2009	PD	12	CBT	PNN50, LF, HF and LF/HF	CBT led to an increase of HRV, but the combined group of CBT and sertraline did not. This was obtained evaluating PNN50.
Hyett et al. 2018	SAD	1	Trauma	RMSSD, HRV-HF, HRV-LF	RSMDD and HRV-HF improved more in an image based intervention rather than in a verbal based intervention and a control group.
Mumm et al. 2019	AG with or without PD	12	CBT	RMSSD, HRV-HF	HRV-HF and RMSSD did not change from pre to post test, but throughout in vivo exposure both indexes increased significantly.

Sack et al. 2009	PTSD	3-10	EMDR	PEP, RSMMD, HR, Resp	During ongoing stimulation, PEP and HRV decreased significantly while respiration rate significantly increased, indicating stress-related arousal. A significant decrease of psychophysiological activity was noticed across sessions, evidenced by progressively decreasing HR and increasing HRV
Schramm et al. 2016	Depression	8	TAU; MBCT; CBASP	The percent of high-frequency coupling (HFC), low-frequency coupling (LFC) and very-low-frequency coupling (VLFC)	CBASP showed more stable sleep (higher HF couple band) compared with TAU on post-treatment.
Stratford et al. 2014	Anxiety	6	PT	LF, HF, LF/HF, and total power	Clinical changes in the client's HRV were evident across the six therapy sessions. Significant associations were shown between some HRV parameters and therapeutic alliance.
Wheeler et al. 2014	Primary diagnosis adhering to DSM-IV Axis I criteria and a previous history of anxiety and/or depression	8	MBCT	SDNN, RMSSD, Triangular index, SDNN, RMSSD, LF, HF	This study did not find a significant change within sessions either time or frequency domain HRV parameters

AG with or without PD: Agoraphobia with or without Panic Disorder; TAU: Treatment as usual; MCBT: Mindfulness Based Conductual Therapy; CBASP: Cognitive Behavioral Analysis System of Psychotherapy; PD: Panic Disorder; PT: Psychodynamic Therapy; MDD w/CHD: Depression with coronary heart disease; PTSD: Post Traumatic Stress Disorder; SIT: Stress Inoculation Training; SAD: Social Anxiety Disorder

Table 18. Characteristics of studies that assessed HRV as a predictor of outcome

Authors	Participants (N)	Patient group	Type of therapy	Number sessions	Type of vagal tone index	Principal results
Blanck et al., 2019	53	Anxiety & depression	CBT	25	HRV-HF	Patient's ratings of alliance were predicted by a higher HRV-HF Baseline HRV-HF predicted improvement of symptomatology
Bornas et al. 2011	37	Flying Phobia	Computer-BT	6	RMSSD & HF	Regression analyses showed a nonsignificant effect both for HRV tone in self-reported treatment outcome
Bornas et al. 2012	20	Flying Phobia	Computer-BT or VRET	-	HF & LF at tonic and phasic levels	Regression analyses showed a nonsignificant effect both for HRV tone in self-reported treatment outcome

Bornas et al. 2007	54	Flying Phobia	Computer-BT	16	lnHF	The ln HF power alone did not demonstrated to be a predictor. A regression model including both the variability and the entropy measures explains up to 26.1% of the variance of the residual gain FFQ total scores and 23.8% of the variance of the residual gain FFQ previous subscale scores. The variability measures alone (i.e. HF power in PB and E conditions) did not explain a significant percentage of the dependent variables' variance.
Davies et al. 2015	60	Anxiety Disorders (PD w/out AG: 31,6%; SAD: 23,3%; OCD: 15%; SP: 5%; PTSD: 3%)	CBT or ACT	12	HF-HRV	Baseline HRV predicted outcome in a nonlinear way. The interaction between time and the quadratic term of HRV during recovery predicted outcome similarly across groups. HRV was a predictor of 12MFU outcome only, with low Recovery HRV predicting better outcome than mean Recovery HRV and marginally better outcome than high. Recovery HRV at 12MFU. HRV during Relaxation did not significantly predict or moderate outcome
Doukas et al. 2014	27	PTSD (although not diagnosed, only symptoms scale)	PT and CBT	12	RSA	RSA predicted working alliance. Higher RSA at baseline predicted higher working alliance at posttreatment.
Mathewson et al. 2013	23	SAD	CBT	12	RSA	Mean resting RSA levels declined over the course of the study.
O'Connor et al. 2005	29 (16 disclosure; 13 control)	Mild depression (not diagnosed, only BDI scores)	3 writing tasks in 3 different days		RSA	Participants with the highest RSA benefited most from the written disclosure, while RSA level did not predict outcome in the control condition
Soder et al. 2019	n= 53 --> CBT (n = 32) or TIPSS (n = 21); n=37 --> 23 in CBT and 14 in TIPSS	PTSD with co-occurring SUD	CBT or CBT + Processing therapy for PTDS	12	HF-HRV	Higher baseline resting HF-HRV predicted greater improvement in PTSD symptoms from baseline to end treatment for both CBT and TIPSS conditions. HF-HRV failed to predict improvement in self-reported substance use as a function of treatment.
Wendt et al. 2018	228	Panic disorder and agoraphobia	CBT	12	HF-HRV - RMSSD	In adults, pretreatment CVT predicted dropout from and residual symptoms after exposure therapy in patients with panic disorder and agoraphobia. These findings indicate that PD/AG patients with low pretreatment CVT are more likely to show residual symptoms after completing exposure-focused therapy.

HRV as a treatment outcome – From the datasets retrieved, 15 explored the extent to which a certain psychological treatment allow for improvements in HRV, a biomarker of ER. From those 15 studies ambivalent results were identified. That is, there are examples in which HRV improves from pre to post treatment assessment (Busscher et al., 2015; Carney et al., 2016; Chien et al., 2015; Garakani et al., 2009; Schramm et al., 2016; Stratford et al., 2014), others it does not improve (Mumm et al., 2019) and there is a third group with mixed findings (Andrea, 2012; Busscher et al., 2015; Wheeler et al., 2014).

HRV as a predictor of outcome – Altogether 12 studies were identified through the systematic search of the aforementioned databases. As in the case of treatment outcome, there were mixed findings.

There were cases in which HRV was indeed a predictor of change. In the case of Mathewson et al. (Mathewson et al., 2013) an opposite conclusion was drawn, given that resting RSA did not predict anxiety reduction, but it was the case with RSA reactivity (change in RSA levels over time). Meanwhile, Soder and colleagues (Soder et al., 2019) found that resting HRV-HF was predictive of greater reduction in PTSD symptoms in two type of treatments (classical CBT and an integrated form of CBT with cognitive processing therapy for PTSD). In the case of Davies et al. (2015), baseline HRV predicted outcome in a nonlinear manner that did not differ by treatment group (ACT vs CBT).

On the contrary, O'Connor et al. (2005) found that participants with the highest RSA benefited most from the intervention that was a written disclosure, while RSA level did not predict outcome in the control condition. Likewise, Bornas et al. (2007) and Bornas et al. (2012) did find that HRV was a significant predictor of outcome.

Despite mixing results, taken together these studies suggest that vagal tone does have an important role as a predictor in psychotherapy for emotional disorders. The great majority of the studies were published in the last 15 years, which is a sign of the novelty of including vagal tone in order to explore its predictive value for the process and outcome of psychotherapy. All the studies were conducted in highly developed countries, which in turn share among them the same cultural background.

Although there are no enough studies to draw definitive conclusions, there is a clear common tendency among the different affective disorders. This goes in line with the idea that vagal tone may be a transdiagnostic marker in psychopathology in general and to present regular patterns in affective disorders. More specifically, vagal tone has been suggested as a biomarker of ER, which is in turn one of the most relevant transdiagnostic processes that has been founded in the appearance and maintenance of emotional disorders (Aldao et al., 2010).

HRV in process and outcome research - Blanck et al. (2019) and Doukas et al. (2014) were the only two studies that considered a non-outcome focused variable. In the case of Blanck et al. (2019), HRV (specifically HF power) was found to predict patient-rated alliance but not therapist rated alliance. The study permitted to identify that in-session HF power predicted the alliance from the patient perspective.

These results can be explained because of the increase of the prosocial behavior when HF power is higher, and therefore facilitate the therapeutic alliance. It would be interesting to know if this is also happening from the therapists' vagal tone, which should be arguably the case. Meanwhile, Doukas and colleagues (2014) also revealed that higher alliance ratings were predicted by higher RSA during baseline.

Although not regarding the process itself, the large-scale RCT conducted by Wendt et al. (2018) revealed that lower HRV at the beginning of the treatment was a predictor of dropout, which may constitute a relevant clinical marker for clinicians when formulating a case in order to expect that the individual is more probable to drop out the treatment. Bornas et al. (2011) studied the slope of change, which is a very relevant topic in psychotherapy process and outcome research (see for example Rubel and Lutz, 2017).

In conclusion, vagal tone seems to be a potentially relevant variable to be taken account in psychotherapy. However, it still lacks more evidence in order to know more precisely how it impacts on therapeutic outcomes as well as other relevant aspects of therapeutic process.

Clinical implications: Is it useful for psychotherapy? – On the one hand, from the existent research it can be stated that vagal tone does predict outcome. Despite the novelty of the result, it seems to be rather logical given the fact that a better functioning of the parasympathetic system is a contributor of mental health and wellbeing. Hence, it is possible to infer that people having a more functional physiological architecture may be more prepared for positive changes and resilient experiences.

This is of particular importance in order to potentially include vagal tone as a measurement in clinical practice and according to the parasympathetic functioning infer a potential level of severity. In other words, if a clinician detects that the functioning level of the parasympathetic system is impaired, it may be another important aspect to take into account as, for example, clinicians usually do with variables like motivation to change, expectations of the treatment, attachment or chronicity of a disorder.

One of the most interesting results revolves around the fact that one study (Hyett et al., 2018) showed that an imagery-based treatment improved autonomic flexibility in comparison to a verbally based treatment. The implications are twofold: First, given that in self-report measures there were no differences between treatments, it is reasonable to believe that autonomic flexibility precedes the psychological improvement and constitutes a possible marker of improvement in SAD individuals. Besides, and although much more research is needed to draw conclusive statements, it supports the new avenue of imagery-based treatments that are being developed for emotional disorders in general (Holmes et al., 2019) and SAD in particular (McEvoy et al., 2020).

The majority of studies were conducted as a secondary analysis of RCTs and therefore with fixed protocols. In many cases a 12 sessions protocol was implemented (Davies et al., 2015; Mathewson et al., 2013; Soder et al., 2019; Wendt et al., 2018), although others used a 6 sessions protocol (Bornas

et al., 2011, 2007, 2012), a 16 sessions protocol in one further trial (Carney et al., 2016) and finally a 2-day group therapy in one study (Busscher et al., 2015).

As regards to the therapeutic approaches, a great majority of studies were conducted with a CBT approach. This was the case in Blanck et al. (2019), Busscher et al. (2015), Carney et al. (2016), Wendt et al. (2018), Mathewson et al. (2013), and one of the experimental arms in Davies et al. (2015) and Soder et al. (2019). Precisely in these two last cases, the other experimental arm was an ACT treatment and an integrated CBT version including trauma related material (denominated TIPSS).

Only three studies (Blanck et al., 2019; D'Andrea & Pole, 2012; Doukas et al., 2014) were conducted in a naturalistic setting, which constitutes an essential aspect to consider when analyzing these results. Over the decades, outcome research has primarily been conducted in laboratory settings in the context of RCTs (Barkham et al., 2008). This supremacy of efficacy studies to the detriment of effectiveness (Hunsley et al., 2014) has greatly contributed to deepen the gap between research and practice. While RCTs may constitute the most rigorous way of studying experimentally the effect of an intervention, a range of problems have been identified for the complexity of psychotherapy (Beutler & Forrester, 2014). Usually, the translation of the results from purely experimental settings to naturalistic settings are not possible, and thus studies like the ones conducted by Blanck et al. (2019) or Doukas et al. (2014) constitute a significant contribution in order to explore how HRV is deployed in real therapeutic contexts.

In all the aforementioned cases, CBT was delivered with an individual format, while Busscher et al. (2015) implemented a CBT protocol in a group format. Besides, the studies conducted by Bornas and colleagues (2011; 2007; 2012) used a computer-assisted exposure treatment, which although was conceptualized as a CBT treatment, it was actually a mainly behavioral intervention. The same can be stated for Busscher et al. (2015), treatment in which the intervention mainly consisted of exposure therapy.

One of the most relevant conclusions of this literature revolves around exposure-based treatments. Traditionally, the principle behind improvement in exposure was habituation. However, this literature sheds light upon the need of increase flexibility of parasympathetic activity rather than lowering arousal when exposed to feared or distressing stimuli and events. These findings, in turn, are aligned with existing theories of exposure (Craske et al., 2014) as well as the gut theory in which anxiety, worry and stress is related to the difficulty of inhibiting the activity even when there are no reasons such as actual stressors (Brosschot et al., 2017). In this sense, it is interesting to mention the case of Mumm et al. (2019), in which there were significant increases in HF-HRV and RMSSD after exposure but not in the treatment as a whole, which supports the potential usefulness of extinction learning in the improvement of the parasympathetic flexibility.

Limitations of existing literature - Although the importance of the topic, few studies have explored the predictive value of vagal tone in psychotherapy. Given that the majority of the studies were

secondary analysis of RCT, there were no sample size calculations to determine the role of vagal tone as a predictor of outcome, dropout or therapeutic alliance.

In clinical research there exist a number of possible designs and depending on that choice it is possible to arrive to different conclusions. The most evident one is whether the design is experimental or observational. Besides, it is of utmost importance either the setting in which the study is implemented is a laboratory in which participants are recruited for the study or a clinical center in which the routine care is incorporated in the treatment. In that sense, it is of utmost importance to establish that these studies were principally conducted in laboratory-based settings. This means that the studies may have a high internal validity but may lack from external validity. Consequently, the results should be taken with caution when considering their usefulness in real world settings.

With regard to the vagal tone measurement, there is a clear limitation within these studies regarding the lack of ecological validity. Only Carney et al. (2016) have used a 24h ambulatory ECG monitoring. While it is true that there is a clear technical hindrance in acquiring ecological ECG data due to the lack of wearable devices that are comfortable enough (without electrodes) and with a proper sampling rate to calculate HRV and RSA indices (for a discussion on this issue see Grossman & Taylor, 2007; Shaffer & Ginsberg, 2017). Nowadays, there are much better tools to measure ECG ambulatory (ter Harmsel et al., 2021).

Major challenges for the future developments - More research in naturalistic settings is needed to know how HRV is deployed in real clinical practice contexts. The mechanism that explain why psychotherapy improves psychophysiological is unknown yet. However, it can be suggested that increasing the level of organization (e.g. increasing the allostatic load of the individual) can lead to a reduction of everyday distress.

In turn, it is important to ascertain that the reciprocity between physical and mental states should derive in the combination of psychological and psychophysiological procedures. Biofeedback, for instance, can improve the physiological architecture that supports mental activity. Needless to say, if physiologically wise a certain individual does not have any problem, but there are a range of significant problems at an experiential, behavioral, interpersonal level, such approaches will not be of much help. Hence, integration of physiological measures is of utmost importance both for the assessment at the beginning and throughout the treatment.

3.2.4. Processes of synchrony between the patient and the therapist

The processes of synchrony between clinicians and patients represents an area of great interest for the study of psychological interventions. By means of sensors and biosensors it is possible to gauge dynamics of physiological processes as well as verbal and non-verbal behaviors. In the therapeutic context, the voice, the movements and the physiological reactions play an indisputable important role

in the establishment of processes such as therapeutic alliance, emotional processing or regulation (Koole & Tschacher, 2016). Different reviews have summarized the evidence of physiological synchrony in a range of clinical conditions (Kleinbub, 2017; Palumbo et al., 2017). In line with the evidence of the ANS functioning, the two processes that have been principally studied are electrodermal activity (Marci et al., 2007)(Bar-Kalifa et al., 2019; Palmieri et al., 2018), and heart rate variability synchronization (Tschacher & Meier, 2019).

Apart from physiology, synchrony can be studied by means of facial displays, speech rate, silence patterns, prosody and lexical or linguistic alignment are some examples (Ramseyer, 2019). Without relying on cutting-edge technology, one of the simplest methods is the assessment of differences in sequences of pictures that can be obtained from video recordings. Motion energy analysis represent the most used current procedure for researchers who have access to their own video material, which is described along with the existing evidence in the paper by Ramseyer (2019).

3.2.5. Ambulatory assessment

The study of contextual and momentary variables outside the therapeutic office can shed light upon the processes of change as well as to understand better the impact of clinical interventions on a wide range of the facets of individuals. In this sense, mobile phones and other wearable technologies permit to acquire tons of data, both actively and passively, which in sum constitute invaluable knowledge that ideally should facilitate the optimization of treatment by means of improving the personalization of the interventions.

All clinical interventions can be assessed either at the beginning, during or after the treatment. Accordingly, these technologies can be incorporated at baseline, throughout the treatment or once the treatment has ended in order to obtain continuous and contextualized information. This opens up unprecedent opportunities to determine the individual dynamics and prioritize idiographic approaches.

Given that mental states cannot be reduced to a set of objective markers, it is essential to triangulate passive sensing with the active self-report answers from the individuals. Subjective experience, i.e. the way people perceives the reality, is probably the core aspect of the definition of what an emotion is (LeDoux & Hofmann, 2018), and this can be extended to the whole mental activity. Therefore, under the umbrella of active assessment are comprised all digital technologies that gather conscious reported information either from a first-person perspective (e.g. a patient) or a third person perspective (e.g. a clinician or a caregiver).

As explained in the conceptualization of ER, dynamic, contextual and momentary factors constitute indispensable facets to fully grasp psychological phenomena. ER is not only a stable trait that may vary between persons, but also a dynamic state that may vary within a single person (Naragon-Gainey, 2019; Park & Naragon-Gainey, 2019). As an illustrative example, reappraisal may be adaptive when stress is uncontrollable, while maladaptive when the situation is controllable (Troy et al., 2013).

Likewise, ongoing negative emotions increase the deployment of rumination (Li et al., 2017), feeling social pressure in a specific situation induces high rates of expressive suppression (Catterson et al., 2017), and cognitive reappraisal has shown to be associated with hedonic goals (English et al., 2017). These are only a few examples of the mounting evidence showing that ER is not a stable trait independent from a vast array of factors (Bylsma & Rottenberg, 2011; Cole et al., 2019; Grommisch et al., 2019; Kalokerinos et al., 2017; Livingstone et al., 2017; Panaite et al., 2020).

In order to better capture these dynamics, Ambulatory Assessment (AA), emerges as an innovative technology, ideal to study ER variability and contextuality (Wang et al., 2020). AA, also denominated Ecological Momentary Assessment or Experience Sampling Method, refers to the repeated assessment of people as they go through daily life, which aims at collecting momentary measures of affect, thoughts and/or behaviors (Stone & Shiffman, 1994). Since the late '80s, AA started to be increasingly adopted in many research fields. However, daily assessments were usually performed by means of paper and pencil diaries, which made this technique inadequate for research and clinical purposes (e.g., low adherence, retrospective fulfillments, errors in data transfer). The use of mobile devices allowed to overcome the shortcomings of traditional assessment methods (Trull & Ebner-Priemer, 2009; Trull & Ebner-Priemer, 2020).

Consistently, the application of this methodology to the study of ER has undoubtedly increased our knowledge about this process (Bylsma & Rottenberg, 2011), and a more complex representation of how people regulate their emotions is emerging (Colombo et al., 2020). While cross-sectional measures permit to assess the trait of a person (tendencies to feel, think, and act), AA allows for quantification of averages and variability in affect or behavior over time and across situations. In other words, AA allow for gauging the frequency and magnitude affect and behavior deviates from their average.

Resistance of emotions to change has been suggested as a key component of depressive symptomatology. It is usually denominated affective inertia (Kuppens et al., 2010), defined as the reduced reactivity to one's changing environment. It represents a facet of affective inflexibility, and in line with all the literature concerning inflexibility, there is evidence showing that it is relate to mental dysfunction and maladaptive deployment of ER strategies (Houben & Kuppens, 2019; Kalokerinos et al., 2019; Koval et al., 2014). On the contrary, variability in ER strategy use shows high sensitivity to switching contexts (Wang et al., 2020).

The degree to which affect triggered a subsequent ruminative response was moderated by habitual characteristics of negative thinking in a theoretically consistent way. Stronger temporal pairing of negative affect and rumination was also associated with greater emotional inertia but less carry-over of rumination from one moment to the next. Depression vulnerability may be in the form of rumination being habitually triggered in response to momentary fluctuations in affect, with deleterious effect on mood. The findings may have clinical implications, as targeting the habitual nature of rumination might help reduce depression vulnerability.

Beyond the exploration of the situated nature of ER processes, AA has also been shown to be an adequate tool for the investigation of ER consequences, which can obviously affect different aspects of our life such as affect, physiological responses, and behaviors (Colombo al., 2020). By means of AA, it is possible to establish a causal rather than correlational association between ER and outcomes: For instance, how ER affects subsequent maladaptive (such as conduct problems, suicide ideations, drugs abuse or abnormal sexual conducts) and adaptive behaviors (including academic or job performance, physical activity or social interactions). Accordingly, there is evidence showing the benefits of implementing AA solutions in the clinical field and, potentially, in the intervention of ER (Colombo et al., 2019).

The initial assessment that patients usually undergo when they are admitted for a psychological treatment, constitutes a relevant in order to build a helpful tool to identify the main clinical issues to be addressed in the therapeutic process. Instead of administering a set of retrospective questionnaires and interviews, AA may enable the collection of more accurate baseline assessment, consisting of repeated measures of different ER (and related) variables before the treatment begins. On the one hand, this would allow to identify specific strategies that might be improved during the therapy with higher precision, and thus foster the delivery of more customized interventions (Fisher et al., 2019). On the other hand, a more accurate baseline assessment may also help to predict treatment outcome. In the case of affective problems, for instance, lower negative affect and higher positive affect at baseline have been found to predict better treatment response (Forbes et al., 2012).

A burgeoning interest is represented by the recent studies applying AA to therapeutic contexts. For example, Husen et al. (2016) and Lutz (2019) implemented an AA during for two weeks and each day prompted the patient four times. That information permitted to explore pre-treatment fluctuations in both positive and negative affect predict early treatment response (Husen et al., 2016). Likewise, in the case of Lutz et al. (2018) used AA together with network analysis to predict dropout in emotional disorders.

Another example of idiographic research was provided by Frumkin et al. (2020) who conducted a pilot study demonstrating the feasibility and utility of using AA at the beginning of the treatment. Apart from showing that therapists are more reluctant that therapists to incorporate AA, it demonstrated that case conceptualizations greatly differ from temporal networks derived from AA data. Likewise, Kaiser and Laireiter (2019) presented a proof of concept study, showing how AA could be harnessed to explore intersession processes, which is of paramount importance to take into account other processes that may be contributing to therapeutic change.

An increasing number of studies explored how an idiographic algorithm could be applied to optimize the treatment (Bosley 2019; Fisher 2019; Fisher & Bosley, 2020). In the case of Fisher et al. (2019), an open trial showed that person specific and dynamic factor models were built based on AA collected for 30 days before the treatment and revealing that personalized treatment using the algorithm resulted in a larger effect size than the usual effect size for the same clinical condition.

Finally, in a sample of 38 individuals suffering from obsessive compulsive with residual symptoms after a cognitive behavior therapy, AA was incorporated before and after a mindfulness-based cognitive therapy. The incorporation of AA permitted to grasp more nuanced changes that without this tool would not have been possible (Landmann et al., 2020).

Besides, AA has the potential to provide a more detailed overview of one's daily functioning and, therefore, it has a higher sensitivity in monitoring and capturing changes during the therapeutic process. In that sense, Routine Outcome Monitoring (ROM) gives the opportunity to explore changes of multiple psychological and social variables during the course of an intervention (Lambert & Shimokawa, 2011), and AA could enhance this prolific and clinically relevant research area. That is, the ongoing monitoring of patients' ER could shed light upon relevant aspects of an intervention, detecting improvements but above all cases of deterioration in daily life. In particular, AA could be of great usefulness to study processes of change and foster the research of personalized mechanisms of change.

To date, EMA have predominantly relied on self-report data. Recently, other sources of information have sparked the interest of clinical researchers. Specifically, the incorporation of passive sensing that is tremendously important to assess how mechanisms of change operate in the therapeutic context. So far, as described at the beginning of this section, psychophysiological and behavioral manures have been included to study therapeutic change but not using passive data from mobile devices in order quantify moment-by-moment data. Hehlmann et al. (2021) conducted the first study that incorporated passive assessment in AA to investigate change process during psychotherapeutic treatment. So far, there is a dearth of studies exploring the role of ER.

However, mobile devices may be harnessed not only to actively and passively record data, but also to intervene in the wild. In the next section the developments in that burgeoning area will be described, which would represent an integration of the DIU framework. That is, harnessing the three advantages that provide digital technologies.

4. Future Perspectives: Integrating the DIU framework

The development of mobile and ubiquitous technologies (mHealth) may help to transform the field of mental health (Marzano et al., 2015; Naslund et al., 2015). Unlike any other technology, mobile and wearable devices (particularly smartphones) have blossomed in the last decade, to the point of giving rise to the smartphone manifesto defending the idea that smartphones could transform psychology even more profoundly than PCs and brain imaging did (Miller, 2012).

They may help to outreach people in need with procedures that would not be possible even if the individuals attend a presential therapist. As described, there are technologies that permit to go beyond the possibilities of traditional treatments, and we have labeled them *improving* technologies.

The possibility of developing technologies that may permit to both the dissemination and improvement of traditional treatments would represent a significant leap forward for the field of clinical psychology.

The most illustrative example are just-in-time adaptive interventions (JITAIs), which emerge as one of the most innovative developments within digital technologies given that they permit to disseminate and augment potential physical treatments (e.g., integrated as homework elements) by means of highly developed systems that enable to identify the exact moment when an individual needs to receive a specific intervention.

That is, JITAIs are considered a design intervention whose goal is to provide the right type of support (i.e. personalized to the contextual and internal needs of the individual) at the right moment (Nahum-Shani et al., 2018). The right moment may be when the person is experiencing a certain dysfunctional belief, emotion or behavior, as well as in anticipation of those outcomes. From the wealth of data that mHealth is able to capture through passive sensing and active assessment, a range of useful interventions can be delivered remotely and automatically through JITAIs. Indeed, from the broad term 'precision medicine' to the more specific 'precision psychiatry' or 'tailored psychotherapy', there is an increasing consensus regarding the paramount importance of adapting the interventions to the clinical and personal needs of the patients (Lutz et al., 2019), and JITAIs may play an instrumental role in this regard.

4.1. From mobile apps to Ecological Momentary Interventions

Ecological Momentary Interventions (EMIs) represent an innovative way of providing psychological support by means of mobile technologies like smartphones or personal digital assistants based on information that is previously assessed either through traditional assessment or ambulatory assessment. EMIs constitute a personalized intervention, given that it is designed to provide psychological support when the patient is likely to need it based on the previous collected information.

Thousands of apps were created for emotional disorders over the last years and both the field of human computer interaction and clinical psychology produced mounting theoretical evidence discussing the state-of-the-art, the adoption and the main challenges. A wealth of commercial apps has been developed with the intention to support mood tracking, relaxation, or mindfulness, or with the aim of reducing affective symptoms and improve ER. Many reviews have tried to assemble and classify this large number of apps, aiming also to establish the extent to which the apps are scientifically based, both in terms of user experience and clinical support (Lecomte et al., 2020; Weisel et al., 2019).

Most of commercial applications do not have a scientific evidence of their efficacy (Bakker et al., 2016), which prevents from finding adequate support in Apple or Google's marketplaces (Shen et al., 2015). This provokes a major ethical concern and an urgent need to develop clear regulations regarding the use and recommendation of these applications. Taken together there is a considerable concern with regard to the lack of penetration of mobile apps in the real life, as well as the scarce quality that present many of these developments (Armontrout et al., 2016; Torous et al., 2018).

There are numerous challenges that can be identified through the large body of literature that has been published in the field of mobile apps. First and foremost, the scarcity of evidence-based apps, an issue that unfortunately is widely agreed and reveals an inescapable reality. Furthermore, they were only rarely incorporated to the routine practice of psychological treatments. However, there is little doubt that the delivery of psychological interventions via smartphone devices have produced important progresses for the clinical psychological realm so far (Donker et al., 2013). Some studies have systematically examined the efficacy of smartphone apps for mental disorders, principally but not only for anxiety and depressive symptoms (Linardon et al., 2019). However, the available evidence of these apps is still unclear, and they are not recommended to be used as standalone psychological interventions (Weisel et al., 2019).

Regarding specific apps, some psychological interventions have been developed through smartphone apps in order to teach patients ER strategies. Just considering mindfulness, acceptance and compassion there is a myriad of studies, which in turn are synthetized in a recent systematic review (Linardon, 2020). Likewise, different apps have been created to support DBT treatments, although they have not been evaluated with regard to usability, acceptability and clinical efficacy (Lungu et al., 2019). Taking into account classical CBT, there are numerous apps that fosters cognitive change (Weisel et al., 2019).

Despite the great evidence showing the feasibility and efficacy of mobile apps (Donker et al., 2013), the proliferation of EMI applications has been much scarcer. However, there is a range of EMIs that have been developed for the treatment of anxiety and stress-related disorders, and there is evidence supporting their efficacy in reducing symptoms severity (Balaskas et al., 2021). For example, Newman et al. (2014) developed a software called The Stress Manager, which allows to monitor daily symptoms and to provide customized CBT-based interventions to patients with Generalized Anxiety Disorder (GAD). More specifically, the software repeatedly assesses patients' symptoms and affect throughout the day; when a high level of anxiety is detected, personalized CBT exercises are triggered in order to manage momentary symptoms, such as relaxation techniques or cognitive restructuring. Among other mental disorders, a recent review also identified nine EMIs for the delivery of psychological support to patients suffering from a psychotic disorders (Bell et al., 2017). Overall, the aim of the included applications was to monitor patients' symptoms and daily affect and, consistently, to provide real-time suggestions about illness management. An example, FOCUS is a mobile application that, through the monitoring of daily affect, is able to provide personalized feedbacks in response to the detection of psychological difficulties in the patient, such as symptoms worsening or high negative affect (Ben-Zeev et al., 2014). Depending on the EMA answers, different type of support can be provided, including strategies to improve momentary mood (for example: "*If you are feeling tense right now, take a moment to relax. Try this strategy, close your eyes and count slowly to 20 […]. With each full breath, you will be more and more relaxed*"). Additionally, four EMIs have been identified in the field of Major Depressive Disorder (MDD) (Colombo et al., 2019). One key example is represented by the mobile

application Mobylize that, differently to the EMIs mentioned in the previous lines, is based on the integration of both active and passive assessments (Burns et al., 2011). Indeed, Mobylize combines self-reported information and sensors data to develop customized predictive models about users' affective states. After a training period, the system becomes able to automatically predict momentary affect just using the information gathered from embedded sensors. Furthermore, triggered feedbacks are provided when low mood is detected that aim at reinforcing improvement or the use of one of the tools included in Mobylize's website, such an activity calendar to reduce avoidance with active coping behaviors.

An innovative recent non-clinical attempt is represented by Calm Mom, a mobile application that specifically aims at enhancing ER through the integration of data from self-reports and electrodermal activity (Leonard et al., 2018). Due to the continuous EDA monitoring, the application triggers alert when a high level of stress is detected, providing users with a consistent customized ER support (i.e., motivational messages or behavioral strategies).

To conclude, as evidenced by the examples reported in the previous lines, most of the EMIs that aim at reducing symptoms in clinical populations also include intervention components that directly or indirectly target ER skills, such as cognitive reappraisal or behavioral avoidance. As there is increasing evidence suggesting ER as a transdiagnostic mechanism of change as well as a growing body of literature suggesting the efficacy of mHealth solutions, it still remains an open question whether the development of EMIs for the improvement of ER could represent a valuable way to psychologically support a vast array of clinical populations.

4.2. Standalone and Mobile based Virtual Reality

Despite the undoubted efficacy of exposure for anxiety disorders, there is conclusive evidence showing that it is not widely disseminated (Harned et al., 2011; Pittig et al., 2019; Schumacher et al., 2017, 2018). For example in the specific case of social anxiety, therapists identify different obstacles in the implementation of exposure, among of which logistic barriers is the most recurrent barrier (McAleavey et al., 2014).

Although VRET emerged as a possible solution to this problem of implementing exposure in clinical practices, VR has not succeeded to penetrate in clinical settings yet. Research shows that the main reason is due to the high costs and the high technical specificity that has required the implementation of hardware and software since the first versions appeared in the early 90s (Schwartzman et al., 2012; Segal et al., 2010). Over the last years, low-cost devices have been developed, facilitating the democratization of VR, which was previously confined to research areas (Lindner et al., 2017).

As VR becomes more accessible, it opens up the scope for new directions and experimental designs for both assessment and intervention (Lindner et al., 2017), integrating psychological inputs with technical disciplines, in particular Human Computer Interaction developments (Kitson et al., 2018). The incorporation of mHealth to VR opens up unprecedent opportunities to integrate

dissemination and improvement. Many of the recent trials were conducted with standalone VR or mobile VR, permitting the integration of disseminating technologies with improving technologies.

Mobile VR interventions are emerging in the last couple of years thanks to the proliferation of off-the-shelf hardware and software. There are a number of new options that are not only wireless and low-cost, but also of easy and intuitive use. Gear VR, Oculus Go, Oculus Quest or simple Cardboards goggle VR are some of the existing options that may support some of the existing developments in virtual environments.

Considerable research has already been published using mobile VR (Donker et al., 2019; Kim et al., 2017; Lindner et al., 2019; Miloff et al., 2019) to provide automated mobile VR interventions for anxiety disorders. That is, without the need of a therapist to deliver the intervention. Hence, this strong emerging evidence is showing that VR can be used to reach people in need that otherwise would not receive any kind of treatment. All of these interventions were developed for specific phobias, such as acrophobia (Donker et al., 2019), spider phobia (Miloff et al., 2019), public speaking anxiety (Lindner et al., 2019) and social anxiety (Kim et al., 2017). The work conducted by Freeman et al. (2018), although focusing on coach sessions, benefited from a VR avatar targeting the treatment of the fear of heights. This study provided a successful example of how tools such as real-time voice recognition and a watch interface can help psychotherapy VR interventions be more ecological. Although much of the physiological or behavioral tracking remains unexplored, the integration of machine learning or portable devices suggests the potential of considering the wearability of the technology platforms, which could render experiences more unobtrusive. Table 12 gathers all the studies that utilized mobile forms of VR in the field of ER for emotional disorders.

Indeed, the first examples of consumer technology in routine care are starting to emerge, particularly in public speaking anxiety. Lindner et al. (2019) showed not only that a one-session VRET for public speaking anxiety can be delivered with basic hardware, but also that a self-led intervention revealed to be equally efficacious than the therapist-led intervention with sustained effects at a 6 months follow-up assessment. Likewise, Kahlon, Lindner and Nordgreen (2019) conducted a pilot study with adolescents with promising results. Finally, Lindner et al. (2021) have conducted the first single-subject effectiveness trial in a private clinical practice, also with positive outcomes, which together to the previous two examples starts to build a considerable solid evidence.

All together, these examples reflect the increasing incorporation of self-guided APPs, which in adjunction to the much lower prices of the VR devices, make it possible that VR will be greatly disseminated in the next years. In this sense, standalone and mobile VR developments emerge as a powerful alternative in order to widely disseminate VR based treatments.

Table 19. Evidence for mobile and automated VR in emotional disorders.

Study	Clinical condition / Design	Technology
(Donker et al., 2019)	Acrophobia: RCT	**Hardware**: Cardboard VR goggles

		Software: RCT, app development, low-cost hardware, fully automated
(Kim et al., 2017)	SAD: Within design	**Hardware**: Samsung Gear VR **Software**: APP developed by Samsung, open source, fully automated (consumer)
(Miloff et al., 2019)	Spider phobia: RCT	**Hardware**: **Software**: APP development, fully automated, low-cost video
(Stupar-Rutenfrans et al., 2017)	FoP speaking: Within design	**Hardware**: Cardboard **Software**: 360 videos, low-cost video
(Hong et al., 2017)	Acrophobia: Within design	**Hardware**: Samsung Gear VR (consumer) **Software**: APP developed by Samsung, open source, fully automated (consumer)
(Lindner et al., 2019)	FoP speaking: RCT	**Hardware**: Samsung Gear VR (consumer) **Software**: VirtualSpeech (consumer)
(Repetto et al., 2013)	GAD: pilot RCT	**Hardware**: Vuzix iWear VR920 **Software**: APP developed (non-consumer)
(Freeman et al., 2018)	Acrophobia: RCT	**Hardware**: HTC Vive (non-consumer nor mobile)[1] **Software**: APP developed (non-consumer)
(Bentz et al., 2021)	Acrophobia: RCT	**Hardware:** Google Daydream (consumer) **Software:** Easy Heights (consumer)
(Lindner et al., 2021)	Phobia	**Hardware:** Oculus Go (consumer) **Software:** APP develop (non-consumer)

However, dissemination is part but not the entire problem of improving the treatment emotional disorders. As previously described, many people do not respond to existing treatments. Hence, over the recent years, numerous relevant studies have been conducted in the field of emotional disorders, which have been trying to enhance the classical CBT components. This is the case of imagery-based interventions, an approach that is rooted in cognitive science and basic research and has proven to be a powerful strategy to target usually unexplored facets of classical CBT treatments (Holmes & Mathews, 2010).

This is the case of social anxiety disorder, which represents a paradigmatic example of emotional disorder due to its impairment both on the negative affect and positive affect. From the classical models developed by Clark and Wells (1995) and Rapee and Heimberg (1997) to the most recent updates (McEvoy et al., 2018), it is strongly supported the fact that negatively valenced mental imagery of the perceived self plays a central role in the appearance and maintenance of the disorder (Hackmann et al., 2000; Holmes & Mathews, 2010; Wild et al., 2008). Individuals suffering from SAD present a distorted image of one's public self, whose content usually entails an individual's feared outcome, such as "being humiliated while presenting in public" (Hirsch et al., 2003).

SAD usually starts with the perception of an audience who will evaluate the person; perception that in turns fosters a mental representation of *how is to be seen by that audience*. This mental

representation is stored as a picture, which naturally stimulates the progressive development of a negative belief regarding the own capacity to perform in social situations. Besides, this usual lack of self-efficacy derives in a commonly biased perception of the opinion of the audience, but far from lowering the expectations SAD individuals tend even to have higher performance standards than the average population (Botella et al., 2003). The whole scenario makes an inevitable perception of frustration and underachievement, which logically drive to high levels of anxiety. The mental representation of the self is increasingly rigid as the individual confirms those biases by new performances in which the visibly signs of anxiety makes him or her to perform under his or her capacity. As a consequence the mental representation of the self as seen by the audience continues to be defined the same negatively valenced imagery and the whole conforms a vicious cycle that is difficult to break (Morrison & Heimberg, 2013).

Hence, one of the most investigated treatment areas for SAD individuals is the self and the negative mental imagery that defines that self. Ample evidence has shown that the negatively valenced mental imagery usually appears in the adolescence and is stored in the memory and is a constitutive hallmark of the appearance and maintenance of SAD (Hackmann et al. 2000).

It has been over the last decade that mental imagery emerged as a dominant topic in the clinical psychology literature. This can be largely explained due to the outstanding contributions of many researchers who conducted dozens of studies in this domain, from basic research to clinical applications (Blackwell, 2018). From the initial works in which the relationship between mental imagery and emotion was proven to be strong (Holmes et al., 2005), the incorporation of these techniques in therapeutic protocols was ever-growing (E. Holmes et al., 2016; E. A. Holmes et al., 2007).

Imagery-based interventions are based on the premise that mental imagery has a powerful impact on emotion, and thus can alleviate emotional distress. One imagery technique that has gained interest is imagery rescripting (IR). A growing body of research has already studied the efficacy of reelaborating the early memories through IR procedures. A recent meta-analysis, for instance, revealed that IR constitutes a powerful technique that permits to improve psychological disorders associated to aversive memories. The study yields large effects of IR for different disorders, showing that it can be effective in a reduced number of sessions (Morina et al., 2017). Indeed, some studies have shown the efficacy of a single IR sesión, showing maintaining effects at three months follow-up assessment (Lee & Kwon, 2013).

IR interventions have proven to be useful for the fear reduction of negative evaluation, anxiety reduction in feared social situations and most importantly a reduction in the distress related to the early aversive social memory as well as the current negative imagery (Morina et al., 2017). Likewise, IR helps to improve maladaptive beliefs regarding the aversive memory (E. A. Holmes & Mathews, 2010; Ji et al., 2016). Besides, the imagery-enhanced CBT developed by McEvoy and tested in several studies (McEvoy et al., 2015, 2018, 2020) has shown very promising results, also compared to classical CBT treatments.

The mechanism that explains the effectiveness of IR relies on the activation of early emotional memories that are encoded in non-verbal formats. Accordingly, it is possible to have access to those constitutive negative moments in which the negative and sometimes traumatic associations were established, enabling powerful changes of those memoires (Arntz, 2020). This structure is suggested to be intimately associated with the capacity of regulating emotions (Romano et al., 2020)

Given the aforementioned developments, it is essential to create integrative protocols that may harness the potentiality of diverse approaches. Accordingly, IR should not be seen as a competing but complementary intervention to classical exposure treatments. While IR permits to elaborate the meaning of past events, any anxiety disorder also requires that patients confront their feared situations (exposure) while refraining from safety behaviors (response prevention).

All existing exposure treatments aim to extinct conditional fear, which is created after the sustained pairing between a given conditional stimulus and an unconditional aversive. Throughout many decades, it was considered that the main mechanisms operating in extinction was habituation. Therapeutically, this consisted of creating hierarchical exposures in order to habituate patients to the feared situation until fear was reduced. However, over the last years, inhibitory learning has emerged as a new mechanism that is supposed to be a better approach to understand how patients reach to extinct fearful associations. An inhibitory association is created between the conditional stimulus and a non-aversive unconditional stimulus. In terms of clinical application this has derived in developing new strategies, such as fostering expectancy violation, multiple contexts, variability or positive affect during exposure training (Craske et al., 2014).

Taken all the aforementioned aspects into consideration, we aimed to implement a brief protocol using consumer VR technology with the goal of facilitating the implementation of a theoretically integrated treatment in a routine care setting (The Psychological Assistance Service at Universitat Jaume I). We planned to used a nonconcurrent multiple-baseline single-case design in which patients meeting criteria for SAD will attend to the same three sessions but will wait different lengths of time between their initial intake interview and the first session. Unlike concurrent multiple baseline designs, in which baseline assessment start at the same time for all the included participants, we planned to use a non-concurrent design. In this type of study therapy phases of the study occur at different points in time for each participant as the baseline assessment is performed only when they are recruited, and it adapts better to contextual needs of the clinical routine care. In comparison to randomized control trials, single case designs constitute an ideal first step to prove the efficacy of a new clinical protocol and particularly suitable for a routine care setting. Besides, unlike open trials, single case designs permit to establish a cause-and-effect association as each subject serves as its own control. Particularly in a multiple-baseline design, the passage of time is controlled until the intervention starts, advantage that open trials do not offer (Barlow & Nock, 2009; Shahar et al., 2017). The principal aim of this study is to test the effectiveness of a brief integrative protocol in SAD, specifically in one of its most frequent forms, public speaking anxiety (PSA).

The present study is a non-concurrent multiple baseline design with three different baseline lengths. Participants in the three groups will complete an initial assessment including ten, twelve or fourteen days. It has received ethical approval from the Universitat Jaume I Ethical Review Board (number "CD/17/2020"). All participants will sign an informed consent at the first assessment session. The Single-Case Reporting Guideline in Behavioral Interventions (SCRIBE) 2016 checklist will be followed (Tate et al., 2016).

The sample will be comprised by the routine care of people consulting for SAD at the university clinic and we will also recruit socially anxious subjects through the Jaume I University, via notices posted in public places and social media diffusion. Subjects who express an interest in the study will be contacted via e-mail in order to complete two items that assess how anxious they would feel giving a formal speech before a live audience and how likely they would be to avoid taking a class that required an oral presentation, each rated on a 0–8 point scale where 0 = none/never and 8 = extremely/always. Participants will be recruited if they score 6 or higher (strongly to extremely) in response to any of those items. This 2-question survey has been used previously to recruit participants highly fearful of public speaking (Tsao & Craske, 2000). Those participants who score above the cut-off and agree to participate in the study will be contacted for an initial baseline assessment at the clinical center.

To be eligible for the study, individuals had to meet the following criteria: 18 to 65 years old, be able to read and understand Spanish, self-rated clinically significant impairment or distress due to PSA, fulfilled criteria of DSM 5 for general SAD or performance only specifier. Besides, participants should not be receiving another psychological intervention, suffering from a severe mental disorder: alcohol and/or substance dependence disorder, bipolar disorder, psychotic disorder, or dementia. Having ideation or a significant plan for suicide (assessed by the MINI). Receiving pharmacological medication while participating in the study is not an exclusion criterion. However, if the patient has an increase in the pharmacological treatment, s/he will be excluded from the study analysis. We will offer alternative treatments to the participants who do not meet the criteria for the present study. Before a final decision of inclusion, the case will be supervised with the clinical center and evaluate the specific case based on the assessment and clinical judgement.

Sample size calculation for a multiple baseline design is not necessary. To conduct this kind of experimental study it is rather necessary to fulfill the measures within each subject, given that every participant serves as their own control. However, the general rule is clear given that the more individuals in each baseline, the better. Besides, given that we are also interested in conducting analysis on for whom and how the intervention work with the aggregated sample, we will have a total sample of 30 with repeated measurement that would permit to follow the analytic strategy of previous studies (Prinz et al., 2019)

All participants will be volunteers. When the study has been explained to them, they will sign the online informed consent to participate. Qualified clinical personnel will conduct the clinical assessment of the participants as part as the recruitment process. Likewise, qualified and trained

professionals will perform the interventions. The assessment protocol is composed of standardized instruments (semi-structured interviews and questionnaires). Likewise, the integrative treatment protocol is based on general principles of change (Castonguay et al., 2019) as well as on empirically validated treatments from the Task Force on the Promotion and Dissemination of Psychological Procedures of the American Psychological Association (Tolin et al., 2015).

Regarding the treatment protocol, a practice-oriented research process was followed in order to develop the intervention (Castonguay et al., 2013). That is, clinicians with experience were consulted from the inception in order to conduct a protocol in terms of form and content. One senior clinical researcher and therapist, as well as two therapists were involved in an iterative discussion until the protocol was elaborated. This procedure was brought forth as it is considered to improve the motivation of the therapists involved in the process of the research as well as it enhances the clinical relevance of the protocol. All therapists involved in the study have at least a master's degree in clinical psychology.

A short-term protocol that integrates imagery rescripting and virtual reality exposure therapy has been developed. The protocol (IR-VRET) is comprised of 3 therapeutic sessions, preceded by a first assessment and a final assessment at post-treatment, each of which lasts approximately 120 minutes. We have denominated Imagery rescripting + Virtual Reality Exposure Therapy Protocol (IR-VRET). While the first session includes psychoeducation, motivation of change and the establishment of the therapeutic alliance, the second session consists in applying an imagery rescripting protocol, based on Arntz and Weertman (1999) with some adjustments in order to adapt the protocol to our targeted population. The three steps of imagery rescripting will be considered: relieving, mastering and compassion. Besides, a positive imagery intervention will be done by the end of the session, which will be used for the homework assignment between the second and third session. Finally, the third session comprises a One Session Treatment (OST) of VRET in order to confront the subjects to the feared stimuli and overcome in this sense the avoidance of social exposures.

The VR equipment consists of an Oculus Quest, which is a standalone device in which the sandbox application was sideload. VR will be used for the third session of the intervention. Mimerse, a Swedish startup dedicated to the development of VR for mental health purposes, developed the app.

Assessment

Primary outcome measures:

(a) Change in Social Anxiety Symptomatology: Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998) and Social Phobia Scale (SPS; Mattick & Clarke, 1998). These two scales are usually used in a complementary manner. The former measures the level of anxiety associated with scrutiny or observation by other people while performing a task or action (e.g., working, eating, drinking, writing, using public bathrooms), and the latter measures the level of anxiety related to the initiation and

maintenance of social interactions (e.g., meeting and talking with strangers, friends, or people of the opposite sex).

(b) Self-statement during Public Speaking (SSPS; Hofmann & DiBartolo, 2000) and Public Speaking Anxiety Scale (PSAS; Bartholomay & Houlihan, 2016). The SSPS is a 10-item self-report measure with good validity and internal consistency. It consists of two subscales for positive (SSPS-P) and negative (SSPS-N) cognitions experienced in public speaking scenarios. The Spanish adaptation and validation will be used, which showed excellent psychometric properties (Ma José Gallego et al., 2010). The PSAS assesses and tracks three dimensions of public speaking anxiety: behavioral, cognitive, and physiological manifestations. The scale contains 17 items with responses measured in a Likert-format with score ranging from 1 "not at all" to 5 "extremely." It has demonstrated to be a highly reliable in terms of its internal consistency (a=0,94) and a valid measure as is strongly correlated to other public speaking anxiety instruments (r=0.84).

Secondary outcome measures:

(a) Patient Health Questionnaire (PHQ-9). Depressive symptoms will be measured with the PHQ-9 at the pre- and post-tests. The instrument has nine items and is based on DSM-V criteria for major depressive disorder. The items are rated on a four-point scale ranging from 0 "not at all" to 3 "nearly every day," e.g., "Over the last two weeks, how often have you been bothered by: little interest or pleasure in doing things?" Scores range from 0 to 27, and cutpoints of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe levels of depressive symptoms. The PHQ-9 is sensitive to change, has good sensitivity and specificity for detecting depressive disorders, and has adequate psychometric properties. This questionnaire will be used to measure change in depressive symptoms from baseline to the post-tests.

(b) Generalized Anxiety Disorder (GAD-7). The General Anxiety Disorder questionnaire (GAD-7) comprises seven items measuring the symptoms and severity of GAD based on the DSM-IV diagnostic criteria for GAD. The GAD-7 has good internal consistency (0.89) and good convergent validity with other anxiety scales. Increasing scores indicate a greater severity of symptoms. Scores of 5, 10, and 15 are taken as the cutoff points for mild, moderate, and severe anxiety, respectively. The GAD-7 is increasingly used in large-scale studies as a generic measure of changes in anxiety symptomatology.

(c) Brief Fear of Negative Evaluation Scale (BFNE; Leary, 1983; Gallego, 2010). The BFNE is also a widely used and well-validated self-report measure assessing anxiety about being negatively evaluated in social situations. The BFNE consists of 12 items rated on a 5-point scale (1 = not at all characteristic of me, 5 = extremely characteristic of me). The BFNE demonstrates high internal consistency (Cronbach's α = .81–.91), test– retest reliability (r = .75) and convergent and discriminant reliability (Leary, 1983; Weeks et al., 2005).

(d) The SUIS is a 12-item measure of habitual imagery use (Reisberg et al., 2003). An example item is "When going to a new place, I prefer directions that include detailed de- scriptions of landmarks (such

as the size, shape, and colour of a petrol station) in addition to their names." Respondents indicate the degree to which each item is appropriate for them using a 5- point scale: 5 1⁄4 completely appropriate, 3 1⁄4 appropriate about half of the time, and 1 1⁄4 never appropriate. Internal consistency was very high in the current sample (alfa= .84).

(e) Affect: Positive and Negative Affect Scale (PANAS; Díaz-García et al., 2020). The PANAS comprises 20 items, scoring from 1 (very slightly or not at all) to 5 (extremely). This scale assesses positive and negative affect, which are two independent dimensions. The scale has demonstrated excellent internal consistency (α between .84 and .90) and convergent and discriminant validity. The first available Spanish version has showed high internal consistency (α = 0.89 and 0.91 for PA and NA in women, respectively, and α = 0.87 and 0.89 for PA and NA in men, respectively) in college students (Sandín et al., 1999). Most recently, Díaz-García et al. (2020) conducted a validation study with clinical population, showing that the scale has excellent psychometric properties.

(f) Self-efficacy will be assessed with the General Self-Efficacy Scale (Herrero et al., 2014). It is a self-report scale, which comprises 10 items on a 4-point Likert scale. It assesses overall efficacy and evaluates the stable sense of personal competence with regard to the affective management of different stressful situations.

(g) Openness to the Future Scale (C. Botella et al., 2018). This 10-item instrument measures positive affectivity towards the future that can be a prospective protective factor for mental health and an indicator of psychological adjustment. The scale has revealed good psychometric properties in Spanish population.

(h) Difficulties in Emotion Regulation Scale (Hervás & Jódar, 2008). This 28-item instrument measures difficulties regulating emotions. It has 5 subscales, and it is a Spanish validation from the original scale that has 6 subscales and 36 items (Gratz & Roemer, 2004). The Spanish validation has adequate psychometric properties.

Table 20. Overview of the assessment points.

	STUDY PERIOD						
	Screening	Preassessment	Ses, 1	Ses, 2	Ses, 3	Postassesstment	Follow-up 6m
TIMEPOINT	$-t_1$	t_0	t_1	t_2	t_3	t_4	f_1
ENROLMENT:							
Eligibility screen	X	X					
Informed consent	X	X					
Random allocation							
SELF-REPORT ASSESSMENTS:							
SPS & SIAS		X				X	X

SPSS & PSAS	X				X	X
GAD 7	X				X	X
BFNE	X				X	X
PHQ 9	X				X	X
PANAS	X				X	X
DERS	X				X	X
SUIS	X				X	X
Self-efficacy	X				X	
SELF-REPORT ASSESSMENTS:						
ECG	X		X	X	X	X
EDA	X		X	X	X	X
DAY RECONSTRUCTION METHOD (DRM):						
Social anxiety	X	X	X	X	X	
PSA	X	X	X	X	X	
PANAS	X	X	X	X	X	
Self-efficacy	X	X	X	X	X	
PHQ	X	X	X	X	X	
Em.Regulation	X	X	X	X	X	
Alliance	X	X	X	X	X	
Expectations	X	X	X	X	X	
INTENSIVE ECOLOGICAL MOMENTARY ASSESSMENTS (EMA):						
	X				X	
Context	X				X	
Activities	X				X	
ER strategies	X				X	

***EMA Questions* -** The ecological momentary assessment questions were developed by the authors of the current study based on previous studies and considering the growing body of evidence regarding how to design EMA surveys (e.g. see Burke et al., 2017; Janssens et al., 2018). Accordingly, the protocol of the EMA protocol was designed in order to guarantee a proper balance between feasibility, burden on the participants, response rate and risk of missed observations with highly frequent observations. Qualtrics® software will be used to provide participants with the EMA.

Intensive Ecological Momentary Assessment before and after the treatment: In the baseline and posttreatment, 12 times a day each participant will receive a prompt in order to answer an ultrashort survey regarding the way s/he is feeling at the precise moment and the place where s/he is. Each of the 12 prompts will be scheduled at the same time between 9 a.m. and 8 p.m. State affect, social context, concurrent activities and emotion regulation strategies are assessed.

Daily retrospective reconstruction method - The final daily retrospective survey is set to be sent at 9 p.m. While the 12 momentary prompts are programmed to be open for 30 minutes, the last one is operative until midnight.

Procedure - Upon arrival for the baseline assessment session, subjects will read and sign the consent form. Participants are told about the structure of the study and after a detailed explanation they answer whether they would like to take part of the treatment. Later, individuals will fill in the questionnaires on a desktop computer. The baseline assessment session will be conducted face-to-face and the successive assessments will be conducted through an Ecological Momentary Assessment using a mobile application. Once fulfilled the inclusion criteria, the randomization of the participant in one of the following three multiple baseline design: a) 7 days; b) 11 days; or c) 15 days. An independent researcher will conduct the randomization using a plan generator (www.randomization.com).

Between first baseline assessment and first session, an EMA will be used in order to monitor daily momentary states as well as retrospective daily assessments. At the end of the baseline assessment, the therapist will show the participant how to answer. Notifications are activated in participants' mobile devices in order to ensure that every prompt will be noticed. Finally, in that first assessment meeting it is scheduled the first session after 7, 11 or 15 days.

Every session will have a total duration of 120 minutes. Besides, in every session the client and therapist will be connected with a biosensor with the aim of monitoring the physiology throughout the treatment. Complete assessment will take place before randomization (T0), one week after the completion of the treatment (T1), and finally, 1 month after baseline as a follow-up assessment.

Table 21. Format and delivery modality of the protocol

First Baseline Assessment	Multiple baseline assessment	First session	Second session	Third session	Post assessment	1 month FU	6 month FU
Face-to-face	EMA + DRM	Face-to-face	Face-to-face	Face-to-face	EMA + DRM	Online	Online

Statistical analysis - Analysis at an individual and at a group level will be performed. First, to establish the efficacy of the SCED, traditional methods will be implemented. In particular, nonoverlap of all pairs (NAP) will be used in order to identify which individuals have improved. NAP is an index of data overlap between phases in single-case research and provides a reliable effect size that has been used in more than 200 publications (Parker & Vannest, 2009).

At an individual level, we will also perform time-series analysis. We will have intensive repeated data on the affect, emotion regulation strategies, the context and the interactions before the start of the treatment, allowing for establishing impact of lagged points on forecasting. In other words, we will try to figure out the extent to which those variables interact among each other. Hence, Vector Autoregressive Modelling (VAR) permits to explore a set of regression equations, in which each of the

endogenous variables is regressed on its own lagged values (autocorrelation) as well as the lagged values of the other variables (cross-correlation). Each subject time periods will be analysed using time-series analysis following the strategy provided by Bonsall et al. (2012).

As a group level analysis, and in order to account for the hierarchical structure of the data, we will do a one-way analysis of variance in order to assess changes in SIAS and SPS scores. Therefore, a two-level multilevel will be run. All effects will be considered to be random at Level 2, which allowed capturing between-subjects variations in these effects. In addition, to account for autocorrelation between adjacent sessions, a first-order autoregressive structure will be imposed on the covariance matrix for the within-person residuals. To test if the effects were above and beyond changes in social anxiety levels, all models will be also examined while treating social anxiety scores on each particular assessment as a covariate.

Discussion - This study describes the protocol for a non-concurrent multiple baseline design of an integrative intervention for patients with SAD. The principal aim of this study is to evaluate the efficacy of the intervention for depressive social anxiety symptoms as well as to determine the principal mechanisms of change of therapeutic outcome.

The study is consistent with some of the most relevant challenges within the field of clinical psychology. First, it is of utmost importance to develop integrative protocols that can consistently address relevant processes. In this case, this treatment IR is integrated to classical exposure treatments in order to relaborate the meaning of encapsulated memories and thus to change the negative image of SAD individuals. In this vein, exposure treatment not only is delivered through VR in order to increase the acceptability of the intervention, but also in order to more easily implement inhibitory learning procedures during the exposure tasks, such as incorporating multiple contexts.

Besides, it is urgent to implement cutting-edge research in routine settings. The University clinical center has an increasing demand of patients and the possibility of showing the effectiveness of a protocol for SAD in three sessions can be of relevance in order to potentially adopt briefer interventions than the usual treatments. In that sense, the development of new treatment modalities that permit to maximize the therapeutic effect of the interventions by means of technology is a very relevant issue in the field of clinical psychology (Kazdin & Blase, 2011). In the present protocol, not only VR-based interventions are provided in order to deliver exposure therapy in a more ecological way, but EMAs are incorporated with the aim of gauging clients' behaviors, emotions and beliefs in a daily life basis. Unlike other technological developments that may be difficult to be implemented in routine settings, consumer VR technology and EMA are two very powerful alternatives that can foster existing procedures in clinical practice. The data obtained with this study can be compared to results obtained in studies with gold standard procedures using benchmarking strategies (Delgadillo et al., 2014).

Furthermore, this study will hopefully help to elucidate mechanisms of change that are at the center of the debate in the field of clinical psychology. Currently, classical CBT is under scrutiny, and

there is an increasing consensus regarding the need of developing more integrative treatments, regardless of the theoretical background.

Among the limitations of the design it may be noted the lack of an active comparator treatment. Such a design would enhance the experimental strength of the study, allowing for a more robust determination of the causal role of the dependent variables as well as of the mechanisms of change.

Case study applying the protocol

Anna (pseudonym) is a 20 years old white woman. She is an undergraduate student studying medicine. She presented a diagnosis of social anxiety disorder. Previously, she had not received either a psychological treatment or psychopharmacology. She arrives to the consultation with diverse problems in a number of areas including symptomatology, interpersonal problems and overall functioning. Particularly she focused his demand on the difficulty to regulate his mood, being during long periods in deep depressive states and particular difficulty to interact with others. She described feeling alone because of the shyness. She had not had previous experience receiving psychological treatment.

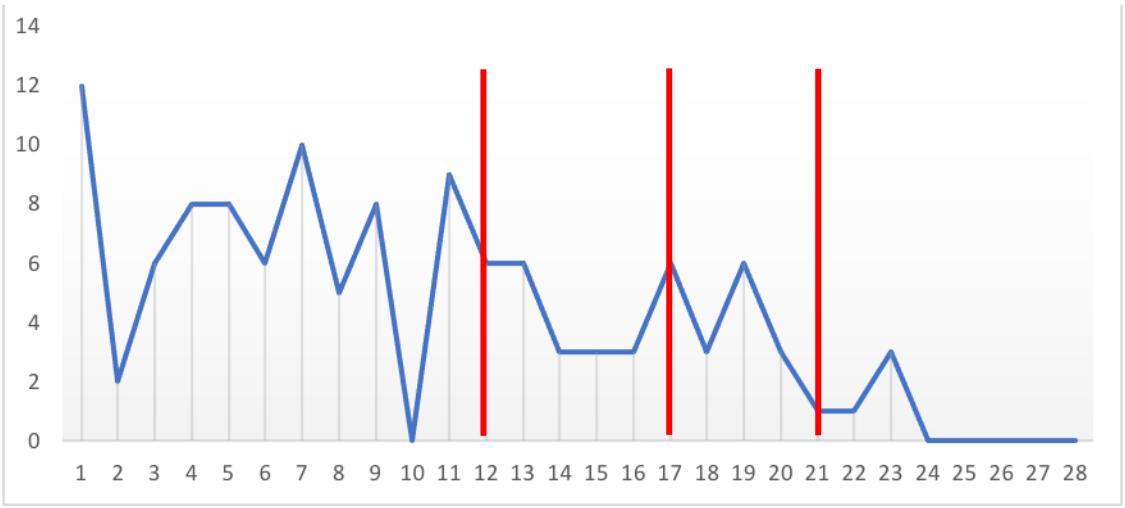

Figure 13. Social anxiety symptoms

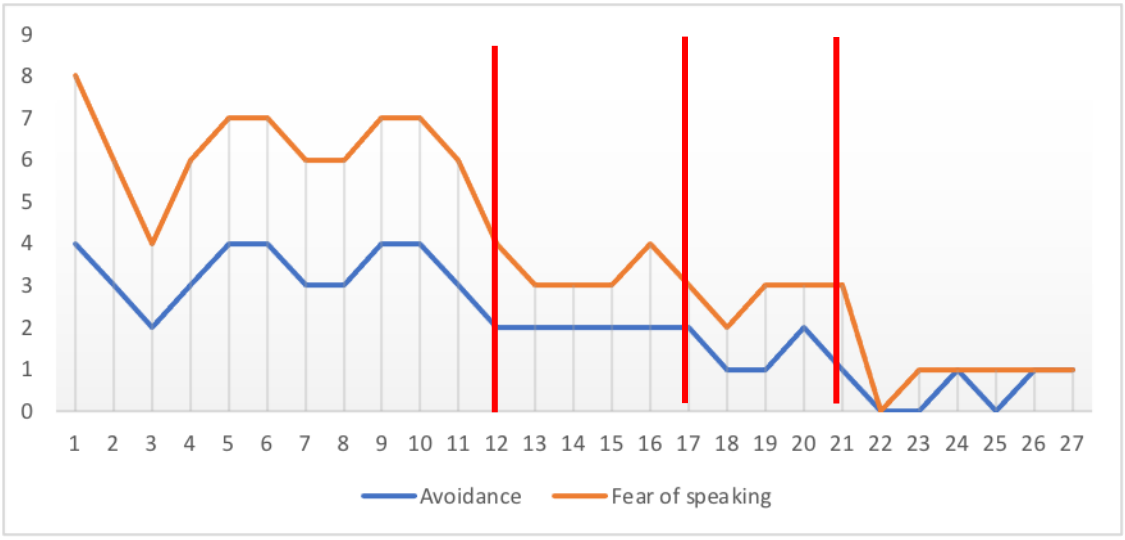

Figure 14. Fear of speaking and avoidance

Overall, a 93% of improvement in the social anxiety symptoms, which represents a high improvement. In fear of speaking and avoidance, an improvement of 100% was achieved. In the interaction with others, including perceived effectiveness and the enjoyment of interactions a total of 98.7% of improvement was reached. Regarding positive and negative affect, the treatment produced an improvement of 81%, which is a moderate improvement. Finally, in the four items of self-image an improvement of 100% was reached.

Regarding the intensive data recruited during the 10 previous days from the start of the treatment, it is possible to visually inspect a clear reduction in the use of putatively maladaptive ER strategies such as worry, post event processing, expressive suppression and experiential avoidance.

With regard to pre-, post- and follow-up assessment of self-report questionnaires, all revealed significant improvement. Indeed, reliable change improvement from pre to post with sustained results to follow-up were achieved.

Figure 15. Interactions with others

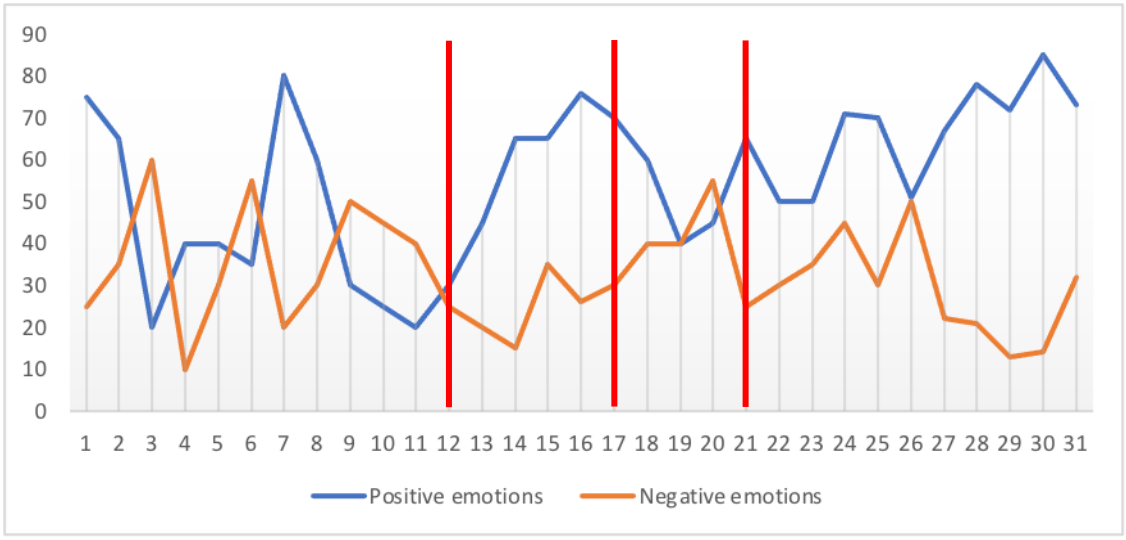

Figure 16. Positive and Negative Affect.

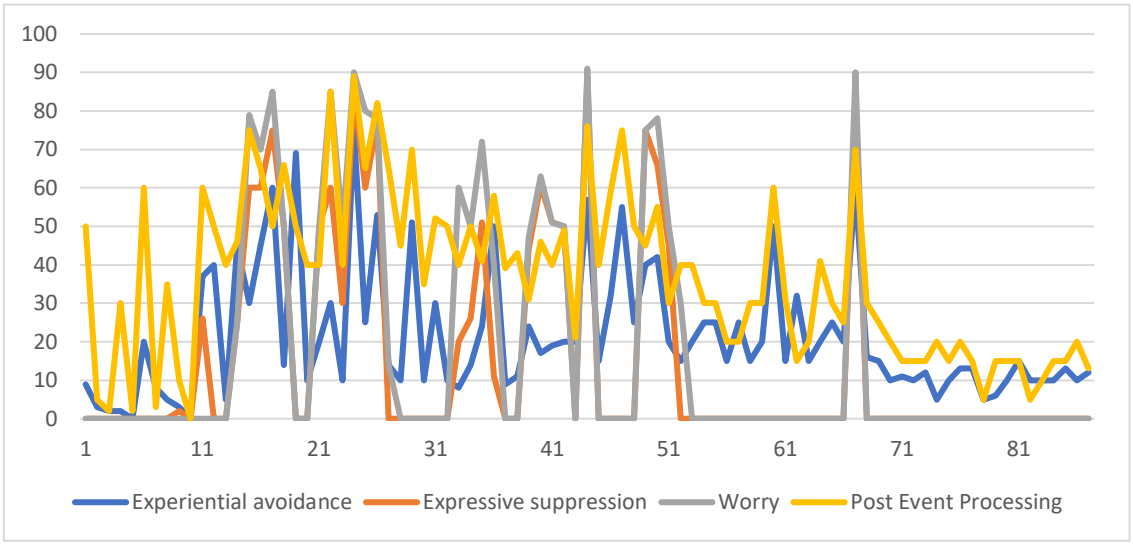

Figure 17. Intensive data ecological momentary assessment before the treatment – maladaptive emotion regulation strate

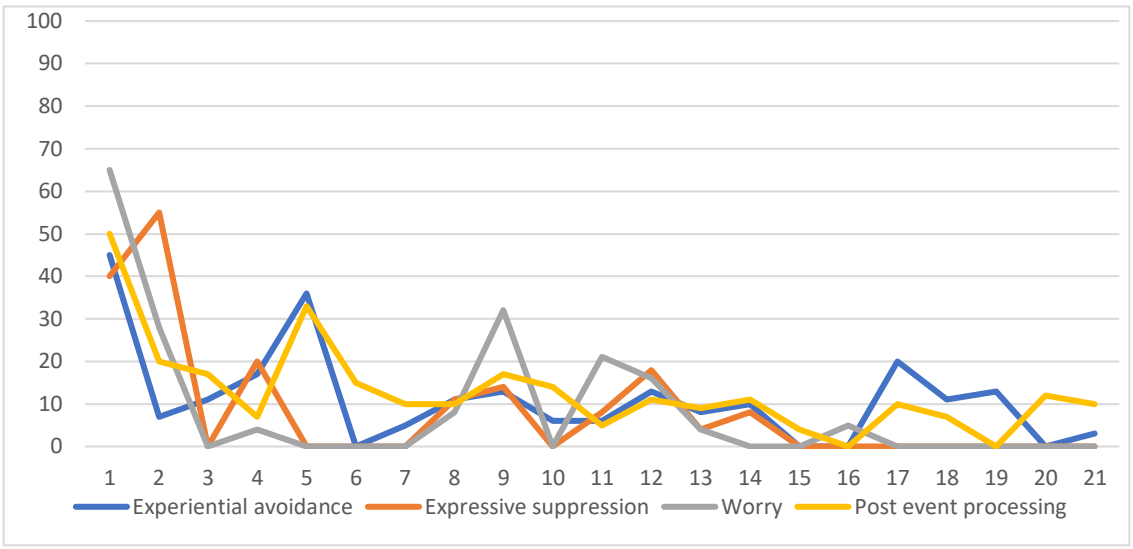

Figure 18. Intensive data ecological momentary assessment after the treatment – maladaptive ER strategies

Table 22. Pre to post self-report assessment of the primary and secondary outcomes

SCALE	PRE	POST	FOLLOW-UP
SIAS	54	13	16
SPS	63	15	10
BFNE	53	29	28
PSAS	62	46	48
PANAS_P	18	32	33
PANAS_N	13	14	13
DERS	71	17	23
OFS	26	33	34
SUIS	28	42	48
GSES-12	30	44	46
GAD 7	16	3	3
PHQ 9	16	5	3

SIAS: Social Interaction Anxiety Scale; SPS: Social Phobia Scale; BFNE: Brief Fear Negative Scale; PSAS: Public Speaking Anxiety Scale; PANAS: Positive and Negative Affective Scale; DERS: Difficulties in Emotion Regulation Scale; GAD 7: Generalized Anxiety Disorder; PHQ 9: Patient Health Questionnaire; GSES-12: Self-Efficacy Questionnaire General; OFS: Openness to the Future Scale

This study provided initial evidence regarding the feasibility of IR + VRET protocol as well as of its preliminary efficacy of IR given that an improvement in the symptomatology as well as core processes of SAD was achieved.

Overall, this study has the aim to build on the existing knowledge in the field of SAD, establishing the efficacy of a new concise and integrative protocol as well as providing clues regarding how and for whom such a treatment could be beneficial. If the protocol proves to be effective, the clinical implication is to implement it as the treatment of choice at the University Clinical Center of Jaume I University.

Most importantly, in the context of this dissertation this protocol is an explicit attempt to pursuit the integration of the DIU framework, given that it uses improving technologies (virtual reality), disseminating technologies (standalones virtual reality) and understanding technologies (biosensors to measure the treatment and ambulatory assessment).

4.3. Ambulatory based biofeedback

Just like VR, biofeedback also constitutes an improving or augmenting technology. However, when integrated to mobile or wearable devices they also can be considered a disseminating technology. In recent years, biofeedback technologies have been inspiring technology-aided clinical research. Table 23 gathers all the studies that utilized mobile forms of biofeedback in the field of ER for emotional and stress disorders.

This is the case of the discontinued StressEraser, a portable biofeedback device that was discontinued. In 2008 (Reiner, 2008), a clinical intervention exploited the concept of respiratory sinus arrhythmia (RSA) to deliver instructions to regulate breathing by means of biofeedback on a daily basis. The study, although acknowledging the need for further research, counted on 24 subjects receiving cognitive behavioral therapy (CBT) for a range of anxiety disorders. Assessment was provided for 3 weeks. The fact that StressEraser was a portable, low-cost biofeedback platform helped the subjects enagage in the prescribed instructions from home, a fact that laid the groundwork for a whole line of research studies. The scores achieved were kept in data logs that were later analyzed by the study conductors in order to assess compliance.

Likewise, StressEraser and RSA biofeedback was used in (Zucker et al., 2009). This study, building upon results that suggested a link between heart rate variability (HRV) and RSA biofeedback, highlighted the role of psychophysiology. Psychophysiology provided robustness to the psychotherapy results by the implementation of baseline pre- post-treatment measurements by means of professional electrocardiography (ECG) and electrodermal activity equipment (EDA) together with the description of HRV features and technical specifications used. The study addressed post-traumatic stress disorder and counted on 53 subjects.

In a combination approach towards chronic pain and depression, a pilot study (Tan et al., 2013) successfully used heart rate variability StressEraser biofeedback and cognitive behavioral therapy routines to argue in favor of the potential of low-cost accessible biofeedback platforms to reach people from rural areas. Graduate students were the scope of a biofeedback intervention StressEraser study targeting stress, anxiety and depression (Ratanasiripong et al., 2015). Although the authors raised concerns in the interpretation of results given the limited population sample (graduate students only), the 4-week study results supported the view that biofeedback interventions with breathing instructions were a cost-effective solution on the reduction of stress, anxiety and depression levels.

Alternatively, other platforms have been used in particular in the treatment of generalized anxiety disorders. This is the case of mobile-enhanced biofeedback VR exposure therapy. A study carried out by Repetto et al. (2013) showed that VR exposure therapy successfully tackled the need to have full control on the variables present in the target experience. In this case, biofeedback was presented as a means to modify properties the VR environment. Pre- and post-treatment baseline assessment questionnaires were accompanied by physiological baseline acquiring heart rate data and electrodermal activity levels. This study example, counting on the therapist input throughout sessions, highlighted the differences in using biofeedback-enhanced mobile-supported VR interventions as opposed to solely mobile-based VR interventions. The provided HTC phone was used as a stimuli and feedback interface giving access to real-time monitoring capabilities that inform about the intervention compliance and success.

A recent study has been conducted in depressive subjects, showing that mobile HRV biofeedback may constitute a complementary therapy. This is the first well powered study, given the fact that 92 subjects were included in the sample. Besides, it provides the first follow-up data, which is key to demonstrate that HRV biofeedback produces long term changes (Tatschl et al., 2020).

When present, the baseline assessment prior and after the controlled trials, together with the measurement of psychophysiological levels, turns out to be a relevant contribution to back up the results of biofeedback-based interventions. Moreover, the clear technical specifications and physiological features description enable the interdisciplinary efforts and knowledge transfer that has the potential to replicate and improve the biofeedback implementations reported.

Table 23. Evidence for mobile biofeedback in emotional disorders.

Study	Clinical condition / Design	Technology
(Tan et al., 2011)	PTSD: pilot open trial	Stress Eraser
(Zucker et al., 2009)	PTSD: pilot open trial	Stress Eraser
(Reiner, 2008)	Anxiety Disorders: pilot open trial	Stress Eraser
(Ratanasiripong et al., 2015)	Stress, anxiety and depression: randomized controlled trial	Not specified
(Tolin et al., 2017)	Panic Disorder: Quasi-experiment design	Freespira
(Repetto et al., 2013)	GAD: pilot RCT	A wireless (Bluetooth) multi-sensor module (GSR/HR Sensor Module)
Tatschl et al. 2020	Depression: RCT	Qiu (BioSign GmbH, D-85570, Ottenhofen, Germany)

.4. Mobile based Virtual Reality Biofeedback

VR can be considered as an advanced biofeedback tool that can be enhanced by utilizing mobile systems. A burning issue regarding biofeedback literature entails the difficulty to represent biofeedback

stimuli in order to achieve that people can be beneficiated from a more adaptive regulation of their emotions. To hurdle this stumbling block the integration of VR, biofeedback and mobile devices is vital and could mean a great leap forward for clinical psychology. Mobile devices and wearable biosensors can enable the transmission of real-time information related to psychophysiological states of patients' providing this data alongside the context in which a certain activity is carried out (Kusserow et al., 2013).

There is a lack of integration of VR and biofeedback in mobile devices. Besides, instead of specifically targeting ER, the main target has been in all these cases a specific disorder (specific phobia, PTSD, social anxiety, etcetera). There are some existing examples that addressed ER as the main target, but in those cases for healthy population and not for emotional disorders. Besides, they were mainly conducted from a human computer interaction (HCI) perspective rather than a psychological perspective. For example, (Lobel et al., 2016). Hence, although they have a great potential value for future clinical applications, so far there are no available results.

Besides, the integration entails the combination of biofeedback with other technologies, such as serious games and VR. Indeed, there is growing evidence of integrated examples for stress management and ER of VR biofeedback (Rockstroh et al., 2019). These examples, either for mobile or stationary modalities, have been also mainly developed in HCI context but scarcely applied to clinical populations. For example, van Rooij, Lobel, Harris, Smit and Granic (2018) developed a biofeedback VR game for children at-risk for anxiety. Besides, a range of other studies has combined VR with EEG, although also mainly based on a HCI perspective (Cai et al., 2017; Cho et al., 2003; Liu Mingyu et al., 2006; Othmer & Kaiser, 2002).

The great majority of the existing examples integrating biofeedback and VR have been conducted in healthy populations, for stationery VR modalities or only developed for design purposes but not for clinical implementation. There is one exception carried out by Repetto et al. (2013) but given the fast-paced growth of the hardware and software in this realm it is already obsolete and it is urgent the need for updated developments.

Given the described potentialities, a relevant approach would be to integrate mobile biofeedback techniques and VR for ER into psychotherapeutic settings as well as self-guided stress management trainings for people, for example, with difficulties in regulating emotions. Therefore, it is essential to count with research-based portable devices that may enable practitioners to incorporate biofeedback techniques not only into their clinical practices but also to be used by the clients within the sessions. For all the described reasons, the elaboration of a VR biofeedback intervention that targets HRV through a mobile device appears as an innovative and necessary technological development. Its main advantage is constituted by the possibility of providing an application outside the laboratory or the clinical settings.

From this systematic search of the literature two main conclusions can be drawn. First, there is a lack of integration of VR and biofeedback in mobile devices. Besides, instead of specifically targeting

emotion regulation, the main target has been in all these cases a specific disorder (specific phobia, PTSD, social anxiety, etcetera). As previously described the high rates of comorbidity and the already proven mechanistic nature of ER as a transdiagnostic process (Sauer et al., 2017) suggest that targeting ER, regardless the specific diagnostic tag, could be more effective and efficient.

Indeed, there are some existing examples that addressed ER as the main target, but in those cases for healthy population and not for emotional disorders. Besides, they were mainly conducted from an HCI perspective rather than a psychological perspective. Hence, although they have a great potential value for future clinical applications, so far there are no available results.

The integration of VR and biofeedback, either for mobile or stationary modalities, has been mainly conducted for design purposes but not applied to clinical populations. Among the examples that have to be highlighted, van Rooij, Lobel, Harris, Smit andGranic (2018) developed a biofeedback VR game for children at-risk for anxiety.

Besides, a range of other studies has combined VR with EEG, although also mainly based on a HCI perspective (Cai et al., 2017; Cho et al., 2003; Liu Mingyu et al., 2006; Othmer & Kaiser, 2002). Therefore, an app that could integrate VR and biofeedback in mobile devices is suggested as a novel progress that represents an integration of the different affordances that digital interventions have to offer.

Therefore, we aimed to develop a new application that could be specifically designed to regulate the psychophysiological markers of ER, and particularly designed to be used by people suffering from emotional disorders. Besides, given that the idea was to develop a tool that could be harnessed in the context of psychological treatments (e.g. as intersessions homework), the perspectives of clinicians was considered from the beginning of the development.

Throughout the process of elaboration of the app different prototypes were created until we reached the first final prototype to be tested in clinical population. The architecture of the Virtual Reality Heart Rate Variability Biofeedback App for Mobile Devices as well as to test the usability of the development. The test was carried out through expert evaluation, followed by tests with target end-users (both therapists and end-users) of the project's tools and services.

The evaluation made by the relevant stakeholders tested the navigation and interaction with the applications from a potential end user's perspective. In particular, this method aimed to test the representations in the applications in relation to understanding, intuitiveness, usefulness, clarity, and aesthetics in order to identify usability problems and propose solutions to the developer's team based on expert perspective before testing the applications with end-users.

This procedure allowed for the identification of episodes of breakdown during the users' interaction with early prototypes. Users were required to participate in task-driven using the initial prototypes. Users were required to perform a series of pre-defined goal-oriented tasks whilst being observed. To identify positive and negative user responses to the applications (including main usability issues and problems), users will be instructed to verbalize their thoughts as they interact with the

applications. Breakdowns were identified, discussed and examined; recurrent problems, the context in which they occurred and the ways in which users solved/overcame/surrendered to the problem. The result of this work redounded in a contextualized description of the main problems that occur during user interactions with the prototypes, taking into account the situation in which they occur, the specific courses of action to which they are linked and the circumstances accompanying them. The findings of this task will be used to refine the interaction design.

Software and hardware: In terms of software and hardware, the most relevant characteristic has been the pursuit of using consumer technology with the aim of enhancing the potential dissemination of the final version of the technology. Automated treatment delivered using consumer technology constitutes an undoubted way of providing potentially effective interventions at scale. If compared to other systems like the CAVE or tethered VR systems, standalone and mobile VR headsets are significantly more economic. Even if the level of immersion may be lower, research has shown that level of presence (that is, the sense of "being there") is determined at a certain extent but not entirely by immersive levels (Cummings & Bailenson, 2016).

Apart from the virtual environment development that entails the interdisciplinary work of psychologists, programmers and designers, the rest of the present technology can be considered a consumer-based technology. Besides, the application will be open source reason for which this initial cost does not need to be afforded for each clinician or end-user. As for the head-mounted displays, Oculus Go, Samsung Gear VR and Cardboard are the three hardware that were selected for the low prices and already massive penetration in the market. Besides, as long as a ubiquitous sensor was needed, we opted to connect the virtual environment to the CorSense sensor. Despite having a lower sampling rate compared to other sensors like Movisense, FirstBeat or Zephyr, CorSense is not only inexpensive but also unobtrusive, as no electrode or chestband has to be used. Instead, it is a photoplethysmography (PPG), which is considered a low-cost optical technique that can be used to measure blood volume changes in the microvascular bed of tissue. It has been demonstrated that even with less precision than ECG, it is accurate enough in order to calculate HRV.

CorSense Heart Rate Variability Sensor by Elite HRV (https://elitehrv.com/corsense) works via Bluetooth. The sensor transmits the raw signal (500 data per second; 500 Hz), which is stored in the phone memory. These data are in turn processed in the following way: (a) Calculation of the maximum peaks of the signal (derivative formula equal to zero with variability or similar); (b). Calculation of 5 indices, using simple formulas that are applied to the signal derived at point 1 (peak-to-peak). Furthermore, two VR environments developed with Unity 5 source codes were used.

Figure 19. Pictures of the mobile application

Usability test - The total sample comprised 14 university students (12 master's degree), aged between 23 and 28 years old, all single and 85% women. All the participants were Italian native speakers. Every participant except one had previous experience using virtual reality and 360 degrees camera videos.

System Usability Scale – The results of the system's usability using the SUS scale were 85 (SD= 9,11), suggesting that the acceptability was excellent.

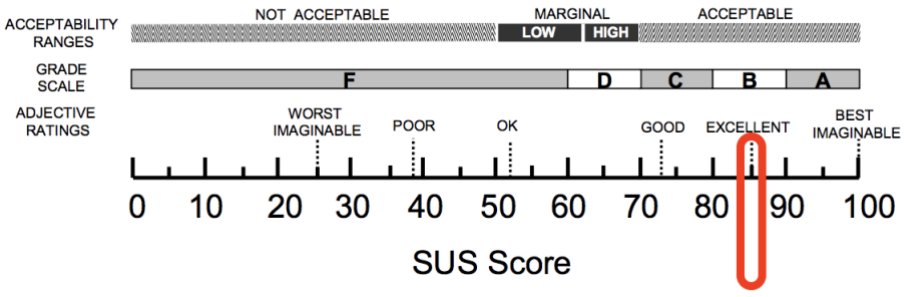

Figure 20. Global score of the SUS scale.

Flow State Scale - The flow scale represents the extent to which the users were engaged with the virtual environment. Overall, a high level of flow has been identified in the sample. This means that the participants were involved in the task.

A global score of flow was obtained calculating the mean of each score of the nine items of the short flow state scale. The mean score for all participants was 4.06 (SD = 0.25); the maximum score of each sub-scale is 5. A single dimension mean score is presented in Table 21.

Table 21. Scores of the usability flow scale.

Dimension	**Mean**	**SD**
Challenge-skill	4,4	0,82
Action-awareness	4,13	1,06
Clear goals	4	1,06
Unambiguous feedback	3,8	1,08
Concentration	4,33	0,48
Sense of control	4	0,78
Loss of self-consciousness	4,33	0,81
Transformation of time	3,8	0,77
Autotelic experience	3,8	0,94
Total	**4,06**	**0,25**

Overall, results yielded good usability of the system in all the measures. With regard to the qualitative interviews a much more interesting feedback could be obtained, identifying aspects in terms of the navigability and the design of the environment to be improved as well as very promising acceptability of the users in order to implement the system in different contexts. Taken together, these findings show that, despite some limitations, the system is usable and provides an enjoyable user's experience.

5. Discussion

Throughout this dissertation it was possible to map the current situation of digital interventions for the regulation of emotions in emotional disorders. In that sense, the DIU framework is proposed to organize the myriad of existing interventions. It outlines the three major affordances that digital technologies entail in the clinical psychological intervention realm: a) to facilitate the dissemination of psychological interventions; b) to foster the development of novel interventions that without the technological input would not be possible to implement and c) to enhance the understanding of the psychological interventions by means of digital phenotyping.

This DIU framework was applied to the specific case of ER, which is a very relevant transtheoretical and transdiagnostic mechanism of change of psychological interventions. Despite the fact that some relevant developments may have not been included due to the vastness of the field, this dissertation has sought to provide a coherent conceptualization of what ER is and how technologies

may facilitate the dissemination, development and understanding of innovative ways of addressing and studying regulatory dysfunctions.

Specifically, this dissertation puts the accent on the exploration of mechanisms of change in technologically based interventions. This is one the most relevant pending questions in a field that needs new and most compelling answers in this regard. As previously explained, mechanisms of change can be explored through different designs depending on the situation and possibilities. This dissertation has provided examples in three different and equally important designs.

5.1 Main contributions of this dissertation

The first study presented in this dissertation is a clear manifestation of how technologies can help to disseminate psychological treatments, in particular in a context like the pandemic in which there were restrictions to conduct in-person psychological treatments. This large clinical study explored the between and within-patient effects of ER on outcome in a sample receiving videoconferencing psychotherapy, that is, revealing that ER is a key mechanism of change that facilitates improvements in an overall outcome measure such as the OQ. These findings represent an unprecedent contribution in the field given that it was implemented in a naturalistic setting, maintaining the conditions under which the patients are treated as usual. Despite the fact the research design was observational, a rigorous approximation to the establishment of a causal effect of ER on outcome could be inferred given the significant within effects.

Furthermore, the second study also constitutes a novel finding to the exploration of mechanisms of change in internet interventions. The goal of the study was to disentangle of between- and within effects in the context of a RCT that aimed to decrease negative affect and potential positive affect. This treatment was a guided internet intervention that had shown significant improvement in the primary outcome measure (depression and anxiety). However, in the study presented in this dissertation we demonstrate both that patients with a greater level of positive affect as well as a lower level negative affect across treatment presented a lower level of symptoms during treatment, and that positive variations in positive and negative affect from patient's own mean across treatment were related with lower symptomatic levels in the next module. This study not only constitutes the first study to look into affectivity as a mechanism of change in internet interventions, but also the first in adults to study mechanisms of change beyond lineal mediation.

Altogether, these first two contributions are a clear manifestation of how the two purposes of this dissertation are reciprocally potentiated. Digital technologies may help to disseminate treatments and that permits to study how these treatments work. However, experiments specifically design to manipulate the mechanism of change are needed, including RCTs that have as the principal dependent variable the putative mechanism of change, or even newer methodologies such as sequential multiple assignment randomized trial (Southward & Sauer-Zavala, 2020) or microrandomized trials (Boruvka et al., 2015).

Next, a series of contributions on the other facets of the DIU frameworks have been presented. The two principal improving technologies are VR and bio- and neurofeedback. With regard to the first one, while there is ample evidence showing the efficacy, a major unanswered question revolves around the potential negative effects. Therefore, an individual patient meta-analysis exploring the deterioration rates in virtual reality was conducted, revealing that this technology yields similar deterioration rates as in vivo exposure and significantly less than waiting lists. Although it was described the implications for ER, it is clear that VR has not produce research on mechanisms of change like disseminating technologies, beyond aspects regarding the exposure principles (e.g. Shiban et al., 2013; 2014) and the technological aspects (e.g. Cummings & Bailenson, 2015; Ling et al., 2014). It will be of utmost importance that new research on mechanisms of change, for example ER, can be explored in VR exposure treatments

However, VR permits to facilitate many other interventions beyond exposure. Hence, a simple intervention was designed and tested based on consumer virtual reality hardware and a freely open-source application such as *Google Earth* VR. Using a single case experimental design and ambulatory assessment, this intervention was suggested as a way of upregulating positive affect and positive emotions by means of positive autobiographical memory recall. Moreover, this type of design is an optimal design when larger studies are unfeasible given that each individual act as their own control.

Meanwhile, bio- and neurofeedback interventions are increasingly integrated to psychotherapy, what their actual contribution is still a matter of discussion. Given that bio- and neurofeedback had been meta-analytically studied for anxiety but not for depression, a meta-analysis on depressive symptomatology in major depressed patients as well as patients with other conditions was conducted. Both HRV biofeedback and neurofeedback showed to be important contributors to depression, and this can be explained given that both the autonomous circuitry and the neural circuitry on which operate HRV biofeedback and neurofeedback respectively, are key indexes of ER functioning.

Undoubtedly, one of the most powerful uses of technology is to help to understand how psychological treatments work. That is, apart from intervening through the different technologies by means of disseminating or improving technologies, a major affordance of novel digital technologies is to incorporate them in technologically based or not technologically based treatments to assess both through the so-called passive assessment and active assessment.

In that sense, an overview of the behavioral and psychophysiological has been presented, and particularly a comprehensive review of the role of vagal tone to the process and outcome of psychological treatments. Besides, the contributions of ambulatory assessment are described. It is expected to especially increase its importance given that it permits to track both passive and active dynamics in real-world settings.

Finally, the integration of the DIU framework is presented as the principal future avenue to expand the role of digital technologies. There are already available examples of mobile just in time interventions that gathers clinical data, usually using ambulatory assessment, and based on that data

trigger personalized interventions. There are also mobile and standalone VR as well as mobile biofeedback developments. Taken together, these are all examples of how the DIU framework can be integrated combining in different ways the aforementioned affordances of digital technologies.

In that sense, two examples of integration of the DIU framework that have been developed for this dissertation are presented. First, a protocol to integrate standalone VR and ambulatory assessment prior and throughout the treatment. It is designed to explore mechanisms of change in different and novel ways, such as an intensive ecological momentary assessment before and after the treatment. Besides, it integrates exposure to imagery rescripting, a powerful integrative intervention that operates on distressing dysfunctional memories that are particularly activated and therefore experienced with high intensity. Apart from the protocol, a case study is presented as a proof of concept.

Finally, the development of a mobile based VR biofeedback application is presented. This application is one of the first to integrate VR and biofeedback in mobile devices, and particularly directed to target heart rate variability. It represents a cutting-edge concept of integration that permit to trigger interventions when needed, harnessing the affordances of portability (dissemination) as well as VR and biofeedback (improving). Preliminary data of its usability was provided, as well as some details and illustrations of the development process.

Apart from adding evidence about ER as a mechanism of change through different technologies, this dissertation also makes a contribution to the discussion of ER as a complex construct. First, across the studies different facets of ER were considered. While in some (e.g. the two SCEDs) different strategies were included, in the VCP study an overall measure of the difficulty of ER was considered. Meanwhile, in internet intervention an overall measure of affect that included items of positive affect and items of negative affect was included. Finally, the VR biofeedback mobile based application incorporated an established physiological marker of ER like heart rate variability.

Besides, as described in the introduction, there are two core systems that regulate people's emotions and behaviors. While the vast majority of interventions are designed to tackle the avoidance system or negative affectivity, it is also of utmost relevance the increasing evidence that is being produced to address the appetitive motivational system and the evidence emerging in digital technologies is not unconnected to this phenomenon that is occurring in the whole clinical psychology realm.

This dissertation provided new evidence with regard to two technologies. On the one hand, the study concerning mechanisms of change in internet interventions contribute to the existing evidence on positive affect regulation in emotional disorders (Carl et al., 2018; Craske et al., 2019; Dunn et al., 2019). Moreover, the study of VR demonstrates how digital technologies can be harnessed to create novel interventions that may help people to promote positive emotion and affect regulation. It constitutes one of the first available examples using VR to address the impairments in the approach system that people with emotional disorders present. The reward system includes three parts: anticipation or motivation for reward, responsivity to attainment of reward.

Besides, technology can bolster the study of unexplored facets of ER. That is, both basic experimental research and applied clinical research on ER have been dominated by a simplistic view of ER, in which the complexity described in the introduction is reduced to single strategies. Interpersonal, spontaneous, and polyregulation are three dimensions of ER that have not been much explored and that may be of most importance for psychological treatments.

Supporting interpersonal ER through digital technologies can be pursued through different ways. For example, VR applications may offer the possibility of interacting through with other users or avatars in virtual environments (Morina et al., 2015). In a near future, psychotherapy group treatments could be complemented with these applications. Likewise, interpersonal biofeedback is starting to emerge, although there are no concrete developments for the improvement of ER in clinical populations yet (Kleinbub et al., 2020).

Finally, people have demonstrated to use simultaneous strategies (Ford et al., 2019), and together with the study of flexibility and spontaneous emotion regulation, it is increasingly pursued the exploration of the process in real life settings. The combination of AA and novel computational techniques may provide new answer for these unexplored topics.

5.2 The future of digital technologies in psychological treatments

Overall, digital technologies are increasingly used in people's everyday life. Certainly, remote human interaction will increase in the upcoming years. This has already been happening for at least a decade. Yet, the outbreak of the pandemic has notably accelerated this process. Psychological interventions will definitely not be the exception, and therefore it is crucial to outline how the field will be transformed in the near and long term. Most probably, the implementation of digital interventions will continue to increase in the coming years (Norcross et al., 2013), and this will happen in a context of decline in the consumption of psychotherapy (Hayes et al., 2019). Therefore, the highest standards to differentiate psychotherapy from pseudoscientific disciplines and demonstrate the value of incorporating psychotherapy into the ever-growing pharmacological treatments should be pursued.

As a consequence, it will be of utmost importance to integrate dissemination and augmentation, particularly using mobile and ubiquitous technologies. Some examples are already available but there is no doubt that this is one of the most unexplored areas in the field of digital clinical interventions. It has been already noticed the need to change the classical research method in the field of technologies. If non-digital technologies fail to produce effective translation processes with the current research designs, much more effort is needed in technological research. All technological developments are characterized by their rapid change and obsolescence is the rule. Mohr et al. (2017) states that the novel designs are required to test the effectiveness of technologically-based interventions. For example, for the evaluation of JITAIs as well as other technologies microrandomized trials may serve as an optimal alternative to test not only the effectiveness but also the mechanisms of change (Boruvka et al., 2015). Factorial designs are also an interesting unexplored option (Watkins & Newbold, 2020), with some

recent examples in the evaluation of internet interventions (Hadjistavropoulos et al., 2020). Finally, a very promising thing is the renewed interest for SCEDs (Dallery et al., 2013), and this dissertation is prove of it with two studies using this design.

Many of the most recent innovative have not been tested in clinical populations. That is, in human computer interaction there are a wide range of cutting-edge developments that could be of great help in order to improve the usability and affordances of technology in clinical settings. However, there is an unarguable gap between HCI and clinical psychology, which prevents from a fluid translation of knowledge. Moreover, the gap between research and practice constitutes yet another gap that prevents from implementing scientific knowledge in the clinical field. Altogether, it is fundamental to enhance the collaboration between engineers, HCI, data scientists, clinical researchers and practitioners (Mohr, Weingardt, et al., 2017). Hence, it is suggestable that future research, not only in the field of ER, considers the wise proposals delineating this problem as well as proposing potential alternatives to hurdle the obstacles (Castonguay & Muran, 2015; Mohr, Weingardt, et al., 2017). Otherwise, technological development will not be able to fulfill one of the main purposes for which it was suggested in clinical psychology that is the dissemination to reach people that otherwise could not receive psychological treatments.

It is indispensable that innovative targets have been recently proposed in the HCI field can be translated into feasible and applicable therapeutic tools. An example is the haptic biofeedback to target other relevant physiological processes for ER, such as the gut (Miri et al., 2017). In the field of HCI, intelligent systems for predicting a person's affective state (Mcduff et al., 2012) and fostering self-awareness (Ståhl et al., 2009) have received increasing attention, using for instance novel interaction methods such as smart materials (Umair et al., 2018) or adaptive virtual environments (Roo et al., 2017) that respond in real time to one's affective state. Overall, there is a burgeoning production in the HCI field that should be harness, including wearables (Choi & Ishii, 2020; Costa et al., 2016; Umair et al., 2018, 2019), integration of serious games and VR (Lobel et al., 2016; van Rooij et al., 2018), among others.

The collaborative effort between HCI, engineers and clinical psychologies should derive in fostering JITAIs. Commercial devices are increasing the accessibility of technology as a result of their low cost and easy-to-use interfaces. If that penetration of technology is articulated with applications specifically designed for clinical interventions, the potential is enormous. Emerging sensors and biosensors, which evolve towards unobtrusive platforms, have the potential to provide more complex biofeedback interventions (e.g., connected to virtual or gamified environments) or even develop EMA and EM triggered by physiological states and behaviors.

When using existing biosensing platforms to support or create new interventions with information derived from physiological signals, several characteristics come into play to assess the advantages and drawbacks of available commercial and research solutions. Whereas research developments open the design space and lie closer to sensor innovations, end user scenarios require a

more constrained product. Besides the technical support, wearability and ready-to-use form factor play a key role. Furthermore, the digital resolution and the signal sampling rate, i.e. the frequency sampling at which every signal is acquired, have also an impact on the accuracy of the acquired signal as well as battery autonomy, essential when creating longitudinal ecological assessment studies. The availability of desktop and mobile apps for real-time data visualization and processing, for instance, are relevant aspects to consider in any out-of-the-lab research study.

A problematic issue is the limited adoption of all evidence based digital technologies, either by mental health professional or through self-help interventions. The problem of adoption constitutes an issue that can be better understood and potentially addressed if the gap between research and practice that characterizes the field of clinical psychology is considered. As shown by Lipschitz and colleagues (2019), a great number of people who regularly use apps, do not use mental health apps even if they express interest in them. In this sense, this study revealed that ratings of interest in using an app were higher if recommended by a clinician. Hence, different authors like East and colleagues (2015) suggest that professional associations have the ethical responsibility to have a deep knowledge and disseminate evidence-based mental health mobile apps. The same applies for the rest of technologies.

If that interdisciplinary articulation could be achieved, technological developments would feed a virtuous circle of research and practice and the best available evidence would be implemented in the real world. So far researchers and clinicians do not collaborate actively enough, and thus scientific knowledge does not reach to have the expected impact on clinicians' decision making.

Although clinicians tend to spontaneously adapt their approaches to the particular needs of patients, it has been observed that these adaptations are made mainly on the basis of intuition and not in a systematic way (Gyani et al., 2014). In the field of clinical psychology models of personalization have recently emerged, aimed at determining forms of adaptation of treatments, based on individual characteristics of patients (Cohen & DeRubeis, 2018). One of the main lines of research has focused on making clinical predictions, using information collected before the start of the treatment (Cohen et al., 2020).

In that vein, technological applications, in particular AA, may play an instrumental role. AA has already started to be incorporated to many studies, this may of relevance given the fact that is both informative for clinical practice as well as useful to recruit naturalistic data. It is expectable that AA will be further incorporated into the routine practice. Together with advances statistical methods, such as multilevel structural equation modeling or complex network analysis, AA may provide the opportunity to shed light upon how and for whom psychological treatments work, including the mechanistic role of ER (Hofmann et al., 2020).

Likewise, machine learning algorithms are models that allow making predictions based on the identification of patterns in the data, which can be validated in new samples (Delgadillo, 2021). These algorithms build a model based on sample data and iterative training processes, generating automated learning that enables the formulation of predictions about a specific problem without the existence of

an a priori model explicitly designed by the researcher. In the area of mental health, some of these algorithms have been used to determine the probability of therapeutic success, identifying patients who have a high probability of not responding to a conventional approach and who require possible clinical adaptations (Gómez Penedo et al., 2021; Hilbert et al., 2021). Another development that has been developed to predict the best available treatment for a single individual is the Personalized Advantage Index (PAI) (Cohen & DeRubeis, 2018). Also, algorithms have been developed to predict differential effects of different treatments (Schwartz et al., 2021), as well as the effect of mechanisms and processes of change (Rubel et al., 2020).

Lutz and colleagues (2019) have not only adapted this principle to be applicable to naturalistic settings of psychotherapy delivery but they have also incorporated ER as a key variable. This development should be taken as the best available illustration of how research and practice can be mutually reinforced, and particularly using advance technological methods. Moreover, this would help to study mechanisms of change and better determine what works for whom under what conditions and what does not work for whom under what conditions.

It will be of paramount importance that AA can be applied into naturalistic contexts. Usually, these technologies are disregarded, given the incompatibility with therapists' needs, lack of therapists' training on how to use those technologies, unaffordable prices or even simple therapists' reluctance to incorporate them. However, the appearance of open-source software, the increasing evidence showing how these tools can support the therapeutic work, and the availability of simple feedback systems, suggest that in the upcoming years they will be implemented more and more in routine practices.

With regard to disseminating technologies, such as asynchronous internet-based interventions, they have been increasingly incorporated to certain regions such as Sweden, Denmark, Canada, Australia and the United Kingdom (Titov et al., 2018). It is clear that the experiences of these countries are worth of consideration. Nonetheless, 80% of the world population lives in low and middle income countries, and research has demonstrated that people living in financial hardship tend to present higher risks of developing mental disorders, but paradoxically are those who have less access to psychological treatments (Frankham et al., 2020).

Luckily, there is an increasing number of cultural adaptations (Salamanca-Sanabria et al., 2020) and we can expect that they will become more usual for the routine care in disadvantage regions. Indeed, there are already reviews and meta-analysis synthetizing the available evidence regarding how digital technologies can help to disseminate psychological treatments (Carter et al., 2021; Fu et al., 2020). The drawback of this literature is that all the evidence come from RCTs based on a categorical classification, and therefore does not take into account the transdiagnostic perspective and the exploration of mechanisms of change. With the ever-growing interest for mechanisms of change, it is expectable that more applications will be created following this conceptual perspective. In this sense, this dissertation presents one contribution conducted in Argentina, a global south country listed in the low- and middle-income countries, and particularly focused on exploring the role of ER as a mechanism of change.

Besides, real world implementation of digital psychological treatments would mean strengthening the active collaboration between researchers and practitioners, redounding to the proliferation of practice research networks in which the practice is evidence based and the evidence is practice-based. That would mean a reciprocal enrichment both for practitioners and researchers (Louis G. Castonguay et al., 2015). However, the context of the pandemic undoubtedly facilitates the possibility of improving the attitudes of therapists and consultants towards technologically-based interventions (Wind et al., 2020). Accordingly, a brighter future can be expected if more collaborative research in naturalistic settings occurs. In this sense, the study conducted with a sample of patients undergoing a psychotherapeutic intervention during the pandemic in a naturalistic context and through videoconference, is a clear example of how technologies can be of tremendous help in a context of need for people who otherwise would not have received any intervention.

While understanding and disseminating technologies have already occurred and are helping to decrease the burden of mental health, improving technologies by means of adding new aspects to the clinical practice that without technology is not possible, is still a challenge to become a reality. However, the examples presented in this dissertation are an example of both aspects: how technologies can be further adopted in the real world with an articulated between disciplines and how emotion regulation can be a mechanism of change of these interventions.

The role that technologically based treatment will have in the future of psychological treatments. That is, for many clinicians the use of remote modalities constitutes a suboptimal resource that is necessary in order to continue their work. However, many stakeholders consider this an efficient way of increasing the prevalence of mental health treatment. Although many therapists may indeed prefer this modality, and for a range of mild conditions it is proving to be equally efficacious, the possibilities of in-person therapy seem to still be superior.

Some years ago, David Barlow (2004) established the difference between psychological treatments and psychotherapy, proposing that for public health and in order to decrease the burden of mental health, brief protocolized procedures may play an instrumental role. In that sense, there is an ever-growing body of literature demonstrating that low-intensity digital interventions can help to improve access to treatment for common mental disorders (Andersson et al., 2019). However, psychotherapy most often differs from other psychological treatments in the sense that the main objective is not only symptomatic reduction but also the reorganization of the personal system and the improvement of the quality of life. Both should coexist and could be simultaneously harnessed in order to improve the situation.

Moreover, technologies such as VCP or blended treatments with unguided and guided interventions or even improving technologies (i.e. biofeedback and VR) can be integrated with psychotherapeutic interventions and harness the *best of all possible worlds*. In this vein, digital interventions will definitely be further expanded and hopefully integrated as a modality through which complex psychological interventions can be delivered.

The three aspects of DIU framework, together with the cutting-edge perspective on transdiagnostic processes and mechanisms of change of psychological treatments, aim to make a modest contribution toward the articulation between research and practice. Overall, this dissertation boosts the discussion concerning some of the current debates in clinical psychology and suggests theoretical and empirical answers in order to improve the field.

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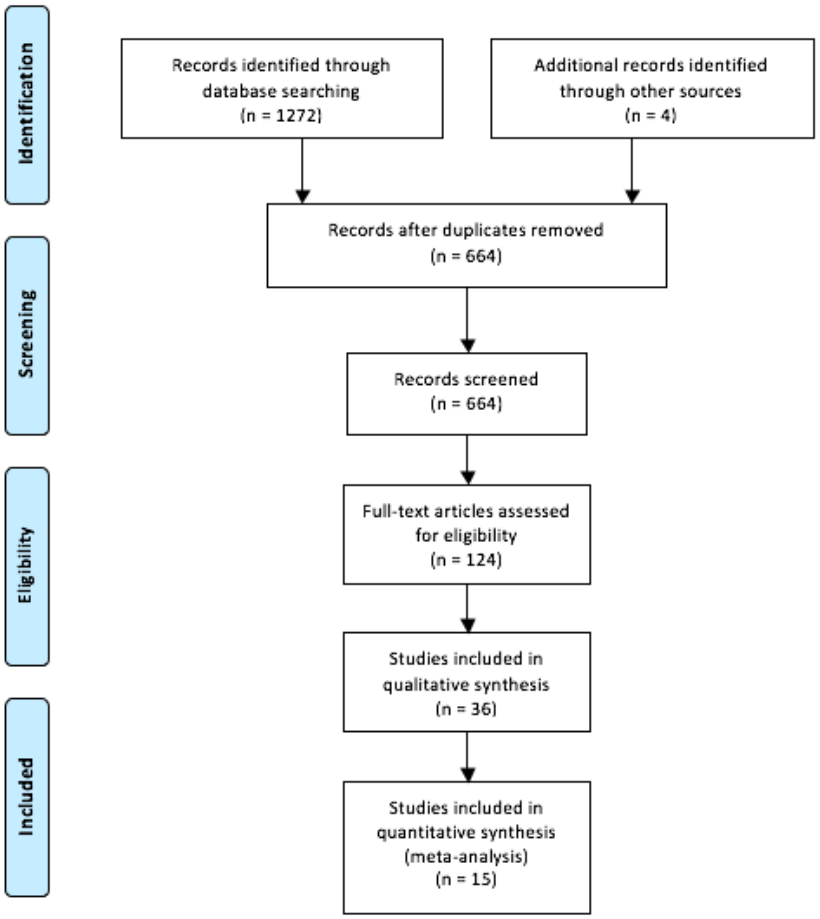
Appendix

Appendix 1: Flowchart

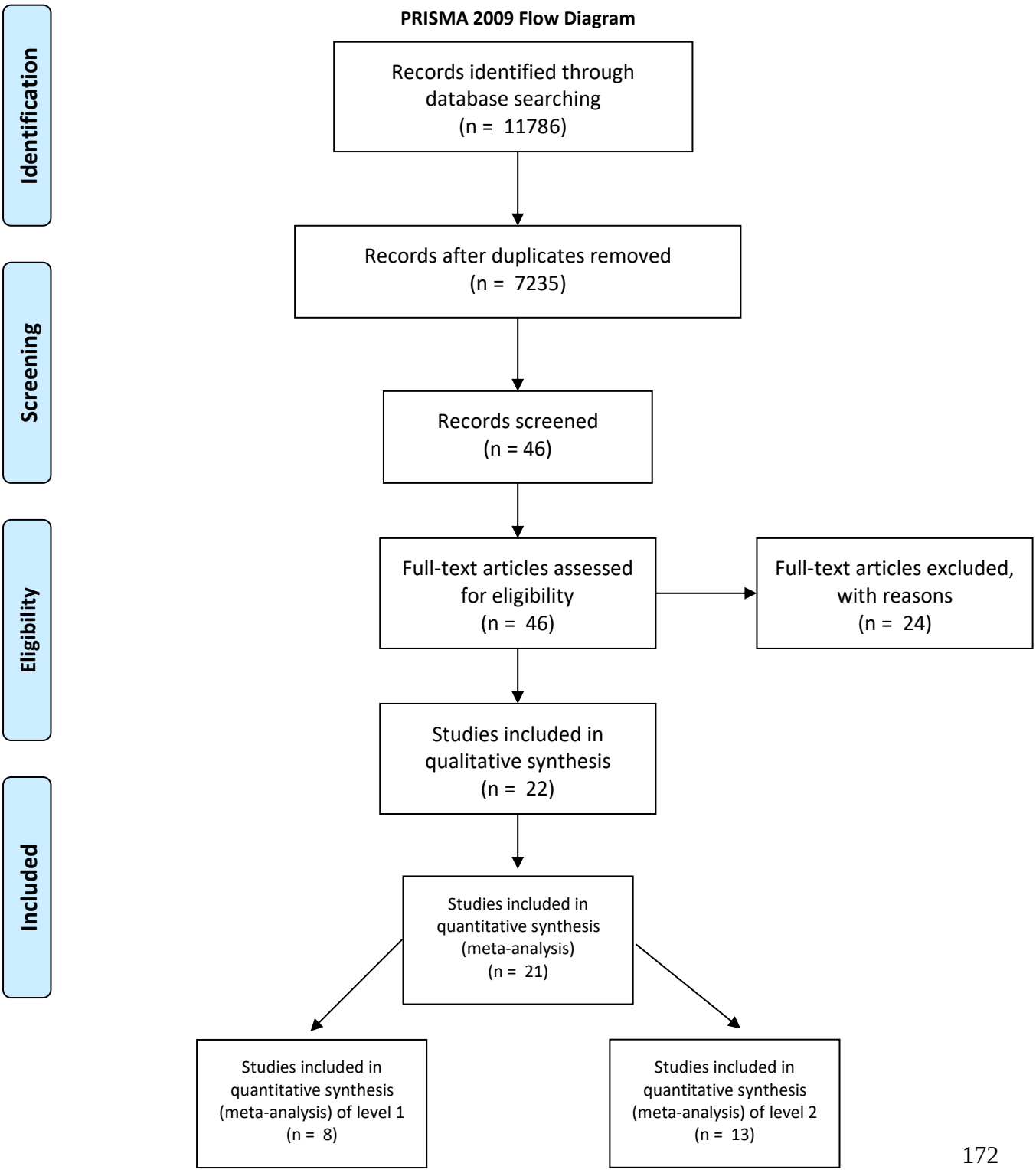


Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Diagram of selected studies.

Pubmed string strategy

((virtual reality) OR (virtual reality exposure therapy) OR ((virtual reality) AND (exposure))) AND ((anxiety disorder*) OR (obsessive compulsive disorder) OR (OCD) OR (general anxiety disorder) OR (GAD) OR (fear of falling) OR (arachnophobia) OR (post traumatic stress disorder) OR (aviophobia) OR (flight phobia) OR (fear of flying) OR (phob*) OR (social anxiety*) OR (SAD))

Appendix 2


PRISMA 2009 Flow Diagram
Identification
Screening
Eligibility
Included
Records identified through database searching (n = 11786)
Records after duplicates removed (n = 7235)
Records screened (n = 46)
Full-text articles assessed for eligibility (n = 46)
Full-text articles excluded, with reasons (n = 24)
Studies included in qualitative synthesis (n = 22)
Studies included in quantitative synthesis (meta-analysis) (n = 21)
Studies included in quantitative synthesis (meta-analysis) of level 1 (n = 8)
Studies included in quantitative synthesis (meta-analysis) of level 2 (n = 13)

Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Diagram of selected studies.

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	-
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7

Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	7
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Figures
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9 & 10
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7, 8, 9
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Table 1 and table 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	-
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10, 11 & 12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12 & 13
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	15

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