

STUDY PROTOCOL

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# MindRegulation-SEL: randomized controlled trial of the effects of a relaxation and guided imagery intervention with socioemotional learning on the psychological and biophysiological well-being, socioemotional development, cognitive function and academic achievement of elementary school children

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## Abstract

**Background** Mental imagery has long been used in psychological therapies, but only recently did research begin to provide a scientific background for it. Imagery interventions are inexpensive and a substantial body of research supports their effectiveness on anxiety reduction, behavior change, promotion of health outcomes, and adherence to medical interventions, in both adults and children. However, literature on the benefits of relaxation and guided imagery interventions for children in elementary school context is very scarce. This randomized controlled trial (RCT) aims to contribute to that knowledge by implementing and testing the benefits of an intervention program MindRegulation-Socioemotional Learning (MR-SEL) comprising breathing and progressive muscle relaxation, instructions for body posture, and guided imagery with socioemotional learning, conveying adaptive beliefs about oneself, the relationships with others and the environment.

**Method** The MR-SEL intervention will be developed in the classroom for 15 min before learning activities, three times per week, for 5 months, and its effects will be measured on a range of psychosocial and emotional, biophysiological, and cognitive outcomes. Seventeen classes will be randomly assigned to three conditions: (a) relaxation and guided imagery with SEL (MR-SEL); (b) relaxation only; and (c) waitlist control. The RCT includes four data collection times: pretest, intermediate, posttest, and a 6-month follow-up. The sample comprises 259 students, elementary school third and fourth graders, 8–11 years old. The variables measured are well-being, affect, anxiety, emotional regulation, socioemotional competencies, attention and processing speed, and perceived benefits of the intervention. Physiological indicators of emotional arousal, emotional regulation, stress, and well-being are also taken, specifically,

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heart rate variability, electrodermal activity, actigraphy, and salivary DHEA-S and cortisol. The validity of the measures will be tested for the population and objectives of the study.

**Discussion** Significant improvements on the children's well-being, socioemotional regulation, cognitive function, physiological activity, and academic performance are expected after 5 months' intervention at posttest and 11 months' follow-up at MR-SEL condition, compared to the relaxation and control conditions. Changes in physiological activity are expected during MR-SEL and relaxation sessions. Emotional regulation, well-being, and anxiety are expected to mediate the effects of the interventions over socioemotional competence, cognitive function, and academic performance. Well-being and anxiety levels at pretest are expected to moderate the interventions' effects.

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**Keywords** Relaxation, Guided imagery, Self-regulation, Socioemotional development, Randomized controlled trial

## Background

### Mental imagery interventions

Mental imagery has long been used in psychological therapies, but only recently has research started to provide a relevant scientific basis [1, 2]. Imagery interventions are inexpensive and have a body of research supporting their effectiveness on behavioral change, promotion of adaptive health outcomes, reduction of anxiety, and adherence to medical interventions [3, 4], as well as improving sports performance [5] in adults and children. However, literature on the benefits of relaxation and guided imagery interventions for children in elementary school context is very scarce. Evidence of the effects of these interventions on well-being, socioemotional competences, emotional self-regulation and behavior, cognitive function, and academic achievement are lacking or have limited scientific validity, with a very low number of RCTs and reduced sample sizes [6].

The pertinence of testing the effects of interventions involving relaxation techniques and guided imagery to promote Social and Emotional Learning and well-being in children is supported by several identified needs: (I) the well documented rise of anxiety in children and adolescents since 2007, which increased after the COVID-19 pandemic (from 11.6 to 20.5%) [7–9], (II) the need to elaborate SEL programs for the development of children and societies was stressed by the international agencies [10, 11] and by the 2030 Agenda for a Sustainable Development [12]; (III) responding to the mental health crises, the need to promote the well-being of children as an important baseline for their cognitive, social, and academic development [7, 8].

Addressing the identified needs, this RCT aims to test the effects of a relaxation and guided imagery protocol for a SEL intervention—on the psychological and physiological well-being, cognitive function, and academic achievement of elementary school children, in comparison with a relaxation intervention and a control group.

### Mental images

Mental images are based on memories, full or partial, but also on the projection of future events. These “flash-forwards” may refer to different themes or life domains, and evoke different positive and negative emotions [13]. Brain imaging studies indicate that neural representations of mental images and perceptions of actual pictures are similar [14]. Thus, “imagining a walk on the beach with all the associated sensory qualities can lead to emotional processing that is similar to an actual walk” [6]. Mental imagery refers to the representation of sensory information without external stimulation, a perceptual experience without the sensory input, like seeing with the “mind's eye.” [15]. Mental imagery can occur in various sensory forms, including visual, auditory, gustatory, and physical sensations [16], and it may trigger emotions like joy, sadness, and fear [1, 17].

Guided imagery is more specific because it involves a practitioner verbally leading a person through the processes of mentally representing and visualizing situations in their mind. These mental representations may occur through various sensory experiences, sights, and feelings associated with them. Details about places and events can make the experience more realistic and vivid [18]. Relaxation-guided imagery for children is generally comprised of a combination of behavioral interventions (body relaxation) and cognitive interventions (guided imagery), which is non-invasive, self-regulative, and appropriate for children and adolescents. It consists of three “active” phases that generate new internal experiences, unlike the passive act of relaxing [19]: Body relaxation helps the child to focus on the body and to progressively release muscle tension from the feet to the head, by taking deep breaths; Imagery is a spontaneous or deliberate mental reconstruction of sights, sounds, smells, tastes, and feelings as if they were actually occurring. During this phase, the child is asked to visualize a favorite place, whether real or not, using the same words for each participant; and returning to reality, the child remains in the chosen

place for a while, knowing that it could be visited any time he/she wants; then, contact with the surrounding environment is gradually resumed until the child opens his/her eyes.

### Theoretical models of mental imagery effects

Initial attempts to explain the effects of mental imagery on behavioral outcomes have put forward two probable processes: (I) mental imagery facilitates effective behavioral regulation by reinforcing the link between thought and action directed toward goals [20]; and (II) mental imagery strengthens reciprocal relationships between mental imagery, emotional memory, and physiological responses [21]. The later would happen by activating physiological and behavioral responses and neural activity consistent with emotional responses [22, 23]. These activations would be expected both from hardwired emotional response systems comprising associations between typical situation appraisals and physiological responses [24] and from experience based stored associations between interoceptive and subjective states [25]. Additionally, the rehearsal of actions through mental imagery has been theorized to involve a neural basis, through which the consistency of mental imagery practice is important to maintain the performance of behavior over time [26].

Taken together, these approaches indicate that mental imagery may serve to activate links between stored representations of action and physiological and behavioral responses. Thus, imagery interventions facilitate behavior change through non-conscious processes, beyond the person's conscious will of the behavioral change [27]. This approach is consistent with empirical research examining the neural bases of the imagery effects on behavior [28]. Besides verbal-based thoughts, mental images may create a cognitive subsystem that is strongly linked to emotions, inducing physiological responses that are often beyond conscious control [29]. Supporting these theoretical models, a meta-analysis of 33 guided imagery studies on health effects showed that imagery interventions were more effective on behavioral and physiological outcomes than on psychological outcomes [3].

Another perspective on the underlying processes of the effects of guided imagery on behavior focuses on its main objectives or goals. It also distinguishes two types of processes: (1) *the outcome simulation* consists of mental imagery related to goal rehearsal or goal-setting technique—which works by envisioning oneself reaching a goal, which is expected to facilitate one's self-efficacy and the necessary action to achieve that goal [30]; and (2) *the process simulation*—consisting in imagining the step-by-step process one must follow to achieve a desired goal,

which is expected to enable a person to achieve that goal by prompting goal-directed actions [31].

In turn, [32] analytic framework of imagery comprises four functions that serve both cognitive and motivational roles that operate either at a specific or at a general level. For instance, considering the sports activity as an example, *cognitive specific imagery* would involve images related to specific sports' skills, whereas *cognitive general imagery* would include images pertaining to routines, strategies, or plans. *Motivational specific imagery*, in turn, would refer to images of goal attainment or goal-related behavior, whereas *motivational general imagery* would refer to images related to physiological arousal levels and emotions. Motivational general imagery can be further divided into motivational general-mastery, through images related to being mentally tough, self-confident, and in control, and motivational general-arousal, through images related to arousal and excitement [33].

Another perspective, closely related to the motivational perspective, uses the *self-determination theory* as a framework to explain how guided imagery can promote the development of specific behaviors. That is, action can be developed from intrinsic motivation [34] and guided imagery interventions can promote intrinsic motivation [35]. Guided imagery scripts may produce images of oneself being skilled at some kind of performance, such as sports or academic performance, social interactions, active play, self-regulation of emotions, and behavior. Thus, these images can stimulate intrinsic motivation and produce behaviors to make them come to reality. Creating vivid images is important to the success of guided imagery interventions and the achievement of higher intrinsic motivation [21, 35, 36]. The process of behavioral change of guided imagery interventions appears to occur by changing individuals' beliefs or internal states, promoting one's confidence and self-efficacy, or more effectively managing one's emotional responses [37].

Finally, Naparstek [38] integrates the previously mentioned dimensions related to guided imagery processes into three main principles: (I) there is a *mind-body connection*; therefore, the mind can give cues to the body about feelings and experiences, and the body can benefit from the images created by the mind; (II) if we enter an altered state of consciousness, brainwave activity and biochemistry change, which can lead to cognitive and emotional changes; and (III) human functioning can be improved if a person believes that he or she can control aspects of his or her own life.

### Mental imagery in children's development in school context

Mental imagery plays an important role in children's development. From 6 months old onwards, it is

possible to measure mental imagery activity in babies from their physical responses [39, 40]. It carries out a simulation function, since it is generated to imagine the likely physical, emotional, and social consequences of forthcoming events or alternative courses of action [28]. Children use it to improve their performance on difficult and new tasks [40, 41]. Therefore, interventions supporting these developmental and competence acquisition processes may be of great help to children.

Previous research also found that children (7–14 years old) reported using imagery in active play, visualizing activities that are enjoyable, their favorites and that they do often. As to relatedness, they report imagining friends, family, and others (e.g., professional athletes), and as regards competence, they report imagining themselves being good at activities. Children's images also include speed (i.e., slow motion, real time, or fast). After middle childhood, mental imagery seems to perform a different role, supporting the emergence of personal and social identity, complex social understanding, and plans for the future—perhaps as a function of the acquisition of typical cognitive and social skills [42, 43].

Therefore, guided imagery in a school context may be an important tool for children's development. Its primary goal was initially stated to be to promote learning, reduce stress, and raise awareness of children's conscious existence as human beings [44]. More recently, other functions of guided imagery have been pointed out [45]. The intent of guided imagery in the classroom is to provide an environment where students can free their minds and create the opportunity to take in new information in a meaningful way. Participating in guided imagery interventions can build the self-confidence of students because they are accountable for their own learning. Further, by teaching children how to use guided imagery, they can improve the balance between the activity of the two hemispheres of their brains and optimize their learning skills [45].

Guided imagery is also useful in a classroom setting because students have the opportunity to use what they already know intuitively and consciously while they develop creative problem-solving competencies. This will also strengthen their natural abilities of photographic memory and perception. The imagery process also encourages the use of the senses in a meaningful way in the learning process, which appeals to the many ways children process new information [45]. Moreover, Chevreau [46] reported that a guided fantasy intervention for children (8 to 12 years old,  $n = 10$ ) encompassing an introductory phase, guided fantasy, a drawing based on fantasy material, and a semi-structured interview based on the drawing was associated with improved

academic self-concept and social relationships in a school context.

### **Guided imagery interventions for the socioemotional development of children**

The socioemotional development in children from early childhood is an important domain of development that interacts with other developmental domains, such as the biophysical, emotional, and cognitive, with an important impact in academic and life success, including learning, health, and well-being [47, 48]. Collaborative for Academic, Social, and Emotional Learning (CASEL) [49], one of the SEL frameworks that has provided more evidence-based results, has identified five core intrapersonal, interpersonal, and cognitive socioemotional competencies: (1) *Self-awareness*; (2) *Self-management*; (3) *Social awareness*; (4) *Relationship skills*; (5) *Responsible decision-making skills*. These skills supply children with the ability to overcome challenges, manage emotions, enhance social interaction, and adapt to different social contexts [50, 51].

The school classroom is one of the most adequate contexts to implement SEL programs aimed at teaching students a combination of social, emotional, and self-regulation competencies that are linked to academic and professional success and physical and mental health [52, 53]. SEL has a higher impact in children who face poverty, violence, and discrimination [54], lower socio-economic status, and academic performance [55].

Different aspects of socioemotional development in early childhood—including self-regulation, hyperactivity, emotional, and peer problems—are critical dimensions of children's development and each has been shown to individually impact student engagement and academic achievement in primary and secondary school [48, 56, 57]. In particular, interventions in relaxation and guided imagery may be an important tool to promote the socioemotional development of this target group [58]. However, a scientific validation of these interventions for school-aged children is lacking [6, 37], indicating a research path to develop that is quite relevant to child development. Nevertheless, a few empirical studies were found and are described below, providing insight into some of their potential effects on the socioemotional development of children [59].

### **Guided imagery on child's psychophysiological well-being**

While mental imagery in children is vivid and contributes to the maintenance of stress, anxiety, depression, and post-traumatic stress disorder, applications of guided imagery in the treatment of psychopathology and in the promotion of well-being and mental health are of special relevance. However, the effects of these interventions in improving the mental health of children remain



understudied [14, 17]. For example, a systematic review from 2020 found 14 studies that provided evidence of the benefits of mental imagery interventions to children and adolescents' psychopathological symptoms, of which only four had a control group [6]. Research on autism spectrum disorders, post-traumatic stress disorders, or focusing on specific symptoms associated with these or other mental health problems, such as social anxiety, stress, anxiety, and depression, showed that interventions targeting mental imagery are effective when adapted to the developmental stages of children [6].

Regarding anxiety and social anxiety, relaxation and guided imagery seem to be particularly adequate because of the negative imagery involved in these disorders [60]. Thus, guided imagery is proposed as an emerging therapeutic alternative to control anxiety. For example, a RCT with eight classes of students tested a guided imagery intervention consisting of exposure to seven 15-min audio scripts. State and trait anxiety levels at post-test and follow-up evidenced the effectiveness of the intervention, as they were significantly lower in the intervention group when compared to the control group [61].

In fact, the available research highlighted that higher intervention effects were obtained from studies with improved methodological validity, on older adults and non-student samples, and when the interventions were longer [37]. Better results were further achieved by trained practitioners giving clear "imaging" or "visualizing" instructions, providing a higher "dose" of imagery exercises in frequency and duration, adjusted to the target population, and making sure that participants were adhering to the imagery exercises.

To address the multifaceted nature of well-being and stress, it is also important to take into account a variety of stress and well-being indicators. Even though the majority of research has relied on self-report measures, integrating physiological measurements may offer complementary insights into how these interventions affect the individuals while the interventions take place and not merely afterwards. Importantly, they may also enable a deeper understanding of how the interventions may affect anxiety by measuring implicit automatic and unconscious bodily arousal and regulation responses, thereby providing objective data pertaining to relaxation and/or to emotional regulation.

Furthermore, a few studies have already provided evidence that guided imagery interventions can be effective on physiological health outcomes [3], yet the meta-analysis available only included body mass index and resting heart rate (HR) as physical and physiological indicators, and the target population was mainly comprised of adults. Interventions assessing both

psychological and physiological responses in children are scarce, and to the best of our knowledge no study has been conducted addressing the impact of guided imagery on physiological indicators relevant to stress, anxiety mitigation, emotional regulation, or wellbeing.

The current study proposes to contribute to filling that gap, departing from the knowledge amassed by prior studies measuring stress, emotion regulation, and well-being with physiological responses. The study will focus on both the autonomic nervous system (ANS) and the neuroendocrine system, which are thought to be strongly coordinated [62]. The ANS is a critical component of our body functioning, activating, coordinating, and regulating various physiological processes involving several nerves, organs, and biological systems (e.g., cardiovascular, electrodermal, and respiratory systems) and it is intricately connected to the neuroendocrine mechanism of the hypothalamic–pituitary–adrenal (HPA) axis. The ANS has two subdivisions with complex and often complementary roles: the Sympathetic Nervous System (SNS) and the Parasympathetic Nervous System (PNS). For the purposes of the study, we consider the most commonly reported indicators of the SNS-activation (skin conductance and heart rate) and of the PNS (specific indexes of heart rate variability (HRV) related to cardiac vagal control). SNS activation tends to occur when one is facing arousing situations, which sometimes can have a positive valence (e.g., positive excitement) or emotionally negative (e.g., triggered by stressful situations or by fight-or-flight responses), and can be captured by both cardiovascular and electrodermal systems. The PNS is responsible for a variety of bodily responses, most often related to resting states, but also to self-regulation, flexibility, and adaptability, and ultimately well-being when considering the vagally mediated heart rate variability [63].

The activation of the HPA axis, in turn, can lead to cortisol release from the adrenal cortex which increases the SNS activity of the ANS and several other physiological processes, such as the metabolism and immune responses. On the other hand, the PNS helps regulate the stress responses [62]. One quasi-experimental study testing the effects of a school-based mind subtraction meditation program for 8 weeks, verified a reduction in social anxiety, aggression, and salivary cortisol levels in the experimental group [64]. In the absence of previous research examining the influence of guided imagery on physiological responses, our study will conduct an exploratory analysis of these indicators, aiming to enhance the current understanding knowledge of psychophysiological mechanisms involved in participating in this specific type of intervention and examine its putative effects on emotion regulation and well-being.

### **Mental imagery, physical activity and behavior regulation**

Physical activity is essential for children's overall health and is linked to a variety of positive developmental outcomes, including self-esteem and academic performance [36]. In turn, hyperactive behavior and attention deficit in children often co-occur with anxiety disorder and other conduct problems and are a sign that care and intervention are needed [65]. Along with a relaxation component, guided imagery may be a useful resource in behavioral problem reduction, via lowering anxiety and promoting physical and social activity. However, as of now a single study with children used mental imagery to promote active play: In a RCT with 59 students in an imagery group ("tigers") and a control group ("lions"), it was found that the imagery group reported higher levels of active play at the end of the intervention when compared to the control group [36]. This 6-week guided imagery intervention aimed at increasing children's intrinsic motivation to engage in active play resulted in higher levels of active play in the intervention group compared to the controls (as measured by a pedometer). Further, intrinsic motivation (at post-intervention) mediated the relationship between the intervention and levels of active play at post-intervention [36]. Imaging can contribute to children's active play, which is an important activity for children's social, emotional, and cognitive development (e.g., creativity, problem-solving) in ways that may not be attainable through structured physical exercise [66]. Recent studies proposed that objective physical activity measured by accelerometry may be a relevant key to behavioral regulation in the classroom, although its relation with cognitive regulation did not reach significance [67]. Further studies are needed to clarify the relationship between behavioral regulation in the classroom, emotional regulation, and cognitive function.

### **Mental imagery, cognitive function, and academic performance**

Research has been unveiling a relationship between mental imagery, visual perception, memory processing, and long-term memory, suggesting that mental imagery activity activates other cognitive functions. For example, a revision of the literature on mental imagery produced by music listening reported a close link between mental imagery produced by music (or by mind-wandering) and memory processes [68]. In fact, mental imagery is generally created from previously stored information held in long-term memory. The link between visual mental imagery and memory is supported by lesion studies showing that damage to areas that support visual imagery can result in an impairment of memory [69]. Similarly, research has demonstrated that individuals with high

working memory capacity are more likely to engage in prospective mind-wandering, frequently involving autobiographical planning [70].

Research resorting to brain imaging has been demonstrating that neural representations from mental imagery and perceptual images resemble one another at the primary visual cortex and at a higher-level visual processing [71] suggesting an overlap between visual imagery and visual working memory. In fact, mental imagery is frequently used as a strategy for mnemonic performance [14].

Together, research evidence suggests that visual imagery abilities can mediate benefits in memory and thinking about the future by enabling cognitive operations that help individuals in their daily lives to better interact with the world and sustain social systems [72].

Research on the effects of guided imagery interventions on cognition and academic performance in children in the school context is, as mentioned before, very limited. It is thus noteworthy to revisit several studies conducted in the 1980 s that analyzed the efficacy of guided imagery interventions as a learning tool—their interesting results are summarized below.

An experimental study tested the effectiveness of three classroom teaching methods in achievement improvement: (a) programmed instruction, (b) simulation, (c) guided fantasy, and (d) control (with conventional methods of instruction). Fourth grade students ( $n = 57$ ) from a Wyoming school were randomly assigned to three conditions and all groups used the same content information in the textbook. Each treatment was administered for 40 min over 3 consecutive days. Results showed that significant achievement gains were made by all groups; however, the guided fantasy group showed a significantly higher gain compared with both the control and the programmed instruction group [73].

Another study with fourth and fifth grade students with poor reading skills ( $n = 124$ ), distributed by two experimental conditions of (1) performing mental imagery or (2) general paying attention while listening to a text, showed significantly higher comprehension-monitoring performance and detection of inconsistencies in the text in the imagery condition group. Therefore, results support the idea that mental imagery may be a useful tool as a comprehension-monitoring strategy [74].

Also related to learning abilities, a more recent study examined the role of visual analysis and mental imagery abilities in the reading performance of 90 primary school students ( $n = 90$ ) at various stages of reading acquisition. Results highlighted that the abilities of mental imagery and visual analysis can influence reading acquisition in the three dimensions of reading skills, comprehension, accuracy, and speed. Different results

were found in children who were in the third grade and had completed the formal learning of reading [75].

A similar study investigated the effect of guided imagery visualizations on science scores in third grade students' ability to access the imaginative mind and the science content. An explanatory sequential mixed-methods design was used with students ( $n = 23$ ), engaging in guided imagery visualization before classroom science lessons, and controls ( $n = 23$ ). Students in the intervention group listened to the guided imagery script before the teachers' lesson (independent variable). Pre and post-test results, on the same end-of-chapter sciences test, were registered for both intervention and control groups. Thematic content analysis revealed that students were able to effectively use guided imagery to access the imaginal mind, and to connect to the science content [56]. Another experimental study [76] tested the effects of a study-skills training combined with a treatment program of relaxation training and cognitive therapy on 45 anxious undergraduates. Students were assigned to one of four treatment conditions: (a) relaxation/cognitive therapy, (b) study-skills training, (c) a combination of relaxation/cognitive therapy and study-skills training, or (d) no treatment. Pre- and post-treatment measures were collected on state anxiety and classroom examination performance. Findings showed that condition (a) relaxation/cognitive therapy was effective in reducing anxiety but failed to improve classroom test scores, while condition (b) study-skills training had no significant effect on either measure. Both combined therapies (a) relaxation/cognitive therapy and (c) a combination of relaxation/cognitive therapy and study skills training significantly reduced anxiety and improved performance compared to the no-treatment control and were significantly more effective than either treatment alone. Finally, a different study on relaxation, meditation, and mindfulness (REMIND) with a large sample of adolescents in secondary schools ( $N = 1120$ ,  $M = 14.27$  years old) showed a positive association between REMIND, emotional competence, and academic performance. The practice of REMIND had an indirect impact on academic performance, mediated by emotional competences. Results highlight the importance of relaxation exercises in the classroom to enhance students' emotional competencies and improve their academic performance [77].

Taken together, the aforementioned studies indicate the need for interventions that promote SEL and well-being in children, stressing the useful role of both for their overall development, school engagement, and academic performance. They also evidence that relaxation allied with guided imagery can be a promising cost-effective

intervention, whose specific features emphasize its potential effectiveness in reducing anxiety and bolstering the development of socioemotional skills in children.

### Objectives

The literature highlights the importance of developing systematic and methodologically valid research to test the potential effects of guided imagery as a cost-effective intervention for the well-being and socioemotional development of children. Thus, this RCT contributes to the body of research by implementing and testing the benefits of MR-SEL intervention—which includes relaxation and guided imagery using scripts with SEL content—compared with a relaxation intervention alone, and a control group.

Explaining the choice of comparators, significantly higher benefits are expected in the MR-SEL condition compared with the relaxation intervention alone, and the control group. The SEL component in this intervention includes visual representations of behavior, emotions, and thoughts of characters, sharing adaptive beliefs related with self-esteem and self-efficacy, positive relationships with others and social responsibility, as well as coping strategies. This component is expected to contribute with extra meanings and motivation, compared with the relaxation intervention alone, aiding self-regulation of emotion and behavior and promoting higher wellbeing and development in children.

### Hypotheses

Through the participation in the MR-SEL intervention program, for 5 months, significant improvements are expected in the well-being, socioemotional regulation, physiological stress, cognitive function, and academic performance in children participants compared with the relaxation intervention, and the control group.

Physiological indicators of stress are expected to significantly decrease during the intervention sessions, compared with the time immediately before the intervention and with the pretest time at the same time of the day, and compared with the control group.

Mental health and emotional regulation are expected to mediate the effects of the intervention on the children's outcome variables such as well-being, socioemotional skills, physiological indicators of stress, arousal and regulation, cognitive function, and academic performance.

Well-being and mental health at baseline are expected to moderate the intervention effects on the outcome variables.

The objectives and hypotheses of this study are grounded in three key theoretical frameworks related to guided imagery interventions. First, Lang's bio-informational model [21] posits that guided imagery strengthens

the reciprocal interaction between mental images, emotional memory, and physiological responses. For instance, imagining oneself—or a character—in a calming natural setting such as a forest or beach can evoke positive emotions and a sense of well-being, which are probably accompanied by physiological responses like decreased electrodermal activity and lower heart rate. Second, as proposed by Pham and Taylor [20], mental imagery facilitates effective behavioral regulation by reinforcing the link between thought and action in the pursuit of goals. Visualizing an action—whether performed by oneself or by others—can enhance the likelihood of performing that behavior. Third, according to Ryan and Deci's self-determination theory, fostering intrinsic motivation supports positive behavior and enhances human functioning [34]. Guided imagery can promote such motivation and behaviors by encouraging children to envision themselves—or characters—striving to achieve goals, cooperating positively with others, or effectively regulating emotions and behaviors [36, 37].

#### Data analysis strategy

Data will be compared within and between subjects in the three groups at three data collection times, before, during, and after the intervention (T0 pretest; Tint Intermediate; T1 post-test), and 6 months after the end of the intervention (T2 follow up) in both intervention groups, with the following objectives:

- 1 To evaluate the effects of a relaxation and guided imagery intervention program on a range of socioemotional, physiological, cognitive, and academic outcomes of school aged children through self-report, behavioral, and neurophysiological variables, as well as across teachers and parent's reports on their children, compared to the effects of a relaxation intervention and a control group;
- 2 To test the mediation effect of children's mental health and emotional regulation on the outcome variables of well-being, socioemotional development, cognitive function, and academic performance;
- 3 To test the moderation effect of the baseline well-being and mental health on the intervention effects.

## Methods

### Study design

The RCT design includes three conditions to which classes will be randomly allocated: (a) the experimental group (will receive MR-SEL intervention—relaxation and guided imagery with socioemotional learning); (b) the alternative condition group (will receive relaxation intervention only); and (c) the control group (will be involved in the regular school activities without any intervention).

The interventions (a and b) will have the duration of 5 months, three school days per week, during 15 min at the beginning of the classes. Data on the measures of the study will be collected at four data points: before the beginning of the intervention (T0), immediately after the intervention (T1), and at follow-up (T2), 6 months after the intervention has finished, for the experimental and alternative condition groups. There will also be an intermediate physiological data collection (Tint) in children, 3 months after the intervention launch, during two school mornings, before, during, and after the MR-SEL and Relaxation interventions application (see flowchart at Fig. 1). Data on each child participant and on all study measures will be compared across the three time points and across the three groups. Data on children's academic performance and socioemotional competences will also be collected from teachers and parents and compared within subjects before and after the intervention.

### Participants

School-aged children ( $N = 240$ ; 3rd and 4th graders, 8–11 years old) will be invited to participate in an intervention-research program. Classes will be randomly assigned by grouping school to one of three conditions: (a) "MindRegulation with SEL"; (b) Relaxation; and (c) Control group. Exclusion criteria of participants' classes is to have previously benefited from the "MindRegulation" or from Relaxation based interventions.

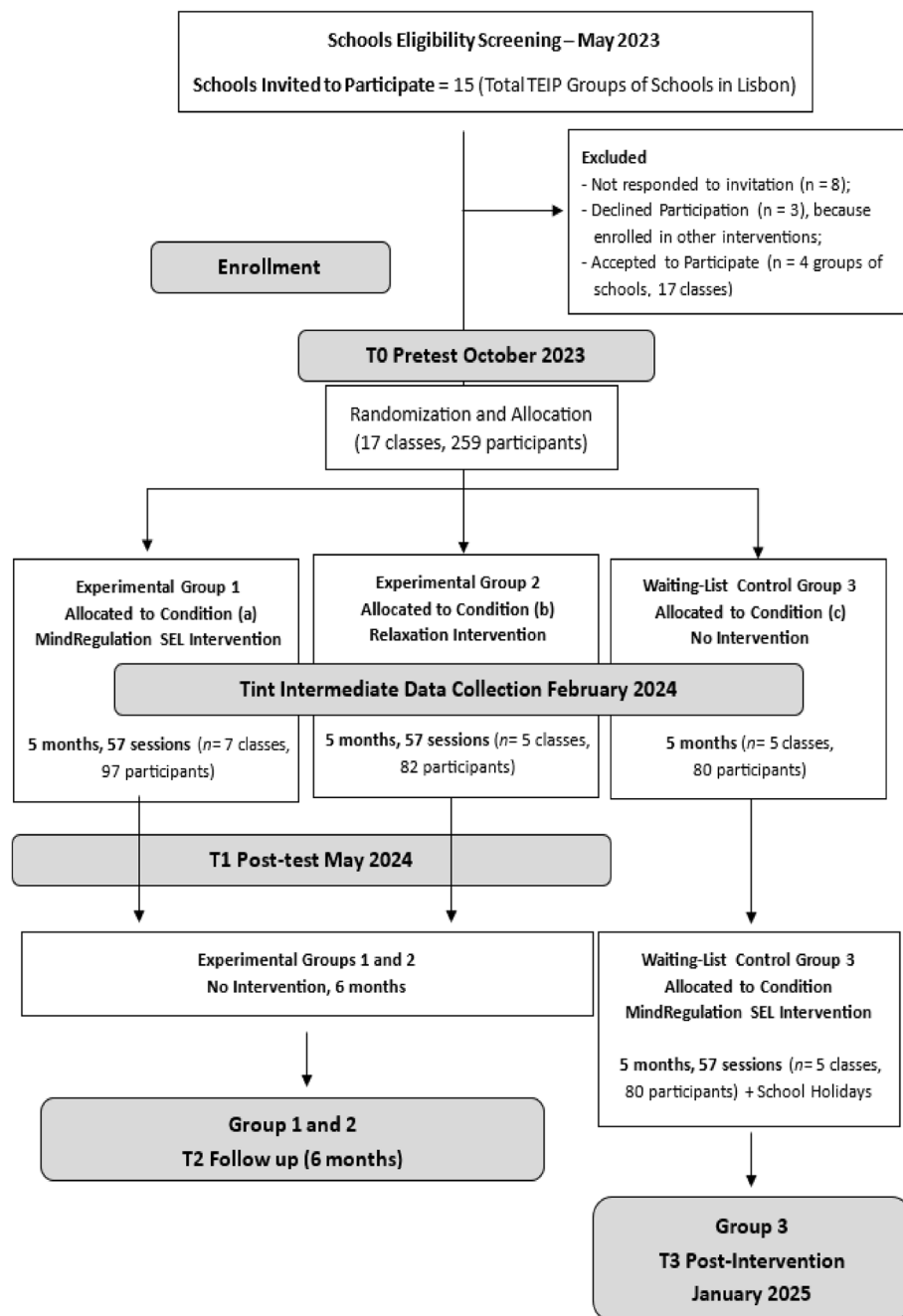
### Sample size estimation

An a priori estimation of the sample size for the study was performed using the GPower software [78]. The calculation was made for repeated-measures ANOVA with intra- and inter-group interaction. Due to the novelty of the study, we are unable to ascertain an a priori effect size for the effect of the intervention. Therefore, we have estimated the sample size by considering a medium effect size of  $f = 0.025$ , 0.80 power, three groups, and a correlation among the repeated measures of at least 0.50. The Gpower yielded an estimation of a minimum sample size of 42 participants (see Fig. 2). In this study, a higher sample will be collected in order that, considering the potential dropouts in the sample across the three data collection times, a total of at least 65 participants per group condition are expected at post-test. The control group will benefit from the MR-SEL intervention after the post-test data collection time.

### Procedures and randomization

The universe of the study is the total of schools classified as priority for intervention (from social and economic underprivileged, social excluded, or violent residential areas) in Lisbon, Portugal, by the Portuguese



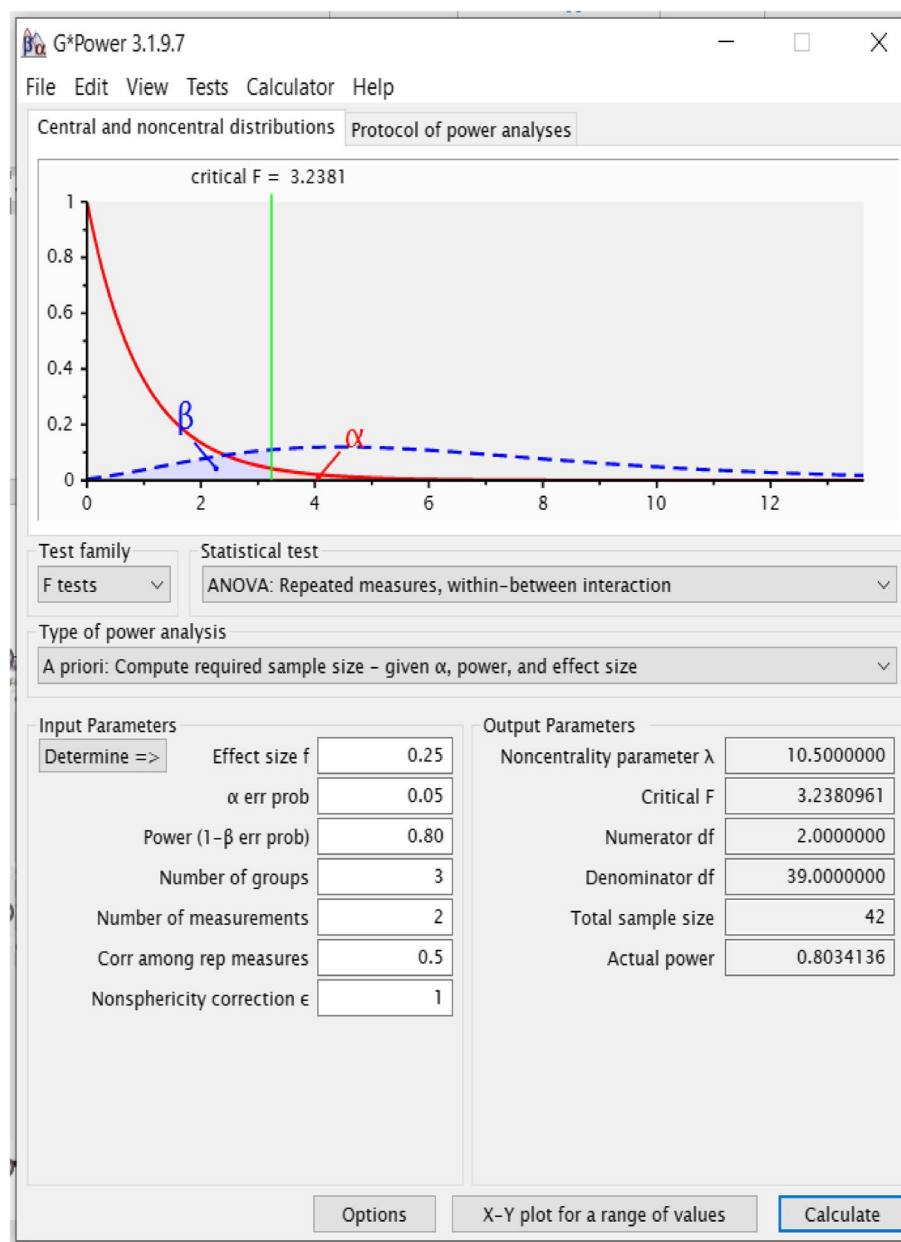


**Fig. 1** Flowchart of participants throughout the study

Government. The School Directors of all these schools will be contacted by the intervention team, inviting the school students and teachers to participate in the Mind-Regulation Project. From the total schools that accepted to participate and did not previously benefited from MR-SEL intervention (for example, the Grouping Schools of Olaias, Alto do Lumiar, Alta de Lisboa, and Reb-oleira), the coordination team of the study will randomly

distribute the selected classes from 3rd and 4th grades by grouping school to the three study conditions, using the randomization tool of the IBM Statistics. Immediately before the intervention, teachers and intervention team will be informed of the classes' allocation to the intervention.

The data will be collected from children by independent researchers, blinded to group allocation at the three



**Fig. 2** Sample size calculation for the validity of statistical analyses of the study

data points: before the beginning of the intervention (T0), immediately after the intervention (T1), and at follow-up (T2). In the intermediate data collection (TInt), blindness to group allocation is not possible, because data will be collected during the intervention. If necessary, unblinding of participants will be possible by contacting the study coordinator or any member of the data monitoring committee, which have access to the list of participants' code by names and classes. In order to promote the adherence of participants to the study, a poster

with all the research and intervention activities in which children will participate will be posted on a classroom wall, and where researchers will stick smiles that children receive from participating in each task.

The structured questionnaires will be given to children in whole-class groups, during a prearranged class period, in the presence of the teacher. Three researchers will be present to read the questionnaire and give children support in filling out the protocols. For the cognitive measures, data will be collected

in smaller groups of 10 children, also supported by three researchers. Physical and physiological measures from electrocardiogram (ECG), electrodermal activity (EDA), and accelerometry (ACC) will be collected in whole class groups of 20 children. Measurements will be made in equivalent morning periods for comparability across groups—from 9 to 11 h o'clock. Data insertion will be double checked by the assistant researchers' team.

### **The intervention program**

The MR-SEL intervention is based on relaxation and guided imagery and includes 3 components: (1) Relaxation exercises, breathing and closing the eyes; (2) The proposal of a guided imagery through narrated scripts, leading children through the visualization of beautiful sceneries and exposure to SEL content (based on CASEL framework), in three major themes: Me with myself (self-awareness and self-management); Me with the others (social-awareness and relationships skills); Me with the world (responsible decision making and social awareness), and (3) Instructions for self-regulation of body posture and the use of touch to support children in posture regulation.

The intervention takes place in class for 15 min before learning activities, three times per week, for 5 months—57 (three-weekly) sessions. The intervention in the experimental group and in the alternative condition group will be carried out by trained technicians in the MR-SEL intervention (for details, see Tidier in Table 1). For each theme, scripts will be applied three times in a total of 57 sessions. The scripts used in the intervention were revised by an independent team of psychologists and education specialists. The MR-SEL intervention begins with a relaxation component for 5 min, which includes diaphragmatic breathing, a progressive muscle relaxation technique, and instructions on body posture, based on a cognitive-behavioral approach [79]. Participants are expected to achieve a mental state between wakefulness and sleep, activating the alpha state, followed by the reading of the script with SEL content with a serene voice, resorting to operant conditioning. In the relaxation condition group, a relaxation technique is applied, similar to that in the MR-SEL group, but extended for the 15 min of the intervention. If a participant does not accept to participate, alternative activities will be provided after agreement of the participant and the teacher, for example, drawing or reading. No other interventions will be accepted during the research and intervention study implementation, in the classes selected for this study.

### **Ethical procedures**

In the development of this study, all procedures are according to the codes of conduct of the American Psychological Association, 7th Edition [80], the Society for Research in Child Development [81], the Declaration of Helsinki [82], and the National Children's Bureau Guidelines for Research [83], described below. The research project and the informed consents were subject to an Institutional Review Board (IRB) evaluation and approval, before obtaining assent from the children, the research team will obtain informed parental or legal guardians consent. The research team will inform the teachers and child participants of all features of the research and intervention that may affect their willingness to participate and will answer their questions in specific terms appropriate to their comprehension. Any ancillary study that may be proposed based on the data collected in the current study will be equally subject to an IRB approval and consequent informed consent when requested. During data collection, only the participant code number will be recorded in the survey protocol. All information that can identify participants (e.g., name, contacts) will be assigned a code number and recorded in a separate file. In a third file, the participant's code number will be linked to the personal information. The ability to link indirect identifiers with names and contacts is still available, but only the coordinator researchers will have access to that file, which is securely stored and password protected in the study intranet site. If parents wish to access or modify their children's registered personal information, they may do so at any time by contacting the scientific coordinators of the study. Data will be archived and kept confidential for at least 5 years after the publication of the results. The anonymity of the information will be preserved, and no information will be collected other than that for which permission was obtained. In complying with requirements for data sharing, researchers will carefully consider not providing data that, if combined, risks violating participant anonymity. The data monitoring committee is comprised by the coordinating team of the project, independent from the sponsor and with no competing interests.

### **Materials**

The study aims to measure a set of psychosocial and physiologic variables, described below. All structured self-report measures are validated for the study population language with adequate psychometric properties, except the self-esteem scale that will be validated in this study to the target population. All outcome variables are primary outcomes of the study. Full protocol is fully

**Table 1** MindRegulation with socioemotional learning—relaxation and guided imagery intervention procedure

TIDieR item	Brief description
1. Brief Name	MR-SEL
2. Why	Imagery or mental images are representations of visual content without a direct stimulus. Guided imagery is based on covert and operant conditioning, and on the premise that mental image function cognitively and neurologically as perceptions, with similar effects as real stimuli, such as pupil dilation. Several studies recognized imagery as an important technique in the treatment of mental health, such as stress/anxiety and insomnia. In this study, to assist the guided imagery technique, a relaxation technique is also used. Several studies in the field of neuroscience have shown that relaxation and the response it produces in the body is a relevant therapeutic tool to neutralize/reduce stress-related disease processes. Psychological therapies have traditionally focused on verbal communication. MindRegulation SEL technique focuses on patient's relaxation and guided imagery. It has been applied in schools with very good feedback from children and teachers; however, this type of intervention needs further scientific validation
3. What (materials)	It is applied in a school context, it needs a classroom with chairs and tables where children are seated. It also needs scripts written for the intervention that include the description of beautiful sceneries and physical sensations, and socioemotional learning content, based on the Collaborative for Academic, Social and Emotional Learning (CASEL) framework
4. What (procedure)	MindRegulation SEL begins with a <i>process of relaxation</i> so that a gateway to abstraction and predisposition to concentration can happen. In this process, the participant can achieve a mental state between wakefulness and sleep, activating the alpha state which can promote a mental development improving the sensation of relaxation, reducing stress and anxiety. In a second stage, a focus on <i>guided imagery</i> is developed with the aid of covert and operant conditioning. The psychologist that applies the technique should start by introducing himself and explaining to the children, in age-appropriate language, what they are going to do. After the explanation, the psychologist should proceed to read the script with a serene voice and in a monotone tone. During the script reading, the psychologist may use a touch on the child's shoulder or upper back if the child is agitated, tense or in a languid body posture. After the technique is done, the psychologist says goodbye and thanks the children for their participation. The scripts used in the intervention were revised for an independent team of specialists
5. Who provided	The scripts and the intervention will be conducted by trained psychologists. The training in the intervention has a duration of 25 h (13 synchronous and 12 asynchronous hours), whose general objectives are to recognize the factors that trigger the occurrence of stress, allowing to recognize the physical and psychological warning signs of stress; to identify characteristics that enhance or inhibit effective strategies for the regulation of stress and, finally, training in the application and reading of scripts in an educational context
6. How	The intervention is performed in the classroom, face to face in the whole class group and in the presence of the teacher. The children remain on their seats with the eyes closed and the psychologist starts reading the script and walking from side to side, starting with the relaxation technique followed by the guided imagery technique. While reading the script, the psychologist can resort to the touch. This touch can happen when the child is unfocused, agitated, or slouched on the chair and can only occur on the child's shoulders, or upper back with the aim of helping the child to regulate its posture and refocus into the activity
7. Where	The intervention will be performed in elementary schools, in the classroom, in the presence of the teacher. Children remain seated on their usual seats
8. When and How Much	The intervention will take place from November 2023 to March 2024, developed in class for 15 min, before learning activities, three times per week, for 5 months. There will be 57 sessions divided in three thematic groups of each of the 240 participants
9. Tailoring	Not applicable
10. Modification	Not applicable
11. How well (planned)	Not applicable
12. How Well (actual)	Not applicable

available online at <https://clinicaltrials.gov/study/NCT06101225>.

Data collected in the study will be available for the team members that collaborated in the data collection. The data as well as the statistical coding of the analysis will be available from the corresponding author upon reasonable request.

#### Data collected from children

**Subjective well-being:** (a) *Global Happiness* will be measured by the Faces Scale originally developed by [84] and widely used in children [85]. This scale has only 1 item, but it has seven simple drawings of faces that

represent participants' response options to the question: "Overall, in the past few months, how do you feel?". Afterwards, the participants must choose the face that best represents feelings ranging from "very unhappy" to "very happy". This scale is adequate for younger children because they perform best when recognizing and labeling emotions when represented as schematic drawings [85]. Single-item measures of happiness are reliable and commonly used. Studies showed a moderate to good test retest reliability with children of 0.53 ( $p < 0.01$ ) [86] and 0.82 ( $p < 0.01$ ) [87]. (b) *Positive and Negative Affect* will be measured with a short version of the PANAS-C [88] validated to the Portuguese by [89]. The short version used



in this study comprises 10 items (e.g., “Indicate to what extent you have felt happy over the past few months”) structured in two subscales: Positive Affect (5 items) and Negative Affect (5 items). Children rate how often they have felt each emotion within a specific time frame, using a 5-point scale (from 1 = very slightly or not at all to 5 = extremely). The results of the confirmatory factor analysis of the Portuguese original version yielded a good fit of  $\chi^2/df = 1.82$ , CFI = 0.932, TLI = 0.918, RMSEA = 0.061. The internal consistency of the 10 items’ short version showed a Cronbach Alpha at two time points for the Negative Affect of 0.70 and 0.89 and for the Positive Affect of 0.76 and 0.94 [89].

**Mental health** will be measured with the Mental Health Continuum Short Form (MHC-SF) [90]—The Portuguese Version for Children of MHC-SF (adolescents) [91]. The scale is composed of 14 items organized in three subscales: emotional well-being (EWB), social well-being (SWB), and psychological well-being (PWB). Respondents rated the frequency of each symptom of positive mental health in the past few months on a 6-point Likert type scale (0 = never to 5 = every day). This scale was adapted for the Portuguese and the best model fit was  $\chi^2/df = 1.53$ , CFI = 0.95, TLI = 0.94, RMSEA = 0.05. The study also showed a high internal consistency with Cronbach Alpha for the EWB of 0.80, for the SWB of 0.81, and for the PWB of 0.85 [91].

**Socioemotional competencies** will be measured with the Questionário de Avaliação de Competências Socioemocionais (QACSE) developed for Portuguese children with 9 to 12 years old [92] and adolescents [93]. This instrument consists of 39 items, answered on a 4-point response scale from A “Never” to D “Always”, organized into six dimensions: Self-control (e.g., “I wait for my turn without getting nervous”); Social Awareness (e.g., “I help others when they have problems”); Relational Skills (e.g., “When there are problems they choose me as referee or judge”); Social Isolation (e.g., “I prefer isolated, barely visible or less crowded places”); Social Anxiety (e.g., “I get nervous when I have to speak in front of several people”); Responsible Decision Making (e.g., “I consider several alternatives before making a decision”). Confirmatory factorial analysis obtained a good enough fit for bifactorial a model [ $\chi^2/df = 2.29$ ; CFI = 0.90; GFI = 91; RMSEA = 0.04]. Internal consistency using Cronbach Alpha for each subscale was: Self-control (0.74); Social Awareness (0.86); Relational Skills (0.77); Social Isolation (0.79); Social Anxiety (0.74); Responsible Decision Making (0.78) [92, 93].

**Self-regulation of emotions** will be measured by the emotional regulation questionnaire—children and adolescents (ERQ CA) [94] Portuguese version [89]. The scale assesses emotional control strategies. The

questionnaire comprises 10 items organized in two subscales: cognitive reappraisal (6 items; e.g., “When I want to feel happier, I think about something different”) and expressive suppression (4 items; e.g., “I keep my feelings to myself”). Responses are given on a 5-point rating scale ranging from 1 (strongly disagree) to 5 (strongly agree). A confirmatory factor analysis of the Portuguese version showed a good fit for a bifactorial structure of cognitive reappraisal (5 items) and expressive suppression (3 items):  $\chi^2/df = 2.07$ , CFI = 0.947, TLI = 0.912, RMSEA = 0.07. Cronbach’s alphas at pre-test and post-test for the cognitive reappraisal subscale were respectively 0.63 and 0.68, and for the expressive suppression subscale were 0.71 and 0.71 [89].

**Anxiety** will be measured with the Trait Anxiety Inventory for Children (STAI-C2) [95] Portuguese validated version [96] that measures a general proneness to anxious behavior rooted in the personality. The STAI-C2 consists of 20 statements that ask children how they usually feel, most of the days (for example “I feel worried”). The answers range from 1 = almost never to 3 = often. The Portuguese validation showed an internal consistency with the Cronbach Alpha for the total sample of 0.76 and, for the feminine sample of 0.76, and for the masculine sample of 0.66. The convergent validity with the Children’s Manifest Anxiety Scale—R showed a correlation of 0.58 ( $p \leq 0.01$ ) [96].

**Self-esteem** will be measured by the Lifespan-Self-esteem-scale (LSE) [97], a global self-esteem scale for individuals aged 5 to 89. It is composed of 4 items and the answers are registered on a 5 point scale from 1 = “really sad” to 5 = “really happy.” The response options are illustrated with faces expressing the appropriate feeling (e.g., really sad = crying face). The 4 items generated an internal consistency with the Cronbach Alpha of 0.71 (ages 5–7) and 0.89 (ages 8–13). The test–retest reliability was  $r = 0.58$ ,  $p < 0.01$  [97]. There is no Portuguese version of this instrument. Thus, the validation of this scale will be performed according with the established procedures of translation, retroversion, and discussion by specialists, followed by an internal consistency analysis.

**Cognitive function** as attention, processing information speed, and working memory will be assessed through: (a) Maze, Symbol Search and Code subtests of the Wechsler Intelligence Scale for Children (WISC III) [98]; and (b) the D2 Test [99]. The Maze subtest analyzes the ability to anticipate and plan using visuospatial strategies in working memory, it yields a coefficient of fidelity of 0.72 for 8 years, 0.80 for 9 years, 0.71 for 10 years and 0.79 for 11 years. The Symbol Search subtest measures the ability of perceptual discrimination, dependent on visual attention capacity and working memory, it shows a fidelity coefficient of 0.65 (8–11 years); and the

Code subtest measures the ability to associate numbers with symbols, and memorizing the associations in order to complete the task as quickly as possible, has a fidelity coefficient of 0.79 (8–11 years). In terms of stability coefficients the results are very similar to the original version. For ages of 6 to 7, the corrected coefficient was 0.49 for the Code subtest, 0.65 for the Symbol Search subtest, and 0.58 for the Maze subtest. For ages 10 to 11 the corrected coefficient was 0.79 for the Code subtest, 0.65 for the Symbol Search and 0.51 for the Maze subtest [98].

The D2 test assesses selective and sustained attention, processing speed, precision, and qualitative aspects of performance. It is considered a cancellation or dam test, where the individual registers a (/) on the letters “d”, from left to right, while ignoring the other stimuli, on each of the 14 lines and having 20 s per line [99]. This test is free of cultural bias and shows temporal stability. With regard to the psychometric qualities of the test, the results found reflect a high internal consistency, with fidelity coefficients above 0.94 for the variables “Total Characters,” “Total number of correct answers,” “Total effectiveness,” and “Concentration index.” Regardless of the method or sample used, most studies show very high fidelity results ( $r > 0.90$ ) [99].

**Physiological indicators** of arousal, emotional regulation, and well-being will be recorded through electrocardiogram (ECG) to record heart rate (HR) and heart rate variability (HRV) and electrodermal activity (EDA, to record changes in skin conductance), both peripheral measures of the autonomic nervous system (ANS) [100]. Emotional arousal will be measured with skin conductance, which is a measure of the fluctuations in the activity of the sympathetic nervous system (SNS), through the eccrine sweat glands, and has the major advantage of being the single direct measure of the ANS [101], while HR or HRV can express combined activity of the ANS and PNS. We will acquire tonic EDA by recording the skin conductance levels (SCLs) and non-specific skin conductance responses (NS.SCRs) of children [100, 102]. Guidelines for collecting and reporting EDA will be followed [103, 104]. As mentioned above, HRV and HR are influenced by both the SNS and the PNS. However, some cardiac autonomic regulation parameters of the HRV are important markers of the balance between SNS and PNS and also of the PNS (or vagal mediated activity), which have been related to emotional regulation, and to physical and emotional well-being in adults, adolescents, and children. Prior studies have also shown that HRV varies as a result of relaxation interventions [105] and biofeedback interventions, which also include guided breathing techniques [106]. We will rely on existing guidelines for collecting and reporting time-domain and frequency-domain parameters of HRV [107, 108], including

established norms and reference values in children [109, 110].

**Physical activity and movement** will be measured by actigraphy with an accelerometer (ACC) to provide information about the frequency, intensity, and duration of children's physical movement in three axes (lateral, vertical and longitudinal) during class [111]. Actigraphy is also proposed as a measure of children's behavioral regulation in school context [67].

Both physiological and physical activity will be collected using Bitalino sensors by Plux, an equipment that has demonstrated adequate validity and reliability, over the past 10 years of implementation, and proposed as equivalent to a reference equipment such as the BIOPAC [112]. The three measures above will be acquired with the Bitalino equipment, in a comfortable armband, from which two wires with four sensors will come out. For the ECG measure two sensors will be attached to the upper chest of children using two electrodes. For EDA two electrodes will be attached to the palm of the hand. For the ACC, the sensor for the three axes will be tied to the armband. These measures will be collected in class, in the morning, continuously for 40 min, in two school days, during regular learning activities in the three groups' conditions, at four times of data collection: T0, Tint, T1 and Follow-up. Based on prior guidelines [109], the study implementation procedures will prevent children from engaging in intense physical activity and heavy meals prior to physiological recordings. Additionally, air temperature and humidity will be measured during data collection to control for external factors that may influence EDA. As far as we know, this is the first time that a set of 20 portable sensors is used for physiologic data collection simultaneously in a naturalistic elementary classroom setting.

**A biological index of stress** will be measured through Salivary Diurnal Cortisol Slope and DHEA-S using Salivettes. The measures will be collected at T0 and T1, throughout 2 days, in a subsample of 100 children (four classes from MR-SEL condition and four classes from the control group). On day 1, four samples will be collected throughout the day (9.15/30 h, 12.15/30 h, 15.15/30 h, and bedtime, with no food ingestion, washing teeth, or vigorous physical activity, half an hour before assessment). On day 2, three samples will be collected at 9.15/30 h, 12.15/30 h and bedtime [113]. With these measures, it is possible to assess the baseline cortisol level and DHEA-S as a complementary measure of each child, taking into consideration the variation resulting from school day activities. The samples will be collected in class by the children themselves with the help of trained technicians, and at home with the help of parents.

The biometric data will be saved in coolers, transported and analyzed by a certified laboratory (Joaquim Chaves).

#### Data collected from teachers

**Children's academic achievement** will be assessed based on the complete report of each student's academic performance reported by the teachers, including grades, behavior, and absenteeism from classes in the 1st, 2nd, and 3rd periods.

**Socioemotional skills of children** will be measured with the Strengths and Difficulties Questionnaire teachers' version (SDQ) [114] in the adapted Portuguese version [115]. The SDQ teachers' version consists of twenty-five items, organized into five scales containing 5 items and each item has three response options on a scale (not true, rated 0 or 2; hardly true, rated 1; very true, rated 2 or 0). It has 5 subscales: emotional symptoms, behavior problems, hyperactivity, relationship problems with colleagues, and prosocial behavior. Internal consistency Cronbach Alpha global scale 0.73. Subscales: Total Difficulties 0.87, Emotional Symptoms 0.78; Conduct Problems 0.74; Hyperactivity-Inattention 0.88; Peer Problems 0.70; Prosocial Behavior 0.84; Impact 0.85. [114].

#### Data collected from parents or legal guardians

**Socioemotional skills of children** will be measured with the Strengths and Difficulties Questionnaire parent version (SDQ), [114] in the adapted Portuguese version [115]. The SDQ parent version is similar to the teacher's version, organized in five dimensions: emotional symptoms, conduct problems, hyperactivity-inattention, peer problems, and prosocial behavior. Internal consistency Cronbach Alpha global scale 0.73. Subscales: Total Difficulties 0.82, Emotional Symptoms 0.67; Conduct Problems 0.63; Hyperactivity-Inattention 0.77; Peer Problems 0.57; Prosocial Behavior 0.65; Impact 0.85. [114].

**Perceived benefits of the participation in the intervention for the children** will be evaluated through semi-structured questions collected from the children, parents/legal guardians, and teachers. Written qualitative data will be collected on the child's perception of the benefits of the intervention. Parents/legal guardians will also be asked to answer to one semi-structured question about their perception of the benefits of the intervention for their children's well-being, behavior, and development. Teachers will answer two semi-structured questions about their perceptions of the intervention's benefits for children's well-being, socioemotional, and cognitive development, as well as how it contributed to class functioning and the work with children.

**Health Status.** Information about the children's health status, including cardiac and respiratory diseases, and the

use of medication (e.g., Adderall, Ritalin, acetylcholinesterase inhibitors, selective serotonin re-uptake inhibitors) that are likely to affect the ANS will be collected from parents and teachers, while body mass index (BMI) will be measured and calculated [103, 109]. For a graphic view of the measures of the study across data collection times, please see Fig. 3.

Strategies for encouraging participants for completion of follow-up included awarding a smiley sticker for each completed activity, which participants could place on a poster displayed in the classroom. Additionally, at the end of the study, participants received a certificate of collaboration and a smiley-themed pencil as a token for participation in the study. No provisions were made for partial data collection in cases where participants discontinued or deviated from the intervention protocol.

#### Data analysis

Quantitative analysis will be performed on the psychosocial structured questionnaires, cognitive tests, physical and physiological measurement, and academic grades. Statistical analyses will test the hypothesis of the study and include within- and between-groups mean comparison of the outcome measures. Psychometric and biometric analysis of the measures will be examined by internal consistency and factorial analysis. Additionally, mediation and moderation analyses will be performed.

Qualitative analysis will be performed on the teacher's qualitative evaluation reports and on the children's, teachers and parent's semi-structured reports. Content analysis will be carried out through categorization by thematic coding according to the objectives of the study and follow conventional guidelines [116]. Two researchers will work on the content analyses independently, after which they will meet to discuss the analyses and resolve any disagreements through consensus.

#### Statistical analysis

Statistical methods include mean comparisons of outcome measures (chi-square, *t*-test, general linear model for repeated measures analysis and ANOVA, after statistical assumptions are verified) between the four times of data collection (pre-test; intermediate; post-test; and a sixth-month follow up) and between experimental, active and control groups. Analyses will control for covariables of grouping school, and class. Furthermore, mediation and moderation analyses will be carried out using Process and Memore Macros. No interim analyses are planned. Per protocol and intention to treat strategies, imputing the last observation carried forward or expected maximization substitution for missing data may be used, depending on whether data is missing completely at random. To avoid the risk of false positives on

TIMEPOINT**	STUDY PERIOD								
	Enrolment	Allocation	Post-allocation						Close-out
	May-September 2023 <i>t</i> <sub>1</sub>	October 2023 <i>t</i> <sub>0</sub>	October 2023 Pretest <i>t</i> <sub>1</sub>	Intervention November-April February 2024 Intermediate <i>t</i> <sub>2</sub>	May 2024 Post-test <i>t</i> <sub>3</sub>	November 2024 Follow up <i>t</i> <sub>4</sub>	October 2024 Intervention <i>T</i> <sub>5</sub>	Waiting-list Group January 2025 Post-Intervention <i>T</i> <sub>6</sub>	February 2025 <i>T</i> <sub>7</sub>
<b>ENROLMENT:</b>									
Eligibility screen	X								
Informed consent	X								
[List other procedures]	X								
Allocation		X							
<b>INTERVENTIONS:</b>									
Condition A EG1									
[Intervention MindRegulation-SEL]				↔					
Condition B EG2									
[Intervention Relaxation]				↔					
Condition C Waitlist-Control CG									
[Intervention MindRegulation-SEL]							↔		
<b>ASSESSMENTS:</b>									
[Measured Outcome Variables]									
<b>PSYCHOSOCIAL</b>									
Global Happiness									
Positive & Negative Affect (PANASC)									
Mental Health Continuum (MHC)									
Socioemotional Skills (QACSE) self-report, teachers and parents report			X		X	X		X	
Emotional Regulation (ERQ-CA)									
Anxiety (STAI-C2)									
Self-esteem-scale (LSE)									
<b>COGNITIVE</b>									
Attention, Processing information speed, and working memory (WISC-III Maze, Symbol Search and Code subtests; and D2 Test)			X		X	X		X	
Children's Academic evaluation reports									
<b>PHYSIOLOGIC</b>									
Heart Rate Variability (HRV)									
Electrocardiogram									
Salivary Cortisol Physiologic Stress			X	X	X	X		X	
Electrodermal Activity (EDA)									
Physical Activity (Accelerometry)									
Classroom temperature and humidity.									
<b>BIOLOGIC</b>									
Cortisol and DHEA-S			X		X				
<b>INTERVENTIONS BENEFITS PERCEPTION</b>									
semi-structured reports by children, parents and teachers					X			X	
[List other data variables]									
<b>SOCIODEMOGRAPHIC VARIABLES</b>									
from children and parents									
Height and weight of children			X						
Health status of children									

**Fig. 3** Example template of recommended content for the schedule of enrolment, interventions, and assessments\*

multiple hypothesis testing, we will use the Holm-Bonferroni procedure.

## Discussion

Guided imagery interventions have received an exponential attention from the scientific community in the last decades; however, studies that tested the effects of these interventions with strong validity are scarce [1, 2, 6, 37]. Particularly, there are very few studies that tested the effects of these interventions in the development and well-being of children in different contexts, with robust methodologies that guarantee internal and

external validity [1, 2, 6]. Also, it is important to distinguish the different components of the interventions to measure the specific effects of intervention components [6].

This study responds to the above identified needs in the literature of guided imagery studies. However, the main strength of this study is probably to be able to collect physiologic data (EDA, HR, and ACC) in large groups of children in a naturalistic setting. To the best of our knowledge, this type of data collection is novel and represents an important contribution to validating the effects of relaxation and guided imagery in the school context.



The study will be developed in Schools in Priority Educational Intervention Territories (TEIP), which are integrated in residential areas with sociocultural and economic diversity, and classified as schools with priority for intervention. Children's participation in the intervention and study will be included as a school activity, in which they will be actively involved in learning the scientific procedures of data collection. Therefore, the study also includes an application feature.

Results of the study will be able to reveal potential effects of the interventions on various domains of development, such as psychosocial, emotional, cognitive, physiologic, and biologic, as well as the interaction between the different developmental domains. The study will also provide qualitative results from the perspective of children, teachers, and parents about the perceived benefits of the intervention.

Limitations of the study are the dimension, frequency, and complexity of data collection that may cause implementation difficulties in school context.

Conclusions of the study will be able to inform future interventions in relaxation and guided imagery interventions, guidelines for application in school context, and their potential benefits for the global well-being and development of children.

## Trial status

Date version: MindRegulation Study Protocol 6th September 2024.

Pretest recruitment began the 10 th of October 2023 and is expected to be completed in February of 2025.

## Dissemination policy

Scientific papers, communications in conferences, and intervention manuals with the dissemination of the study results are expected for scientists, mental health providers, and teachers. Authorship byline will be defined by the relevance in the contribution to the manuscripts and each author's contribution will be disclosed. Priority in writing the outputs of the study will be offered to the study coordination team of each scientific domain that collaborated in the implementation and data collection of the study. If not available, co-authorship for publications will be made available for other potentially interested researchers, mainly through postdoctoral applications.

## Abbreviations

ACC	Accelerometer
ANS	Autonomic nervous system
BMI	Body mass index
CASEL	Collaborative for Academic, Social, and Emotional Learning
ECG	Electrocardiogram
EDA	Electrodermal activity
ERQ-CA	Emotional Regulation Questionnaire for Children and Adolescents
EWB	Emotional well-being
HPA	Hypothalamic-pituitary-adrenal

HR	Heart rate
HRV	Heart rate variability
LSE	Lifespan-Self-esteem-scale
MHC-SF	Mental Health Continuum Short Form
MR-SEL	MindRegulation Socioemotional Learning
NS.SCRs	Nonspecific Skin Conductance Responses
PANAS-C	Positive and negative affect
PNS	Parasympathetic nervous system
PWB	Psychological well-being
SWB	Social well-being
QACSE	Questionário de Avaliação de Competências Socioemocionais
RCT	Randomized controlled trial
SCLs	Skin conductance levels
SDQ	Strengths and Difficulties Questionnaire parent and teachers' version
SEL	Socioemotional learning
SNS	Sympathetic nervous system
STAI-C2	Trait anxiety inventory for children
WISC III	Wechsler Intelligence Scale for Children III

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## Project Composition and Roles

Iolanda Costa Galinha (Principal Investigator) - Responsible for the conception of the study, methods, procedures, and ethical criteria with contributions from the research team. Coordination of the research activities, data collection and training of the research team. Management of funding resources. Research Team Coordination by Scientific Domains - Responsible for the scientific supervision, data analysis and writing of research reports in each scientific domain.

Iolanda Costa Galinha, Joana Sampaio de Carvalho & Cristina Oliveira - Well-being, Mental Health, and Mindfulness.

Hugo Plácido da Silva, Catarina Lima - Physiologic Data Processing and Analysis - Team partially funded by FCT/MECI national funds and by EU under UID/50008: Instituto de Telecomunicações

Patrícia Arriaga, Sinah Tiler - Heart Rate Analysis and Report

Augusta Gaspar - Electrodermal Activity Analysis and Report

António Labisa Palmeira & Helder Miguel Fernandes - Actigraphy Analysis and Report

Carlos Cardoso, Emma Adam - Cortisol Analyses and Report

Gina Lemos & Susana Martins - Cognitive Function and Academic Achievement

Diego Pinal & Iolanda Costa Galinha - Data Analysis and Report

Intervention Team Coordination:  
Ana Cristina Oliveira & Vitória Ortega - Responsible for the conception of the Intervention MindRegulation, Protocol Establishment with the Schools for the Intervention and Research activities; Training and Supervision of the Intervention Technicians, Collection of Informed Consents from parents, Teachers and Children.

Ângela Almeida & Iolanda Galinha - Responsible for the writing the updated Relaxation and MindRegulation with SEL scripts.

Project Management:

Cristina Dias - from the Office for Research and Development Support of Universidade Autónoma de Lisboa.

Data Monitoring Committee:

Iolanda Galinha, Hugo Plácido Silva, Patrícia Arriaga - Responsible for data collection planning and procedures, as well as data assessment, reporting, and protection. It is independent from the sponsor and competing interests, but not from the researchers team. It is responsible for elaborating an annual report on the development of the project, as well as communicating important protocol modifications and unexpected or adverse outcomes to relevant parties as the sponsor, the hosting institution, the investigators team, the IRB, trial registries and journals.

## Authors' contributions

I. C. G., Principal Researcher, contributed with the conception and design of the study, bibliographic revision, materials selection and description, ethics procedures, intervention improvements, drafted and substantively revised

the manuscript; J.C.S. contributed with the design of the study, bibliographic revision, materials selection and description, ethics procedures, drafted parts of the manuscript, and substantively revised the manuscript; Cristina Oliveira contributed with the design of the study, bibliographic revision, materials selection and description, ethics procedures, intervention improvements, and drafted parts of the manuscript; Patrícia Arriaga contributed with bibliographic revision on physiologic measurement, drafted parts of the manuscript, and substantively revised the manuscript; Augusta Gaspar contributed with bibliographic revision on physiologic measurement, drafted parts of the manuscript, substantially revised, and edited the manuscript; Hugo Silva contributed with bibliographic revision on physiologic measurement; Vitória Ortega contributed with the original intervention drafts that were adapted in this study.

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This funding source had no role in the design of the study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results. It is responsible for annually auditing the development of the study according to the proposed and approved project.

### Data availability

The data collected, as well as the statistical coding of the analysis will be available from the corresponding author upon reasonable request. Materials will be publicly available in an open science repository.

### Declarations

#### Ethics approval and consent to participate

The Study Protocol and the informed consent for participants were approved by the Ethics Committee of the Centro de Investigação em Psicologia, from the Universidade Autónoma de Lisboa, CIP UAL, Approval Nr. 3/2023, 12–02–2023, and are available at [https://osf.io/8pr7c/?view\\_only=b74eb2f1a489458ea5c816a676181b33](https://osf.io/8pr7c/?view_only=b74eb2f1a489458ea5c816a676181b33).

#### Consent for publication

Not applicable, no individual person's data in any form is visible in the paper.

#### Competing interests

The authors declare that they have no competing interests.

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