

MindRegulation: Randomized Controlled Trial of the Effects of a Relaxation and Guided Imagery Intervention on the psychophysiological well-being, socioemotional regulation, cognitive and academic development of children in school

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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 behavior change, promotion of adaptive health outcomes, anxiety reduction, and adherence to medical interventions, in both adults and children. However, literature on relaxation and guided imagery interventions benefits 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 (MR) comprising relaxation, instructions for body posture, and guided imagery with socioemotional learning (SEL), conveying adaptive beliefs about oneself, the relationships with others and the environment.

Method

The MR intervention will be developed in the classroom for 15 minutes before learning activities, three times per week, for five months, and its effects will be measured on a range of emotional, physiological, and cognitive outcomes. Fifteen classes will be randomly assigned to three conditions: (a) relaxation and guided imagery-MR; (b) relaxation only; and (c) waitlist control. The RCT includes four data collection times: pretest, intermediate, posttest, and a six-month follow-up (trial registration NCT06101225, 05th October, 2023). The sample comprises 240 students, elementary school third and fourth graders, 8–11 years old. The variables measured in all times, except the intermediate, 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, heart rate variability, electrodermal activity, actigraphy and salivary 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 condition, compared to the relaxation and control conditions. Changes in physiological activity are expected during MR 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.

Trial Registration: MindRegulation

<https://ichgcp.net/clinical-trials-registry/NCT06101225>

Date version: MindRegulation Study Protocol 4th November 2023

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 11.6–20.5%) [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. *Cognitive specific imagery* involves images related to specific sports skills, whereas *cognitive general imagery* includes images pertaining to routines, strategies, or plans. *Motivational specific imagery* refers to images of goal attainment or goal-related behavior, whereas *motivational general imagery* refers 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, [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 Development in School Context

Mental imagery plays an important role in children's development. From six 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, [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 competences: 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, 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-minute 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 disorder are common associated symptoms of children's anxiety and 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 minutes 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 gradestudents' ability to access the imaginative mind and the sciencecontent. An explanatory sequentialmixed-methods design was used with students (n = 23), engaging in guided imagery visualization before classroomsciencelessons, 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 thatstudentswere 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 bothfor 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 stresses 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. This RCT contributes to the body of research by implementing and testing the benefits of the intervention program MR which

includes relaxation, guided imagery using scripts with SEL content, and body posture regulation, in comparison to a relaxation intervention and a control group.

Explaining for the choice of comparators, this study aims to compare and account for the effects of the relaxation intervention alone and the effects of relaxation intervention combined with guided imagery. Significant higher benefits are expected in the MR condition compared with the relaxation intervention, because mental imagery and SEL content components in this intervention add visual representations, conceptual meanings and SEL information and coping strategies, providing further dimensions for well-being and enhancing social and emotional development.

Data will be compared across three groups at three data collection times, before, during and after the intervention (T0 pretest; Tint Intermediate; T1 posttest), and within subjects comparison six-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.

Hypotheses

Through the participation in the MR intervention program, for five 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.

Methods

Study Design

The RCT design includes three conditions to which classes will be randomly allocated: (a) the experimental group (will receive MR intervention - relaxation and guided imagery); (b) the alternative condition group (will receive relaxation intervention); 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 five months, three school days per week, during 15 minutes at the beginning of the classes. Data on all 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, three months after the intervention launch, during two school mornings, before, during and after the MR 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), enrolled in 15 classes, will be invited to participate in an intervention-research program. Classes will be randomly assigned to one of three conditions: (a) “MindRegulation”; (b) Relaxation; and (c) Control group (5 classes each). 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 $f = .025$, .80 power, three groups, and a correlation among the repeated measures of at least .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. The control group will benefit from the MR intervention after the posttest 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 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 MindRegulation Project. From the total schools that accepted to participate and did not previously benefited from MR intervention (for example, the Grouping Schools of Olaias, Alto do Lumiar, and Alta de Lisboa), the coordination team of the study will randomly selected 15 classes from 3rd and 4th grades and distribute it 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 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. 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 9h to 11h o'clock. Data insertion will be double checked by the assistant researchers' team.

The Intervention Program

The MR 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 minutes before learning activities, three times per week, for five 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 intervention (for details, see Tidier in Table 1). For each theme, scripts will be applied three or four 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 intervention begins with a relaxation component for five minutes, 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 group, but extended for the 15 minutes of the intervention. If a participant does not accept to participate, alternative activities will be provided after agreement of the participant and the teacher. No other interventions will be accepted during the research and intervention study implementation, in the classes selected for this study,

Table 1
– MindRegulation - Relaxation and Guided Imagery Intervention Procedure

TIDieR item	Brief description
1. Brief Name	MindRegulation
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 images 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 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 begins with a process of relaxation 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 guided imagery 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 hours (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 minutes, before learning activities, three times per week, for five 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

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 five 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 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. This is a single-item measure and single item measures of happiness are reliable, valid and commonly used [84]. 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". (b) *Positive and Negative Affect* will be measured using a Portuguese short version of the PANAS-C [85] developed by [86]. 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 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). These items were chosen considering the results of confirmatory factorial analysis, factor weights and reliability.

Mental health will be measured with the Mental Health Continuum Short Form (MHC-SF) - The Portuguese Version for Children [87] of MHC-SF (adolescents) [88]. 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).

Socioemotional Competencies will be measured with the Questionário de Avaliação de Competências Socio emocionais (QACSE) adapted for children with 9 to 12 years old [89] that derives from de QACSE for adolescents (7th to 9th grade; [90]).

This instrument consists of 39 items, answered on a four-point response scale from A “Never” to D Always”, organized into six dimensions: Self-control; Social Awareness; Relational Skills; Social Isolation; Social Anxiety; Responsible Decision Making.

Self-Regulation of Emotions will be measured with a Portuguese version [86] of the emotional regulation questionnaire—children and adolescents (ERQ CA); [91], used to assess emotional control strategies. This questionnaire comprises 10 items organized in two subscales: cognitive reappraisal and expressive suppression. Responses are given on a 5-point rating scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Anxiety will be measured with the Trait Anxiety Inventory for Children (STAI-C2); [92], that measures a general proneness to anxious behavior rooted in the personality, as an anxiety trait. The STAI-C2 consists of 20 statements that ask children how they usually feel, most of the days. The answers range from 1 = almost never to 3 = often. In this study, the Portuguese version of STAI-C2 [93] will be used.

Self-Esteem will be measured by the Lifespan-Self-esteem-scale (LSE) [94], a global self-esteem scale for individuals aged 5 to 89. It has 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 scale was translated and back translated by two psychologists, one of which is bilingual Portuguese-English.

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) [95]; and (b) the D2 Test [96]. The Maze subtest analyzes the ability to anticipate and plan using visuospatial strategies in working memory, the Symbol Search subtest measures the ability of perceptual discrimination, dependent on visual attention capacity and working memory, 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. 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 seconds per line [96].

Physiological indicators of arousal, emotional regulation, and well-being will be recorded through Electrocardiogram (ECG; to record Heart Rate and Heart Rate Variability) and Electrodermal Activity (EDA, to record changes in skin conductance), both peripheral measures of the autonomic nervous system (ANS) [97]. 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 [98], whilst 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 [97, 99]. Guidelines for collecting and reporting EDA will be followed [100, 101]. 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 [102] and biofeedback interventions, which also include guided breathing techniques [103]. We will rely on existing guidelines for collecting and reporting time-domain and frequency-domain parameters of HRV [104;105], including established norms and reference values in children [106, 107].

Physical activity and movement will be measured by actigraphy with an ACC to provide information about the frequency, intensity, and duration of children’s physical movement in three axes (lateral, vertical and longitudinal) during class [108]. 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 [109]. 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 minutes, 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 [106] 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.

A biological index of stress will be measured through Salivary Diurnal Cortisol Slope using Salivettes. It measures will be collected at T0 and T1, throughout two days, in a subsample of 100 children (four classes from MR condition and four classes from the control group). On day 1, four samples will be collected throughout the day (9.15/30h, 12.15/30h, 15.15/30h, 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 9.15/30h, 12.15/30h and bedtime [110]. With these measures it is possible to assess the baseline cortisol level of each child, taking into consideration the variation resulting from school day activities.

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) [111] in the adapted Portuguese version [112]. 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.

Data Collected from Parents or Legal Guardians

Socioemotional skills of children will be measured with the Strengths and Difficulties Questionnaire parent version (SDQ), [111] in the adapted Portuguese version [112]. 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.

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 [100, 106].

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 [113]. Two researchers will work on the content analyses independently, after which they will meet to discuss the analyzes 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. 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 are missing completely at random.

Discussion

The study will be developed in a Portuguese Priority Educational Intervention Territories schools (TEIP), which are integrated in residential areas with sociocultural and economic diversity, and classified as schools with priority for intervention. Childrens' participation in the study will be integrated as a school activity for sciences procedures learning. Children will be actively involved in learning the procedures of data collection.

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: MindRegulation; 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 Sócio-Emocionais; 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.

Declarations

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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

Consent for publication

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

Availability of data and materials

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.

Competing interests

There are no financial and non-financial competing interests from the authors in this study. The study protocol was not funded by a commercial body.

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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.

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; Vitória Ortega – contributed with the intervention conception.

All authors read and approved the revised version of the manuscript and agreed to the byline order. Authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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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.

Margarida Gaspar de Matos & Cátia Branquinho - Mental Health and Socioemotional Development.

Hugo Plácido da Silva – Physiologic Data Processing and Analysis

Patrícia Arriaga - Heart Rate Analysis and Report

Augusta Gaspar – Electrodermal Activity Analysis and Report

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

Carlos Cardoso – 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 - Responsible for the writing the Relaxation and MindRegulation 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. It is responsible for elaborating an annual report on the development of the project, as well as communicating important protocol modifications to relevant parties as the sponsor, the hosting institution, the investigators team, the IRB, trial registries and journals.

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.

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Figures

Figure 1.

Flowchart of participants throughout the study

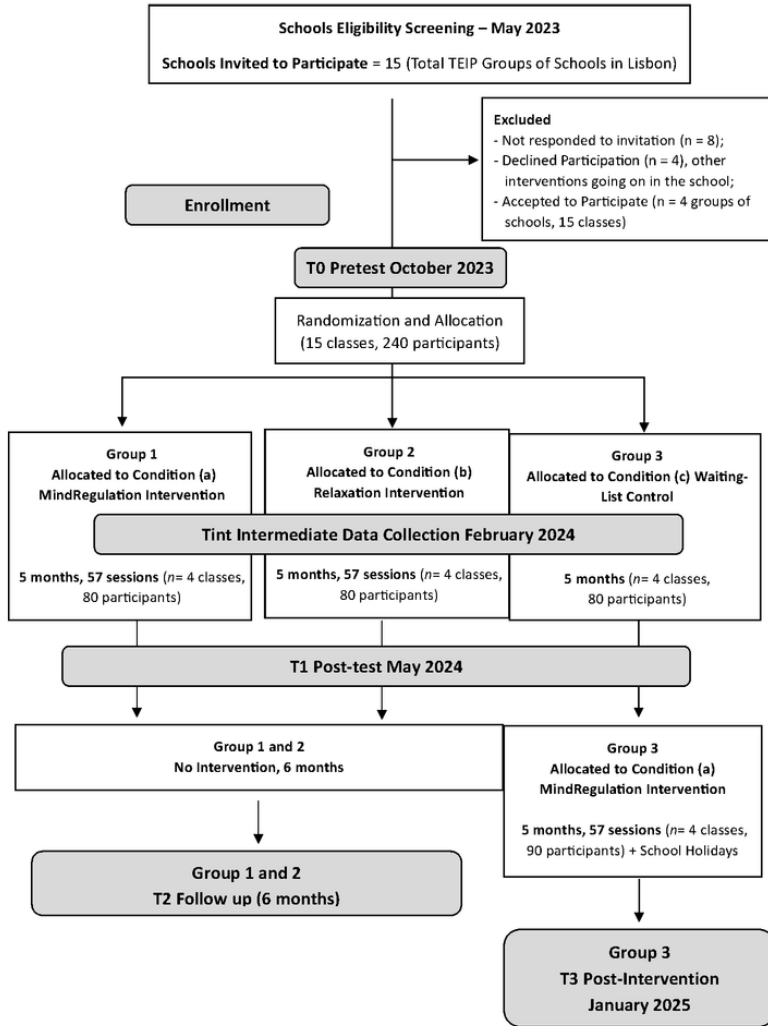


Figure 1

See image above for figure legend

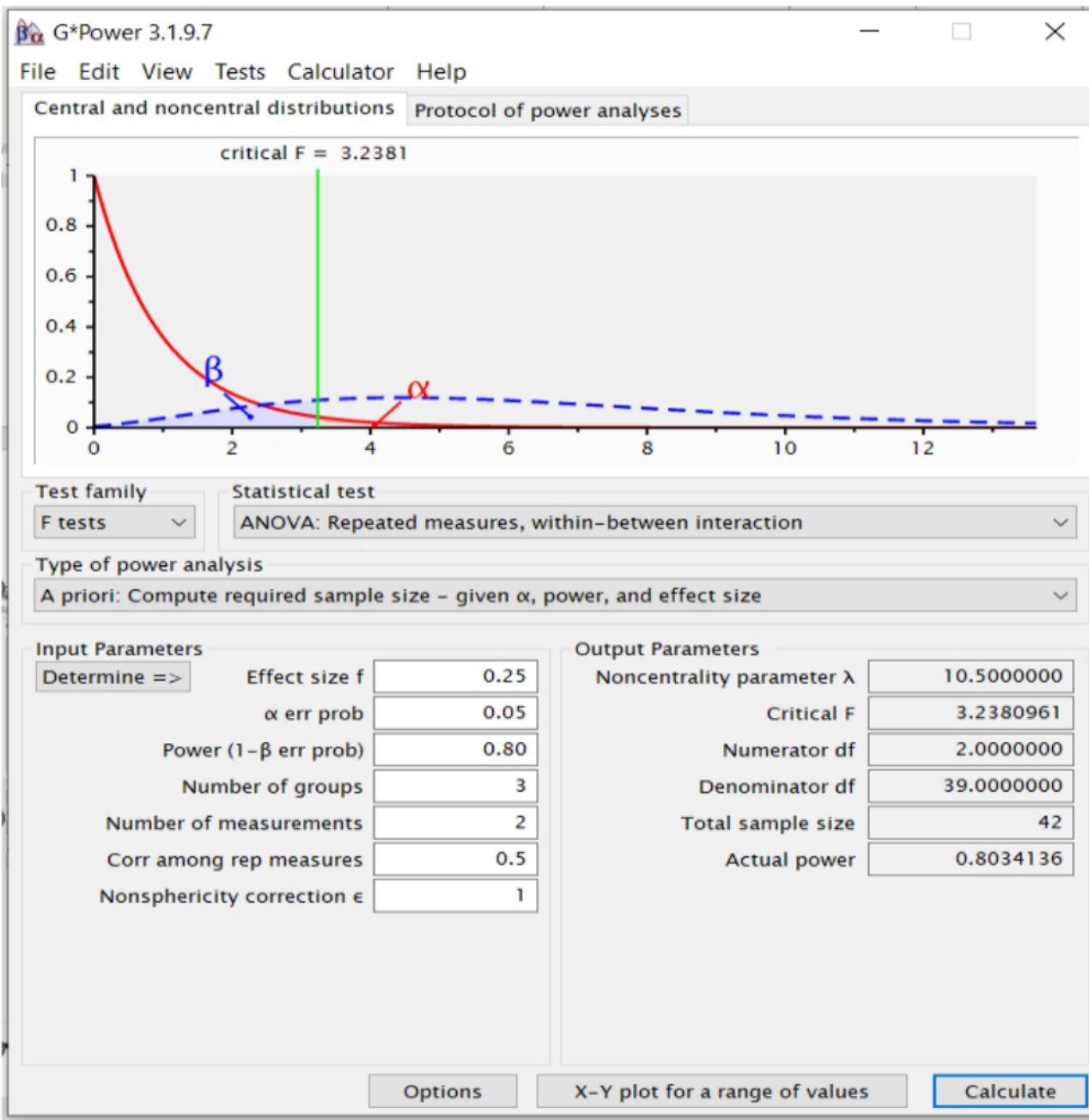


Figure 2

Sample size calculation for the validity of statistical analyses of the study.