Emotion regulation training for adolescents with ADHD

Study Protocol (including analysis plan)

This is a brief protocol and proposed plan for data analyses corresponding to the pre-registered research aim: *To evaluate feasibility and potential effectiveness of a psychological intervention (SKILLS-ER) designed to strengthen adaptive regulation skills for adolescents with ADHD*. Due to un-foreseen conditions related to data or other unexpected circumstances, this plan may have to be revised.

Intervention

The intervention (SKILLS-ER) has been developed by the authors, and aims to increase a participant's emotion regulation capacity by targeting different stages of the emotion regulation process proposed by the extended process model of emotion, i.e., identification, selection, implementation and monitoring (Sheppes et al., 2015). SKILLS-ER will comprise of eight sessions and include identification and differentiation of emotions, tolerance/acceptance of emotions, education of different regulatory skills, as well as on how to select, implement and monitor strategies. Sessions will take place at the Uppsala child- and adolescent psychiatry unit and consist of activating and experiential exercises administered by a clinical psychologist. Participants will gain access to internet-delivered material, such as homework assignments in-between sessions. SKILLS-ER will be delivered individually to the participants, where their parents will be involved in some sessions.

Participants

Adolescents (n=9; 13-18 years of age) with ADHD and emotion dysregulation will participate in SKILLS-ER in order to evaluate feasibility, potential effectiveness and to detect mechanisms that could strengthen adaptive regulation skills. The participants will be recruited from Uppsala child and adolescent psychiatric outpatient unit. Inclusion criteria is an ADHD diagnosis and self- and/or parent-rated emotion regulation difficulties, as indicated by the Emotion Questionnaire, on which the adolescent and parent rate either "strongly disagree" or "disagree" on the specific item: "when I (he/she) am (is) angry/sad/afraid/happy I (he/she) can change my (his/her) mood" (note: this item encompasses four separate questions related to being i) angry, ii) sad, iii) afraid or iv) happy). Further, emotion regulation difficulties should be identified as a problem for the adolescent. Exclusion criteria includes intellectual disability, autism, psychosis, bipolar disorder, severe depression, non-stabilized medication for ADHD at intake (if on medication for ADHD), and other ongoing psychological treatment.

Study design

A single-case multiple baseline design will be used, where the participants will be randomized to pre-intervention concurrent baselines at different lengths (5, 6 and 7 weeks).

Primary outcome measures: Rated emotion regulation

The participants and their parents will rate emotion regulation weekly using the Difficulties in Emotion Regulation Scale Short Form (DERS-SF; Kaufman et al., 2016). In addition, the parents will rate two daily measures of individually defined target behaviors associated with emotion regulation of their child (e.g., number of tantrums), collected during all phases (baseline [5-7 weeks], intervention [8 weeks] and post-intervention [2 weeks]). We will analyze the data with a combination of visual and quantitative analyses. For the visual analyses, we will follow the steps outlined by Kratochwill and colleagues (2013), investigating level, trend, variability, immediacy of effect, overlap and consistency of data patterns. To complement the visual analyses, we intend to use Tau-U as an effect size measure. We will follow the recommendations by Fingerhut and colleagues (2021) to decide which specific index of Tau-U is most appropriate in relation to the data as indicated by visual inspection.

Hypotheses

We hypothesize that emotion dysregulation (operationalized as the total summed score of DERS-SF) will decrease and that the individually defined target behaviors will change in frequency (with a decrease of emotion dysregulation or increase in emotion regulatory behaviors) during the intervention, comparing baseline with the intervention phase, and that any effect will remain up to two weeks after the intervention. In addition, we expect to see changes in the DERS-SF subscale scores during the intervention in a manner that corresponds to specific sessions dealing with content relevant to certain subscales. We hypothesize that ratings of the emotional awareness and clarity subscales will change first in the treatment, followed by the subscales nonacceptance, engaging in goal-directed behavior and emotion regulation strategies. Further, we hypothesize that time to change will be related to start of intervention, not start of baseline. An exploratory hypothesis will be adopted for the impulse subscale since it may correlate more with ADHD core symptomatology than other subscales and may not be as sensitive to the effects of the emotion regulation training.

Secondary outcome measures: Rated emotion regulation, functional impairment, client satisfaction, adverse events, ADHD symptoms and comorbidity

The participants will rate emotion regulation with the Cognitive Emotion Regulation Questionnaire (CERQ) pre- and post-intervention. Both participants and parents will (pre- and post-intervention) rate functional impairment in every-day life, ADHD symptoms with total score on the Adult ADHD Self-Report Scale Adolescent version (ASRS-A) and anxiety with total score on the Spence Children's Anxiety Scale (SCAS). Parents will also rate symptoms of oppositional defiant disorder with eight items from the SNAP-IV scale. Post-intervention, participants and their parents will rate adverse events using the Negative Effects Questionnaire (NEQ), and some items targeting client satisfaction (e.g., would recommend the treatment, can better handle emotions and ADHD, has benefitted from the treatment, impressions of the treatment). Difference in ratings between pre- and post-intervention will be calculated using Wilcoxon (paired) signed-rank test. We have no hypotheses in relation to these secondary outcomes, given the small sample size, but expect that these analyses will generate an effect size and enable calculations of appropriate sample size for a future randomized controlled (RCT) study. Post-intervention rating on NEQ and client satisfaction will be presented using descriptive statistics.

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Feasibility

The overall aim to assess feasibility will include the outcome measures, as well as information on participants attendance to sessions, completed homework assignments, and the therapist adherence to the intervention measured with self-ratings after each session (rated for different elements of the intervention: "not completed", "partly completed", "completed"). We will focus on sample characteristics, data collection procedures and outcome measures, acceptability and suitability of the intervention and study procedures, and preliminary evaluation of participant responses to the intervention.

References

Fingerhut, J., Xu, X., & Moeyaert, M. (2021). Selecting the proper Tau-U measure for single-case experimental designs: Development and application of a decision flowchart. Evidence-Based Communication Assessment and Intervention, 15(3), 99–114. https://doi.org/10.1080/17489539.2021.1937851

Kaufman, E. A., Xia, M., Fosco, G., Yaptangco, M., Skidmore, C. R., & Crowell, S. E. (2016). The Difficulties in Emotion Regulation Scale Short Form (DERS-SF): Validation and Replication in Adolescent and Adult Samples. Journal of Psychopathology and Behavioral Assessment, 38(3), 443–455. https://doi.org/10.1007/s10862-015-9529-3

Kratochwill, T. R., Hitchcock, J. H., Horner, R. H., Levin, J. R., Odom, S. L., Rindskopf, D. M., & Shadish, W. R. (2013). Single-Case Intervention Research Design Standards. Remedial and Special Education, 34(1), 26–38. https://doi.org/10.1177/0741932512452794

Sheppes, G., Suri, G., Gross, J. J. (2015). Emotion regulation and psychopathology. A Annual Review of Clinical Psychology, 11, 379-405. doi: 10.1146/annurev-clinpsy-032814-112739.