

Study Preregistration: Targeting Parental Risk Factors for Children's Anxiety: A Factorial Experiment With Three Intervention Components

STUDY SYNOPSIS

Introduction Summary

Anxiety is one of the most common mental health problems in childhood, and causes severe and persistent impairment in children's lives.¹ Parents can play a key role in the development of children's anxiety symptoms²; yet, the evidence of parent-focused interventions is relatively thin.³ This may be because little is known about what the optimal content of these interventions should be. Interventions typically either use parents as lay therapists, or target multiple different family risk factors at the same time.⁴ Traditional randomized trials of these "package deal" interventions provide little insight into what specific parental risk factors should be targeted to most effectively reduce children's anxiety.⁵ We will examine the effects of targeting distinct parental risk factors to provide more information on the role of these factors in children's anxiety, and to guide the development of intervention programs.

First, family accommodation, the process by which family members change their behaviors and expectations to reduce children's anxiety, facilitates avoidance and increases children's anxiety.⁶ Accommodation can be targeted by making parents aware of this, and by constructing a plan to reduce accommodating behaviors (component A).⁷ Second, low parental warmth can lead to the child developing less self-competence and a perception of the world as threatening and hostile. This can be targeted by increasing parental empathetic reactions to children's anxiety (component B).^{2,8} Third, parental maladaptive cognitions about children's anxiety interfere with parents' ability to effectively support their anxious child,⁹ and can be targeted by cognitive restructuring (component C).⁴

We will test whether the components reduce parent-reported children's anxiety (research question 1), clinician-rated children's anxiety symptoms (research question 2), and children's life interference (research question 3). We will investigate whether the components reduce the risk factor that they target (research question 4), and will examine wider and boundary effects (research question 5).

Method Summary

Participants. We aim to include 266 parents of children aged 7.0 to 11.11 years who score ≥ 4 on the Overall Anxiety Severity and Impairment Scale for Youth. Participants will be recruited through Dutch primary schools, social media, and existing collaborations of the University of Amsterdam.

Design. We will use a factorial experiment with random allocation to any possible combination and order of components (Figure 1). This design provides a stringent test of the effect of each component, both in the presence and in the absence of other components. Participants will be randomly allocated to 1 of 34 conditions. Assessments will take place at baseline (T_0), after the first component (T_2), after the final component (T_6), and 6 weeks after the final component (T_{12}).

Intervention Components. Each component consists of a therapist-led videocall intervention and 14 daily online assignments. Component A is based on behavioral perspectives, and aims to reduce family accommodation: parents identify and make a plan to reduce accommodation. Component B is based on relational perspectives, and aims to increase parental warmth: parents increase empathetic reactions to their child's anxiety by labeling the emotion, empathize, and communicate confidence. Component C is based on cognitive perspectives and aims to reduce parental maladaptive cognitions: parents identify and challenge thoughts about their child's anxiety. Pilot data suggest that parents find all components acceptable ($N = 6$ parents, Means = 3.50-4.33 on a scale from 1 to 5).

Measures. Measures to be used are as follows: Children's anxiety symptoms: Screen for Child Anxiety Related Emotional Disorder-71 (primary outcome) and a clinician rating. Children's anxiety life interference: Child Anxiety Life Interference Scale. Family accommodation: Family Accommodation Scale-Anxiety. Parental empathetic reactions: adapted Empathy Formative Questionnaire, validated in a pilot study ($N = 39$; $\alpha = 0.88$). Parental cognitions: Parental Beliefs about Anxiety Questionnaire. Wider and boundary effects: Behavior and Feeling Survey; Depression, Anxiety and Stress Scale, Me as a Parent, adapted Anxiety Change Expectancy Scale.

FIGURE 1 Design of the Factorial Experiment

Week	0	1 – 2	3 – 4	5 – 6	7 – 12
Condition (n)					
1 (35)		0	0	0	
2 (7)		0	A	0	
3 (7)		0	0	A	
4 (7)		0	A	B	
5 (7)		0	A	C	
6 (7)		0	B	0	
7 (7)		0	0	B	
8 (7)		0	B	A	
9 (7)		0	B	C	
10 (7)		0	C	0	
11 (7)		0	0	C	
12 (7)		0	C	A	
13 (7)		0	C	B	
14 (7)	A		0	0	
15 (7)	A		0	B	
16 (7)	A		0	C	
17 (7)	A		B	0	
18 (7)	A		B	C	
19 (7)	A		C	0	
20 (7)	A		C	B	
21 (7)	B		0	0	
22 (7)	B		0	A	
23 (7)	B		0	C	
24 (7)	B		A	0	
25 (7)	B		A	C	
26 (7)	B		C	0	
27 (7)	B		C	A	
28 (7)	C		0	0	
29 (7)	C		0	A	
30 (7)	C		0	B	
31 (7)	C		A	0	
32 (7)	C		A	B	
33 (7)	C		B	0	
34 (7)	C		B	A	

Note: 0 = no intervention component. A = reducing family accommodation to reduce parent accommodation to children’s anxiety. B = increasing empathetic reactions to increase warmth in parental responses to child anxiety. C = cognitive restructuring to reduce maladaptive parental cognitions about children’s anxiety. Please note color figures are available online.

Analytic Strategy. Data will be analyzed using analyses of covariance following intention-to-treat principles, with baseline levels of the dependent variable as covariate. For all research questions (stated above), we will investigate the

effect of an aggregated set of conditions on the outcome variable (anxiety [parent and clinician rated], life interference, parental risk factors, wider and boundary effects). At T₂, we compare 4 aggregated sets of conditions: each




individual component ($n = 49$ each) vs control ($n = 119$). At T_6 and T_{12} , we compare 2 aggregated sets of conditions: families who received the target component ($n = 147$) vs families who did not ($n = 119$).

Significance Summary

Knowledge of which parental risk factors should be targeted in treatment can help researchers to identify the most influential parental risk factors for children's anxiety. In addition, it can inform the development of more effective intervention programs, and match these to the needs of individual families.

CRedit authorship contribution statement

Karen Rienks: Writing – review & editing, Writing – original draft, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Elske Salemink:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Conceptualization. **Patty Leijten:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Conceptualization.

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REFERENCES

- Schwartz C, Barican JL, Yung D, Zheng Y, Waddell C. Six decades of preventing and treating childhood anxiety disorders: a systematic review and meta-analysis to inform policy and practice. *BMJ Ment Health*. 2019;22(3):103-110. <https://doi.org/10.1136/ebmental-2019-300096>
- Peris TS, Thamrin H, Rozenman MS. Family intervention for child and adolescent anxiety: a meta-analytic review of therapy targets, techniques, and outcomes. *J Affect Disord*. 2021;286:282-295. <https://doi.org/10.1016/j.jad.2021.02.053>
- Simon E, Bogels S, Voncken J. Efficacy of child-focused and parent-focused interventions in a child anxiety prevention study. *J Clin Child Adolesc Psychol*. 2011;40(2):204-219. <https://doi.org/10.1080/15374416.2011.546039>
- Breinholst S, Esbjorn BH, Reinholdt-Dunne ML, Stallard P. CBT for the treatment of child anxiety disorders: a review of why parental involvement has not enhanced outcomes. *J Anxiety Disord*. 2012;26(3):416-424. <https://doi.org/10.1016/j.janxdis.2011.12.014>
- Creswell C, Nauta MH, Hudson JL, *et al*. Research review: recommendations for reporting on treatment trials for child and adolescent anxiety disorders—an international consensus statement. *J Child Psychol Psychiatry*. 2021;62(3):255-269. <https://doi.org/10.1111/jcpp.13283>
- Lebowitz ER, Woolston J, Bar-Haim Y, *et al*. Family accommodation in pediatric anxiety disorders. *Depress Anxiety*. 2013;30(1):47-54. <https://doi.org/10.1002/da.21998>
- Lebowitz E, Marin C, Martino A, Shimshoni Y, Silverman W. Parent-based treatment as efficacious as cognitive-behavioral therapy for childhood anxiety: a randomized noninferiority study of supportive parenting for anxious childhood emotions. *J Am Acad Child Adolesc Psychiatry*. 2020;59(3):362-372. <https://doi.org/10.1016/j.jaac.2019.02.014>
- Bögels SM, Brechman-Toussaint ML. Family issues in child anxiety: attachment, family functioning, parental rearing and beliefs. *Clin Psychol Rev*. 2006;26(7):834-856. <https://doi.org/10.1016/j.cpr.2005.08.001>
- Manley S, Francis S. The role of parental anxiety sensitivity and beliefs about child anxiety in the relationship between parent and child anxiety. *J Psychopathol Behav Assess*. 2022;44(1):125-138. <https://doi.org/10.1007/s10862-021-09937-5>

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Clinical trial registration information: The Relative Effects of Three Parent-Intervention Components to Reduce Children's Anxiety; <https://clinicaltrials.gov/>; NCT05854602.

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