Effectiveness of an integrated, blended mindfulness- and psycho-education program for the prevention of co-rumination and internalizing problems in Dutch primary school girls: A cluster Randomized Controlled Trial

PROTOCOL TITLE 'Effectiveness of a blended school-based mindfulness program for the prevention of co-rumination and internalizing problems in Dutch 10-to-12-year-old girls: A cluster Randomized Controlled Trial'

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Coordinating investigator/project leader	**Dr. Patricia Vuijk** **p.vuijk@hr.nl**
Principal investigator(s) (in Dutch: hoofdonderzoeker/ uitvoerder)	**Dr. Patricia Vuijk** **p.vuijk@hr.nl**
Sponsor (in Dutch: verrichter/opdrachtgever)	**Hogeschool Rotterdam**
Subsidising parties	**NRO/Citylab010/SIA KIEM/SIA RAAK PRO**
Independent expert(s)	**Dr. P. So-de Bruin** **Kinder- en Jeugdpsychiater** **p.so@youz.nl**
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PROTOCOL SIGNATURE SHEET

Name	Signature	Date
Sponsor or legal representative:	**dr. Marleen Goumans** **directeur Kenniscentrum Zorginnovatie Hogeschool Rotterdam**	**30/04/2025**
Principal Investigator:	**Dr. Patricia Vuijk** **Lector Meisjes en mentaal welbevinden Kenniscentrum Zorginnovatie Hogeschool Rotterdam** 	**30/04/2025**

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	**General Assessment and Registration**
APIM	**Actor-Partner Interdependence Modeling**
AEs	**Adverse events**
BROK	**Basic course on Regulations and Organization of Clinical Trials**
CA	**Competent Authority**
CASTOR EDC	**CASTOR Electronic Data Capture**
CAMM	**Child and Adolescent Mindfulness Measure**
CBSK	**Competentie Belevingsschaal voor Kinderen**
CCMO	**Central Committee on Research Involving Human Subjects**
CDI-2	**Child Depression Inventory 2**
CoDEQ	**Co-Dampening and Co-Enhancing Questionnaire**
COTAN	**Commissie Testaangelegenheden Nederland**
cRCT	**Cluster Randomised Controlled Trial**
CRQ	**Co-rumination Questionnaire**
DANS	**Data Archiving and Networked Services**
DERS-NL	**Difficulties in Emotion Regulation Scale NL**
DSMB	**Data Safety Monitoring Board**
DTSA	**Discrete-Time Survival Analysis**
EudraCT	**European drug regulatory affairs Clinical Trials**
FIML	**Full Information Maximum Likelihood**
GAD	**Generalized Anxiety Disorder**
GB	**Gigabytes**
GCP	**Good Clinical Practice**
IC	**Informed Consent**
ICC	**Intraclass Correlation**
ISCED	**International Standard Classification of Education**
ISO	**International Organisation for Standardisation**
LCT	**Latent Class Analysis**
LTA	**Latent Transition Analysis**
LGCM	**Latent Growth Curve Models**
MAAS-A	**Mindful Attention Awareness Scale-Adolescents**
M	**Mean**
MB	**Megabytes**

METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
MLR	**Robust Maximum Likelihood**
MYRIAD	**My Resilience in Adolescence**
NRI	**Network of Relationships Inventory**
PANAS-C	**Positive and Negative Affect Schedule for Children**
PI	**Principal Investigator**
RCADS	**Revised Children's Anxiety and Depression Scale**
RMSEA	**Root Mean Square Error of Approximation**
SD	**Standard Deviation**
SES	**Socio Economic Status**
SAEs	**Serious Adverse Events**
SPONSOR	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SRMSR	**Standardized Root Mean Square Residual**
SUSARs	**Suspected Unexpected Serious Adverse Reaction**
TAU	**Teaching-and-care-as-usual**
UNESCO	**United Nations Educational, Scientific and Cultural Organization**
WLSMV	**Weighted Least Squares Minimum Variance**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Research shows that young adolescent girls who engage in excessive, speculative, and negatively focused discussions with close friends about interpersonal problems and worries — a behaviour also known as co-rumination— face a greater risk of developing internalizing symptoms (i.e., depression and anxiety) and reduced friendship quality. Currently there are no school-based prevention programs available that specifically address high levels of co-rumination in young adolescent girls aged 10-12-years old. Mindfulness training, with a focus on present-moment awareness, appreciation, gratitude, and awareness of the dynamics between thoughts, emotions, bodily sensations, and impulses, in combination with psycho-education, can be helpful for girls who engage in repetitive and judgmental negative interactions. To address this need, we developed a blended, primary school-based mindfulness prevention program called Girls United and the current cluster Randomized Controlled Trial will test program's effectiveness in reducing co-rumination and internalizing problems. Girls United aims to teach mindfulness skills at a dyadic level, i.e., between two close female friends and thereby helps young girls prone to co-rumination incorporate these techniques into their daily lives. This evidence-based prevention program will then be implemented across Dutch primary schools.

Objective: The primary aim of the cluster Randomized Controlled Trial (cRCT) is to evaluate the effectiveness of the Girls United prevention program on self- and parent-reported mental health outcomes in a sample of max 320 young adolescent girls aged 10 to 12 (attending mainstream primary schools in the Netherlands) displaying high levels of self-reported co-rumination. Additionally, the study aims to identify the mechanisms of change of the program.

Study design: The Girls United cluster Randomised Controlled Trial has two arms: (1) an intervention condition in which max 80 girls' friendship dyads (*n* = max 160 with high levels of self-reported co-rumination) will receive the Girls United program for 14 weeks, and (2) a control condition in which max 80 girls' friendship dyads (*n* = max 160 with high levels of self-reported co-rumination) will receive teaching-and-care-as-usual (TAU). The intervention will be offered in two consecutive cohorts during academic year 2025/2026 and 2026/2027.

Study population: Max 160 friendship dyads, who are girls from 10-12 years old in grades 5 and 6 of mainstream primary schools across different regions in the Netherlands. The dyads are primarily characterized by at least one of both girls having a high level of co-rumination as displayed on the co-rumination screener (so-called high risk friendship dyads).

Intervention (if applicable): The Girls United prevention program aims to foster social-emotional-behavioural self-regulation within a supportive close-friendship context through incorporation of both dyadic and individual experiential mindfulness-based learning. Developed between 2020 and 2023 using the Intervention Mapping Approach for health

promotion planning, the program includes 14 weekly online lessons delivered by trained facilitators. These lessons integrate psychoeducation and mindfulness practices, guiding participants in using the application *App yourself Happy* app within their friendship dyads. The program's aim is to support max 160 Dutch girls (max 80 dyads) aged 10 to 12 who are at high risk, helping them shift from maladaptive to adaptive emotion regulation patterns in their daily interactions. This approach encourages the benefits of close, intimate friendships while introducing healthy alternatives to excessive co-rumination.

Main study parameters/endpoints: The primary outcome measure is self-reported co-rumination. Data will be collected at baseline (T0), while the intervention (and TAU) are being offered (T1; T2; T3), immediately after the program (T4), and at 1-year follow-up (T5). Secondary outcome measures are self-reported depression and anxiety symptoms, self-reported friendship quality, self-reported positive and negative affect, self-reported interpersonal responses to positive affect, and self-reported self-worth. Mediator variables consist of self-reported trait mindfulness and self-reported emotion regulation. Implementation measures are self-reported participant responsiveness towards the intervention, trainer-reported implementation fidelity, trainer-reported experience with delivering mindfulness-based programs and self-reported competence in training delivery, as well as the extent to which participants practice outside the training sessions (girls self-report).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The study is expected to pose minimal burden and risks for participating girls, as it does not interfere or disrupt their regular education practices and focuses on naturally occurring interactions and activities within their close friendships. Additionally, the study provides an opportunity for participants to contribute to research aimed at enhancing understanding and preventing excessive co-rumination and internalizing issues in early adolescent girls.

1. INTRODUCTION AND RATIONALE

According to the Healthy Behaviour in School-aged Children study, focussed on examining trends in youth's health and well-being, there has been an explosive increase in mental health problems among Dutch early adolescent girls (Boer et al., 2022). In 2021, 33% of girls in upper primary education and 43% in secondary education experienced emotional problems, compared to 14% and 28% in 2017 respectively. Mental health problems have a major negative impact on youth's daily functioning and well-being. These problems are associated with poor academic performance, sleep problems, psychosomatic complaints and impaired physical health (Mendle, Turkheimer & Emery, 2007; Morales-Muñoz & Gregory, 2023; Sellers et al., 2019). Moreover, suffering from mental health problems at an early age poses a great risk of developing psychopathology later in life (Beesdo-Baum et al., 2015). Therefore, it is important to prevent, identify and treat mental health problems in girls as early as possible.

Early adolescence typically starts around the ages of 10 to 13 and marks the beginning of transitioning from childhood into adolescence, and is characterized by significant physical, emotional and cognitive changes (Verhulst, 2021). For instance, exploring ones' own identity, striving greater autonomy from caregivers, and establishing close and intimate friendships during early adolescence may confer challenges (Verhulst, 2021). These challenges can evoke intense and complicated unpleasant and pleasant emotions (Lerner & Steinberg, 2009). Given these stressful challenges and related complicated emotions, early adolescence is a particularly vulnerable period for mental health development (Twenge, Cooper, Joiner, Duffy, & Binau, 2019). The combination of significant developmental changes and the emotional turmoil associated with this stage of life necessitates careful attention to the mental health needs of early adolescent girls to promote healthy psychological and emotional growth.

One of the most profound changes in early adolescence is the increasing influence of dyadic friendships on girls' mental health. Friendships with other girls become increasingly central sources of emotional support and intimacy. Girls rely on their close friendships to develop and consolidate social-emotional skills that are essential for good mental health (Narr, Allen, Tan, & Loeb, 2019). Social-emotional skills refer to the abilities that enable girls to communicate effectively, build relationships, regulate their emotions, and behave in a socially responsible manner (Verhulst, 2021). An important developmental task for girls is learning to skilfully manage self-disclosure which is defined as sharing personal or private information about oneself in order to make themselves known to another person (Buhrmester & Prager, 1995).

During adolescence, self-disclosure increases, playing a vital role in understanding and fulfilling each other's emotional support needs. More importantly, it fosters intimacy, trust, and strong social connections (Rose & Rudolph, 2006; Bauminger et al, 2008; Costello et al.,

2024). When girls share personal and intimate information about themselves, and their close friend responds with a similar level of vulnerability, it reinforces a sense of safety within the relationship. This mutual openness strengthens trust and confirms that sharing personal information in this friendship is secure. Developing self-disclosure helps girls establish deep and meaningful relationships by fostering comfort with vulnerability, which, in turn, enhances their emotional well-being (Costello et al., 2024). However, within close friendships, self-disclosure can also have a detrimental impact on adolescent's social-emotional development. Co-rumination is considered a maladaptive form of self-disclosure and refers to 'excessively discussing personal problems within a dyadic relationship and is characterized by frequently discussing problems, discussing the same problem repeatedly, mutual encouragement of discussing problems, speculating about problems, and focusing on unpleasant feelings' (Rose, 2002, Rose, 2002, p. 1830).

Given its pervasive negative focus, co-rumination is extensively related to internalizing problems (Rose, 2002). Indeed, a growing body of literature indicates that excessive co-rumination is related concurrently and prospectively to internalizing problems, such as (early onset of) increased levels of depression and anxiety symptoms or disorders (Spendelow, Simonds & Avery, 2017; Tilton-Weaver & Rose, 2023). Mental health problems during adolescence are indicators of a wide range of short- and long-term health issues and lifelong impairments in daily functioning (Global Burden of Disease Collaborative Network, 2022). Detecting these problems early and implementing evidence-based interventions during this critical stage are essential to preventing their escalation and long-term impact on life trajectories (Shorey, Ng & Wong, 2022).

The link between excessive co-rumination and internalizing problems can be explained from various perspectives. The central idea is that co-rumination intensifies focus on negative thinking, especially when co-rumination becomes the default mode of communication. This makes concerns and problems seem more serious and less solvable than they are (Rose, Glick, Smith, Schwartz-Mette, & Borowski, 2017). Consequently, girls may experience and intensify feelings of unpleasant affect (e.g. anger, sad, nervousness, hopelessness, self-doubt, or guilt), particularly regarding their perceived problem-solving abilities and their capacity to support friends (Kirmayar, Khullar & Dirks, 2021; Nolen-Hoeksema, 2000; Stone et al., 2019). Moreover, co-rumination fosters dysphoric rumination, an established maladaptive emotion regulation strategy and transdiagnostic risk factor for depression and anxiety (McLaughlin & Nolen-Hoeksema, 2011; Stone & Gibb, 2015). Furthermore, co-rumination confers a risk for mutual depression and anxiety contagion (Schwartz-Mette et al, 2012; Schwartz-Mette & Smith, 2018). Adolescents can strongly experience empathic distress in response to their friends worries, meaning that they share their friends' distress in ways that they are experiencing the distress as their own (Smith, 2015; Rose et al., 2017). Finally, spending

excessive time on co-rumination with friendships prevents adolescents from engaging in more positive activities that could mitigate negative affect.

Paradoxically, co-rumination is also associated with positive social-emotional outcomes and high-quality friendships, which makes it a complex construct for preventive intervention efforts (Rose, Schwartz-Mette, Glick & Smith, 2014). Specifically, some co-rumination components (i.e. extensively talking about problems, rehashing problems, speculating about problems, and mutual encouragement of problem talk) are related to friendship quality and closeness, whereas another component (i.e. dwelling on unpleasant feelings) is associated with internalizing problems (Rose et al., 2014). Similarly disturbing consequences of co-rumination are presented by more recent studies examining the physiological responses of the heart and blood vessels to co-ruminating. Physiological responses are part of the body's "fight-or-flight system," regulated by the autonomic nervous system. These studies show that co-rumination leads to, among other things, an increased heart rate within the first few minutes of a conversation. This is a stress response designed to pump more blood (and thus oxygen) to vital muscles and organs, heightening alertness to prepare for action in the face of potential threats (see Tudder, Wilkinson, Gresham, & Peters, 2023; DiGiovanni, Peters, Tudder, Gresham, & Bolger, 2024). What these studies demonstrate is that co-rumination does not calm but rather induces stress. Despite this, co-rumination is still attractive due to its social benefits (Rose, 2021). Co-rumination involves self-disclosure, which can lead to more emotional closeness and higher friendship quality (Rose, Smith, Glick, & Schwartz-Mette, 2016). Thus, co-rumination may bring friends together, creating a close relationship context in which internalizing symptoms may spread. Furthermore, the relationship between co-rumination and high friendship quality is bidirectional, suggesting that breaking this cycle is crucial to preventing the worsening of internalizing problems (Felton, Cole, Havewala, Kurdziel & Brown, 2019; Hankin, Stone, & Wright, 2010; Rose, Carlson, & Waller, 2007).

Because of the associations between dwelling on unpleasant emotions, feelings, thoughts and physical sensations, co-rumination is considered as a maladaptive interpersonal emotion regulation strategy to regulate or modify distressing emotions, feelings, thoughts and physical sensations (Battaglini, Tracy, Jopling, & leMoult, 2024; Dixon-Gordon, Bernecker & Christensen, 2015; Waller, Stone & Dahl, 2014). Emotion regulation involves efforts to adjust the quality, intensity and duration of both pleasant and unpleasant emotions in oneself and others (McRae & Gross, 2020; Torre & Lieberman, 2018). Among adolescents, gender and age are strong predictors of excessive co-rumination. As adolescence progresses, girls in same-sex friendships are more likely to co-ruminate than boys (Hankin et al., 2010; Rose et al, 2007; Rose, Schwartz-Mette, Glick, Smith & Luebbe, 2014). From a developmental psychology viewpoint, several factors explain why girls are more prone to excessive co-rumination. In friendships, girls tend to prioritize psychological aspects (e.g., intimacy, social

support) often adopting a more community-focused approach (Rose & Rudolph, 2006; Rudolph & Dodson, 2022). They also show greater emotional expressiveness and show higher levels of cognitive and affective empathy (Calandri, Graziano, Cattelino & Testa, 2021; Winters et al., 2023; Zeman, Cameron & Price, 2019). As a result, they are more skilled at mentalizing and responding empathetically to the emotions and concerns of their friends compared to boys, making co-rumination more likely to become part of their interactions. Another reason is that girls discuss interpersonal problems more frequent with their friends compared to boys thereby often concentrating on uncertainties or aspects of the problem they do not fully understand (Bastin, Mezulis, Ahles, Raes & Bijttebier, 2021). This tendency to clarify and resolve ambiguities in social situations can heighten negative emotions tied to interpersonal concerns and insecurities (Hamilton et al., 2016). As a result, girls are more likely than boys to engage in excessive co-rumination driven by the intention to understand and resolve these problems and emotional responses.

Emotion regulation skills are crucial for adolescents' mental health (Chervonsky & Hunt, 2019). Peer relationships play a significant role in shaping and refining these skills. As young girls spend increasing amounts of time with their same-sex friends, discussing their (often stressful) experiences, they develop greater emotional awareness and recognize the need for effective emotion regulation strategies (Cook, 2020, Zeman, Cassano & Adrian, 2013). Despite the well-documented impact of co-rumination on mental health, there are currently no prevention programs specifically designed to address this maladaptive emotion regulation strategy in young adolescent girls. United Nations Educational, Scientific and Cultural Organization (UNESCO) urges schools to prioritize teaching social-emotional skills in order to prevent internalizing problems, emphasizing the importance of mindfulness training as a core component (UNESCO MGIEP, 2022). Recent research on the effects of excessive co-rumination similarly underscores the value of mindfulness-based approaches in prevention efforts. Essentially, schools are a key context for developing healthy emotion-regulation skills as well as building and maintaining friendships. Young adolescent girls report placing high value on friendships formed at school (Sime, Gilligan & Scholtz, 2021). They spend a large amount of their day and week in close proximity to these friends during school hours and maintain extensive physical and online contact outside of school (Waygood, Olsson, Taniguchi & Friedman, 2020). For these reasons we developed a blended school-based mindfulness prevention program 'Girls United' that teaches girls to develop healthy emotion regulation skills within their friendships thereby reducing excessive co-rumination. The Girls United school-based mindfulness prevention program includes two key components: (1) psycho-education to enhance emotional awareness and understanding of both pleasant and unpleasant emotions, and (2) training in mindfulness-based healthy emotion regulation techniques to manage pleasant and unpleasant emotions, feelings, thoughts, physical sensations, impulses,

memories, and reactivity. This program aims to help girls to relate to their emotions in healthier ways, breaking the habit of excessive co-rumination by shifting their focus away from dwelling on negative affect and distressing feelings. Well-developed emotional competencies serve as a protective factor in friendships and reducing the likelihood of co-rumination becoming their default way of interacting (Miller et al., 2020, Zeman et al, 2018).

Mindfulness has the ability to use qualities like attentiveness, curiosity, and responsiveness to bring awareness to both internal (such as bodily sensations, emotions, thoughts and behaviours) and external (such as stressors and friendships) experiences. This approach is done without judgement and with focused attention in the present moment, enabling individuals to respond more skilfully and insightfully. Furthermore, mindfulness training has shown to be effective in promoting positive thoughts about oneself and one's experiences, improving relationships, enhancing empathy, compassion, self-compassion, gratitude, present-moment awareness, and meta-awareness of the interactions between thoughts, emotions, bodily sensations, and impulses/reactions (Garcia-Campayo et al., 2024; Montero-Marin et al., 2022; Roeser et al., 2023, Webb, Swords, Lawrence, & Hilt, 2022; Webb, Swords Murray & Hilt, 2021). Previous research has shown that mindfulness programs can reduce symptoms of depression, anxiety, stress in adolescences, while also increasing empathy and prosocial behaviour (Baelen, Esposito & Galla, 2019; Cheng, Gilsons & Sparkes, 2019; Dunning et al., 2019; Roeser, Galla & Baelen, 2022; Schindler & Friese, 2022). Notably, girls show improvements in emotion regulation, anxiety, and positive affect (Butzer, LoRusso, Shin & Khalsa, 2017; Galante & van Dam, 2024; Johnson, Burke, Brinkman, & Wade, 2016; Kang et al., 2018). Given this strong foundation of evidence, the program is designed using well-established mindfulness techniques and theoretical frameworks, with a focus on reducing co-rumination and related internalizing challenges in adolescent girls.

2. OBJECTIVES

Primary Objective: The primary objective of the Girls United cluster Randomized Controlled Trial (cRCT) is to examine the effectiveness of the Girls United prevention program on self-reported co-rumination.

Secondary Objectives: The second objective of this study is to investigate the intended active mechanisms of this program, especially enhancement of mindfulness and emotion regulation skills. Furthermore, the effectiveness of the Girls United mindfulness-based prevention program on self-reported symptoms of depression and anxiety, self-reported contagion of depression and anxiety symptoms, self- and friend-reported friendship quality, self-reported positive and negative affect, interpersonal responses to positive affect, self-reported self-worth

and parent-reported health care use will be studied in Dutch young adolescent girls from age 10 to 12 years old.

The research question is: To what extent does the app-based mindfulness prevention program Happy Friends, Positive Minds impact mental health and well-being in Dutch 10-to-12-year-old girls?

Hypotheses:

(1) Girls in the intervention group will have a greater reduction in co-rumination (primary outcome) about distress and difficult emotions and feelings, (and thereby) internalizing symptoms (depression/anxiety, secondary outcome) and negative affect (secondary outcomes) during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
(2) Girls in the intervention group will have less dyadic depression contagion, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
(3) Girls in the intervention group will demonstrate less dyadic anxiety contagion during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
(4) Girls in the intervention group will experience better friendship quality, higher levels of positive affect and higher levels of interpersonal responses to positive affect, during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
(5) The hypothesized intervention effects on co-rumination will be mediated by the development of mindfulness and emotion regulation skills during the intervention period, immediately after the intervention period and after one-year follow-up.
(6) Girls in the intervention group will experience greater feelings of self-worth and will show less health care use during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.

3. STUDY DESIGN

Design

The Girls United cRCT aims to evaluate the effectiveness of the Girls United program, a school-based intervention blending targeted mindfulness and psychoeducation. Delivered by trained and experienced mindfulness health professionals, the program is compared to a teaching-and-care-as-usual (TAU) approach. The study includes two groups: (1) an intervention group where girls' friendship dyads participate in the Girls United program, and (2) a control group where girls' friendship dyads receive TAU.

Duration

The 14-week Girls United program will be delivered in two cohorts across two academic years: cohort 1 in 2025–2026 and cohort 2 in 2026–2027. The program will run in four phases from October 2025 to May 2026 for both cohorts. Baseline measurements (T0) will occur in September 2025 for cohort 1 and February 2026 for cohort 2. Subsequent measurements include T1 (November 2025 for cohort 1 and April 2026 for cohort 2), T2 (January 2026 for cohort 1 and June 2026 for cohort 2), T3 (March 2026 for cohort 1 and October 2026 for cohort 2), and T4 post-intervention measurements (May 2026 for cohort 1 and December 2026 for cohort 2). A long-term follow-up measurement (T5) will be conducted in May 2027 for cohort 1 and December 2027 for cohort 2 (see Figure 1).

Setting

The study will take place at mainstream primary schools of school partnerships such as RiBA, BLICK op onderwijs and Scholenetwerk BSI and schools that are involved via our social media channels and webinars. These schools will be broadly representative of Dutch mainstream primary schools with respect to the type of school (urban/rural, large/small) and high/middle/low Socio Economic Status (SES) of the school.

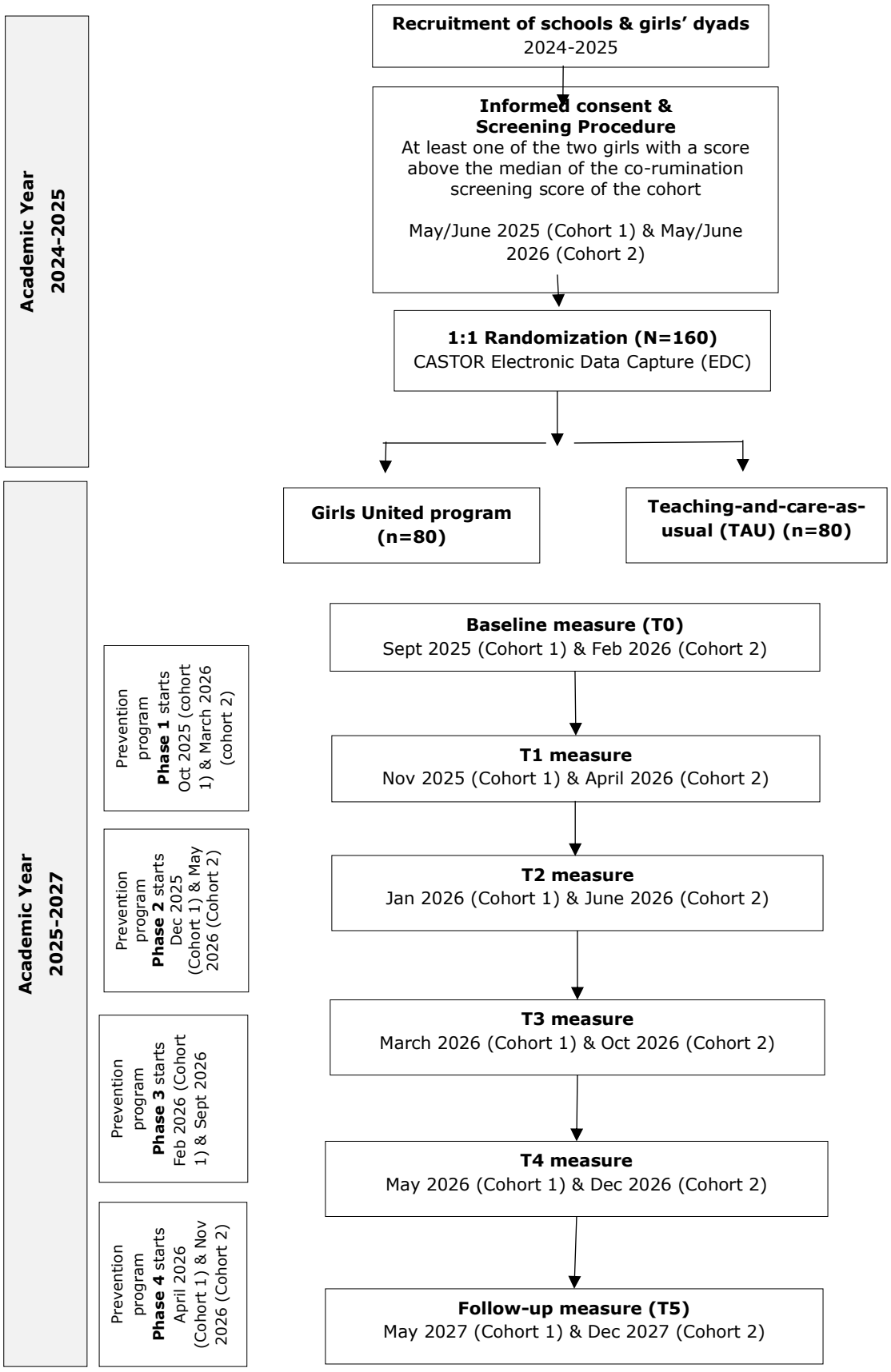

Figure 1. Flowchart of study assessment time points for cohort 1 and 2.

4. STUDY POPULATION

4.1 Population

The study population will consist of high-risk friendship dyads who are primarily characterized by high levels of co-rumination within their daily interaction patterns. “High risk” is defined on the dyadic level and implies that at least one of the two girls of one friendship dyad, or both girls, should have a score above the median co-rumination screening score of the cohort the dyad belongs. The study collaborates with school partnerships such as RiBA, BLICK op Onderwijs, and Scholen-netwerk BSI, with most friendship dyads expected to be drawn from the upper grades of mainstream primary schools within these networks.

4.2 Inclusion criteria

To be eligible for inclusion, a *participant/girl* must meet all of the following criteria:

1) Aged 10 to 12 years.
2) Visiting a primary school of RiBA, BLICK op Onderwijs, and Scholennetwerk BSI (i.e., collaborative school network).
3) Attending 5th or 6th grade of mainstream upper primary education in academic year 2025/2026 or 2026/2027.
4) Being a cisgender woman or being a transgender woman.
5) Having a good or best friend (being a cisgender woman or being a transgender woman) at the same school.

To be eligible for inclusion, a *dyad/girls* must meet the following inclusion criteria:
By lack of an official cut-off score for high co-rumination levels, we will base our inclusion on a distribution-based technique. That is, we will include friendship dyads of which at least one of the two girls, or both girls, have a score above the median co-rumination screening score of the cohort on the Co-rumination Questionnaire-Short (Hankin, Stone & Wright, 2010). This will result in a sample of the 50% highest scoring girls on co-rumination. Note that a distribution-based technique is a common-used technique to select a high-risk population of clinical significance in the absence of meaningful clinical cut-offs (Sloan, Symonds, Vargas-Chanes & Fridley, 2003).

4.3 Exclusion criteria

Exclusion criteria at *participant/girl* level:

1) Following and/or participating in an another individual or group-based mindfulness-based training in academic year 2025/2026 or 2026/2027.

Exclusion criteria at the *school* level (to mitigate any risk of difficulties in trial implementation):

1) Not having a headteacher in academic year 2025/2026 or 2026/2027.
2) Judged as 'inadequate' during the most recent school inspection by the Dutch Inspectorate of Education.
3) Implementing another mindfulness-based intervention in academic year 2025/2026 or 2026/2027.

4.4 Sample size calculation

Multi-level models are used with individuals nested in dyads. To determine the required sample size for this cRCT study power analyses were conducted using Optimal Design Plus – Evidence (Raudenbusch, 2011). These analyses were based on an alpha level (α) of .05, with three measurement points (baseline and two follow-up measurements), and an intraclass correlation (ICC) of .40 between two friends (ρ). This ICC was derived from observed ICCs for perceived support within friendship dyads (*n* = 266 pairs) in an existing dataset of adolescents with an average age of 13. For average risk girls (M), the multilevel power analysis was based on an expected effect size (Cohen's d) of 0.50, indicating a small to medium effect. The power analysis showed that, to achieve a power level of 0.80, at least 122 average-risk friendship dyads would need to be included. However, we will aim to oversample to a maximum of 160 dyads in order to be able to compensate for loss to follow up .

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

Girls United blended mindfulness program

The Girls United prevention program aims to foster social-emotional-behavioral self-regulation within a supportive close-friendship context through incorporation of both dyadic and individual experiential learning. Developed between 2020 and 2023 using the Intervention Mapping Approach for health promotion planning (Vuijk & Bierhaus, 2023a; 2023b; 2023c; 2023d; Vuijk & Norrgren, 2024) the program includes 14 weekly online lessons delivered by trained facilitators. The training sessions will be recorded with BigBlueButton for training and intervision purposes but only when the parents/main caretakers provided their approval on the informed consent form. The dyads will receive links via email for entering the BigBlueButton meeting rooms. The lessons integrate psychoeducation and mindfulness practices, guiding participants in using the application *App yourself Happy* app (Vuijk et al., 2023) within their friendship dyads. In order to teach and stimulate girls to discover new healthy and positive shared alternatives for excessive co-rumination and rumination (getting out of autopilot negative reactivity), to stimulate present-moment awareness and appreciation of pleasant shared experiences and interactions, to encourage girls to share their interpersonal responses to pleasant experiences and positive affect with each other, to teach girls to work skillfully with difficult emotions during activities and interactions and to support friendship dyads to incorporate these healthy alternatives in their daily lives, dyadic-friendship girls will participate and will be supported together by the training program and encouraged to use the App yourself Happy module ‘Healthy, joyful dyadic activities’ on a daily basis. This module contains 150 healthy and joyful behavioral activation activities for dyadic use with the following categories: Beauty, On the road, Creative, Educative, Game time, Indoor, Outdoor, Mindfulness, Sport, Relax, and Kitchen. Each activity is presented on a photocard with fun and inspiring tips about the preparation of the activity and information about the costs and other important aspects (e.g., ‘for this activity you need a towel’). Girls will be able to select five activities and share these with their dyad-friend via a WhatsApp message.

Friendship dyads will be encouraged in the weekly training sessions to do at least one or two activities each week. These behavioral activities (including the preparations and the reflections on the activities through journaling and reflections during the weekly training sessions) will function as a natural backbone to train several mindfulness-skills: being in the present moment (present-moment awareness), conducting random acts of kindness, experiencing joy and gratitude using the ten fingers gratitude practice, using the pleasant experiences calendar and creating more nurturing experiences, and using the unpleasant experiences calendar and diminishing the impact of depleting experiences. In every training

session, a new mindfulness practice will be introduced by connecting practice with upcoming activities and skills practicing. The use of these practices will be stimulated by several animation videos with explanations about co-rumination, brain functioning on automatic pilot and a guided mediation practice. Working with mindfulness skills and practices during the activities and within daily live interactions will be evaluated and reflected on during the online training sessions, and girls will be encouraged and trained to incorporate these mindfulness practices within other and new activities in their daily interactions.

This continuous process of training, reflection and integration in daily live will be supported by using the journaling module of the app, with daily journaling guided by randomly selected positively formulated mindfulness-based questions (morning, afternoon and evening), aimed at practicing gratitude and optimism related to (a) daily experiences (always) and (b) positive anticipation on upcoming shared activities and (c) recalling positive memories after completing an activity (during activity planning and after completing activities). This module encourages girls three times a day to actively report on the positive aspects of preparing the activities together with their dyad friend, to actively recall positive memories about the activity as well as aspects of the friendship/sharing and the mindfulness practices after completing an activity. They will be encouraged to share their positive thoughts and positive emotions within their daily journaling and daily interactions and conversations.

During the training sessions, girls will be invited to share their experiences about their cultivated adaptive awareness of together dwelling on negative emotions and the impact of their training practices on awareness of sharing and responding on positive affect. This process will be specifically supported by the using the mood tracker and calendar, facilitating girls to reflect on practicing mindfulness-based activities and their daily emotions.

Daily state mood monitoring possibilities (three times a day: morning, afternoon and evening) are Positive Affect (PA): Cheerful (high arousal), Content (low arousal), Happy (high arousal), Energetic (high arousal), Relaxed (low arousal) and Joyful (high arousal) and Negative Affect (NA): Worried (high arousal), Anxious (high arousal), Low/Depressed (low arousal), Insecure (low arousal), Irritated (high arousal), and Guilty (low arousal). Girls will be asked to report one PA and/or one NA on a 5-point scale, ranging from 0 (*not at all*) to 4 (*very much*). The PA and NA items were derived from work of Barrantes-Vidal and colleagues [65]. A monthly overview of the experienced moods and their intensity will be available within the Mood calendar. Girls will receive daily empathetically formulated prompts on pre-programmed moments (indicated by the girls themselves) for using the mood monitoring, journalling and diary function of the app and daily rewards (i.e, psychoeducation), offered at completing daily mood monitoring and journaling. This is embedded to boost engagement with the app on a daily basis. It is hypothesized that actively practicing these skills and reflecting on the impact on their emotions and thoughts will explicitly target repetitive negative, judgmental emotions

and thoughts in the interactions and communication of the participating girls. Girls will spend a total of no more than 15 minutes a day completing the mood tracker and diary.

The program's aim is to teach emotion regulation and mindfulness skills on *the dyadic level* that support resilience and the positive qualities of girls' dyadic friendships with the aim to prevent excessive co-rumination and (early onset of) internalizing symptoms (depression, anxiety).

Teaching-and-care-as-usual (TAU)

In the control condition, girls receive unchanged any regular care and regular education. No other classroom-based mindfulness interventions will be implemented during the intervention period of the cRCT.

Train the trainers to deliver the program

The training sessions will be delivered in academic year 2025/2026 (cohort 1) and 2026/2027 (cohort 2) by eight mindfulness-trained staff members (i.e., PI, PhD students and external staff members). Five of the eight trainers are certified mindfulness-trainer. All trainers have followed an 8-week Mindfulness for Life course at the Oxford Mindfulness Foundation in academic year 2021/2022 (seven 2-h sessions per week and one all day-session, supported by a course booklet and several digital guided mindfulness practices to facilitate mindfulness practice during and after the 8-week course). Furthermore, they all have an established mindfulness practice of more than six months before the prevention program will start in October 2025 Between October 2023 and June 2015, all trainers attended a 4-day training program, developed and delivered by Per Norrgren (BAMBA certified mindfulness supervisor and trainer) and Dr. Patricia Vuijk, who also finalized the Mindfulness Frame by Frame course (Oxford Mindfulness Foundation) and the Teacher Training course "Dot-b" (Mindfulness in School Projects) (Vuijk & Norrgren, 2024) to learn how to deliver the program to the friendship dyads. During the implementation of the program, all trainers will receive weekly supervision on competence and adherence by Per Norrgren and Dr. Patricia Vuijk.

5.2 Use of co-intervention (if applicable)

Not applicable.

5.3 Escape medication (if applicable)

Not applicable.

6. INVESTIGATIONAL PRODUCT

6.1 Name and description of investigational product(s)
Not applicable.

6.2 Summary of findings from non-clinical studies
Not applicable.

6.3 Summary of findings from clinical studies
Not applicable.

6.4 Summary of known and potential risks and benefits
Not applicable.

6.5 Description and justification of route of administration and dosage
Not applicable.

6.6 Dosages, dosage modifications and method of administration
Not applicable.

6.7 Preparation and labelling of Investigational Medicinal Product
Not applicable.

6.8 Drug accountability
Not applicable.

7. NON-INVESTIGATIONAL PRODUCT

7.1 Name and description of non-investigational product(s)
Not applicable.

7.2 Summary of findings from non-clinical studies
Not applicable.

7.3 Summary of findings from clinical studies
Not applicable.

7.4 Summary of known and potential risks and benefits
Not applicable.

7.5 Description and justification of route of administration and dosage
Not applicable.

7.6 Dosages, dosage modifications and method of administration
Not applicable.

7.7 Preparation and labelling of Non Investigational Medicinal Product
Not applicable.

7.8 Drug accountability
Not applicable.

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

All data will be collected online via Qualtrics.

Screening measure (girls) and T0, T1, T2, T3, T4, and 1year follow-up measures T5 (girls)

Self-reported co-rumination

The original co-rumination measure consisted of 27 items designed to measure the extent to which youth typically engage in co-rumination with same-sex friends (Rose, 2002). It addresses nine key content areas, including (a) frequently discussing problems, (b) discussing problems rather than doing other activities, (c) friend encouraging discussion of problems, (d) target child encouraging friend to discuss problems, (e) discussing repetitively the same problem, (f) speculating about cause of problems, (g) speculating about consequence of problems, (h) trying to understand parts of problems, and (i) focusing on negative affective

feelings. The items are designed to assess a more intense form of discussing problems, going beyond typical self-disclosure. For this study, 9 items (one for each content area) will be used to evaluate co-rumination as screening and at T0, T1, T2, T3, T4, and the 1-year follow-up at T5. This shorter version is referred to as the Co-rumination Questionnaire-Short (CRQ-Short). These items include: “We talk about problems that my friend or I are having almost every time we see each other”, “When we see each other, if one of us has a problem, we will talk about the problem even if we had planned to do something else together,” “When my friend has a problem, I always try really hard to keep my friend talking about it.,” “When I have a problem, my friend always tries to get me to tell every detail about what happened,” “When we talk about a problem that one of us has, we’ll talk about every part of the problem over and over,” “When we talk about a problem that one of us has, we talk about all of the reasons why the problem might have happened,” “When we talk about a problem that one of us has, we try to figure out every one of the bad things that might happen because of the problem,” “When we talk about a problem that one of us has, we spend a lot of time trying to figure out parts of the problem that we can’t *understand*,” and “When we talk about a problem that one of us has, we talk a lot about how bad the person with the problem feels.” Rose (2002) found that her 27-item co-rumination measure was unifactorial, and a factor analysis of the 9-item version used by Hankin et al. (2010) similarly identified a single factor. In the studied sample, the 9-item measure demonstrated strong internal consistency, with Cronbach’s alpha values of 0.89 at Time 1, 0.91 at Time 2, and 0.91 at Time 3. Girls will respond to the items using a 5-point Likert scale ranging from 0 (“not at all true”) to 4 (“really true”), with the overall score calculated as the mean of the nine items. Rose et al. (2007) reported excellent internal consistency, good test–retest reliability, and strong validity for the measure.

8.1.2 Secondary study parameters/endpoints

T0, T1, T2, T3, T4, and 1-year follow-up measures T5 (girls)

Self-reported depressive symptoms/disorder

The self-reported level of depressive symptoms will be assessed using the Child Depression Inventory 2 (CDI-2; Bodden, Braet, & Stikkelbroek, 2016), a 28-item questionnaire. Each item provides three response options, scored from 0 to 2 (e.g., 0 = “I am sad once in a while,” 1 = “I am sad many times,” and 2 = “I am sad all the time”), with respondents selecting the option that best describes their experience. Higher scores indicate greater depressive symptoms, with total scores ranging from 0 to 56. A score of 12 or higher is considered clinically relevant. The CDI-2 demonstrates strong internal consistency, test–retest reliability, and convergent validity

(Bodden, Braet, & Stikkelbroek, 2016). For the current study the item concerning suicide has been left out, resulting in a 27-item questionnaire.

Self-reported generalized anxiety symptoms/disorder

Self-reported generalized anxiety disorder will be assessed using the Dutch version of the Generalized Anxiety Disorder (GAD) subscale from the Revised Children's Anxiety and Depression Scale (RCADS) (Chorpita et al., 2000). This subscale consists of six items (e.g., "I worry about things") and evaluates generalized anxiety on a 4-point scale (0 = never, 3 = always). The RCADS is known for its strong psychometric properties, demonstrating excellent reliability and validity (Chorpita et al., 2000; Chorpita, Moffitt & Gray, 2005). The official Dutch translation of the RCADS, which is available for free, will be used. Previous studies have shown that the Dutch version of the Generalized Anxiety Disorder (GAD) subscale has good internal consistency, validity, and sensitivity to change (Kösters et al., 2015).

Self-reported positive and negative affect

Self-reported positive and negative affect will be assessed using the Dutch version of the Positive and Negative Affect Schedule for Children (PANAS-C; Laurent et al., 1999; De Bolle, De Fruyt & Decuyper, 2010). The PANAS-C includes two subscales: Positive Affect (15 items, e.g., energetic) and Negative Affect (15 items, e.g., nervous). Participants will be asked to indicate how often they have experienced each feeling over the past few weeks, using a scale from 1 (very slightly or not at all) to 5 (extremely). The internal reliability of the Dutch version was found to be moderate to good, with Cronbach's α ranging from 0.66 to 0.83 for the Positive Affect subscale and 0.67 to 0.81 for the Negative Affect subscale. Additionally, a dummy variable will be created to represent the type of day (0 = weekend, 1 = weekday). To account for the time of day, separate dummy variables will be created to indicate whether the assessment occurred in the morning (1 = morning, 0 = afternoon and evening), afternoon (1 = afternoon, 0 = morning and evening), or evening (1 = evening, 0 = morning and afternoon).

Self-reported interpersonal responses to positive affect

Self-reported interpersonal responses to positive affect will be measured using the Co-Dampening and Co-Enhancing Questionnaire (CoDEQ; Bastin, Nelis, Raes, & Bijttebier, 2018). The questionnaire consists of 18 items, with nine items measuring co-enhancing responses and nine items measuring co-dampening responses to positive feelings within dyads. Co-dampening responses describe reactions such as thinking about the fleeting nature of positivity, focusing on worries, emphasizing negative aspects of a positive event, making upward social comparisons (e.g., considering how others are better off), making external attributions (e.g., attributing success to luck), and reflecting on past negative events. In

contrast, co-enhancing items focus on positive reactions, including behavioral displays, focusing on positive feelings (e.g., thinking about how energetic one feels), thinking about positive past or future events, making downward social comparisons (e.g., comparing oneself to others who are less fortunate), and recognizing positive personal qualities (e.g., believing in one's ability to achieve goals). Respondents will indicate how often they respond in these ways when they or their friend feel happy and discuss it. The rating scale has four response options: almost never (1), sometimes (2), often (3), and almost always (4). The Cronbach's alphas for co-enhancing and co-dampening were 0.84 and 0.86, respectively.

Self-reported quality of the friendship with the dyad friend and investments in the interpersonal relation

Self-reported support quality of the friendship with the dyadic friend and investments in the interpersonal relationship will be measured using the Dutch version of the Network of Relationships Inventory (NRI; Furman & Buhrmester, 1992), which includes 36 items across seven subscales. The subscale Support consists of eight items. Girls and their best friend were instructed to take each other in mind while answering items such as: "How much does your best friend really care about you?". The subscale Relative Power consists of six items ("To what extent is your friend the boss in your relationship?"). The subscale Negative Interaction consists of sex items ("Are you and your friend annoyed by each other's behavior?"). The subscale Seeks Safe Haven consists of three items ("To what extent do you visit your friend when you are upset?"). The subscale Provides Safe Haven consists of three items ("To what extent does your friend visit you when she is worried about something?"). The subscale Seeks Secure Base consists of three items ("To what extent does your friend support you in the things you do?"). Finally, the subscale Provides Secure Base consists of three items ("To what extent do you support your friend in the things she does?"). Responses will be rated on a 5-point Likert scale 0 (little or none) to 4 (the most). The English version of the NRI shows good psychometric properties in adolescent samples, such as high internal consistency and moderately high stability over a 1-year period (Furman & Buhrmester, 2009). Furthermore, in a Dutch sample that used a shorter version of the NRI friend-scales, it was shown that the internal consistencies were high for all variables (Cronbach's alpha range α = 0.82–93) and that the factor and construct validity of the NRI are adequate (De Goede et al., 2009).

Self-reported self-worth

Self-reported self-worth will be measured with the original Dutch version of the Competentie-Beleving Schaal voor Kinderen (CBSK; Veerman, Straathof & Treffers, 1994) and is intended to measure self-worth in children between 8 and 12 years old. It assesses children's perceived competence and self-value, offering insights into their self-esteem and overall self-concept. It

consists of 36 items across six subscales (e.g., scholastic competence, social competence, athletic competence, physical appearance and behavioural conduct and global self-worth). The CBSK has been evaluated through the Commissie Testaangelegenheden Nederland (COTAN). On three criteria it scored good: test construction principles, quality of test materials, quality of the manual. The aspects of norms, reliability and construct validity are rated as sufficient. The aspect of criterium validity is rated as insufficient (Kraijer & Plas, 2006).

T0 and T4 measures (parents)

Parental health care use of their child/family

Parental health care use for their child/family will be assessed through three questions: (1) whether the child and/or family received health care for psychosocial, emotional, or behavioral problems in the past 12 months, (2) the underlying cause(s) of the care, and (3) the duration of the care received.

8.1.3 Other study parameters

Mediators

T0, T1, T2, T3, T4, and 1-year follow-up measures (girls)

Self-reported trait mindfulness

Self-reported trait mindfulness will be assessed using the Mindful Attention Awareness Scale-Adolescents (MAAS-A) (Brown, West, Loverich, & Biegel, 2011) and the Child and Adolescent Mindfulness Measure (CAMM) (Greco, Baer, & Smith, 2011). The MAAS-A comprises a single scale with 15 items rated on a 1–6 Likert scale, providing a single score to represent dispositional mindfulness. Test-retest reliability for the MAAS-A has been found to be moderate in adolescent samples over 3- and 10-month periods (r = 0.35–0.52; Black et al., 2012). The study will use the Dutch translation of the 10-item CAMM (de Bruin et al., 2014), which proposes a two-factor structure: (1) Present moment, non-judgmental awareness; and (2) Suppressing or avoiding thoughts and feelings/distractibility or difficulty paying attention. However, the second factor has shown lower internal consistency in Dutch studies (α = 0.58 and α = 0.50). Reported internal consistencies of the CAMM and its subscales are generally lower than those of the MAAS-A but remain acceptable in most studies (α = 0.70–0.85). An exception is a study by Noggle and colleagues (2012), which reported poor internal consistency (α = 0.58). Test-retest reliability data for the CAMM in intervention-focused studies are unavailable. However, findings by de Bruin and colleagues (2014) consistently indicate

that the second factor (suppressing or avoiding thoughts and feelings/distractibility or difficulty paying attention) has lower internal consistency compared to the first factor.

Self-reported emotion regulation

Self-reported emotion regulation will be assessed using the Dutch version of the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004; Neumann, van Lier, Gratz, & Koot, 2010). The DERS is a 36-item self-report questionnaire designed to evaluate individuals' ability to identify, understand, and manage their emotions (Gratz & Roemer, 2004). The scale comprises six subscales: Lack of Emotional Awareness (6 items), Lack of Emotional Clarity (5 items), Difficulties Controlling Impulsive Behaviors When Distressed (6 items), Difficulties Engaging in Goal-Directed Behavior When Distressed (5 items), Nonacceptance of Negative Emotional Responses (6 items), and Limited Access to Effective Emotion Regulation Strategies (8 items). Each item is rated on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). Subscale scores will be calculated by summing the corresponding items. The subscales of the Dutch version of the DERS have demonstrated satisfactory to high reliability, with Cronbach's alphas ranging from 0.72 to 0.87 (Neumann et al., 2010).

Implementation measures

T1, T2, T3, T4

In order to study how implementation impacts the hypothesized effects of the Girls United program, the following variables will be studied:

(1) *Program dosage*, i.e., how much of the program has been followed, will be measured by the total amount of complete delivered training sessions within each dyad (one question) and the percentage of dyadic attendance to the sessions (one question). Data on both variables will be collected by the trainers, who will have to fill out a digital form after each training session.

(2) *Participant responsiveness*, i.e., the degree to which the program engages and stimulates the interest of the participants, will be measured by seven questions assessing rates of usefulness, perceived benefits, engagement, enjoyment, helpfulness, intentions to apply to daily life, and perceived success in applying to daily life. Girls will be asked to rate their answers on a 5-point Likert scale, ranging from "not at all" to "very much." Data will be collected by digital questionnaires immediately following each training session.

(3) The extent of participants' self-reported practice outside of the training sessions will be measured by the percentages of (1) completed activities (i.e., back-end data collected by the app), (2) completed daily state mood monitoring activities (i.e., back-end data

collected by the app), and (3) completed daily mindfulness-based questions (i.e., back-end data collected by the app). Moreover, data on self-reported practice outside of the training sessions will be collected by asking girls to fill out digital questionnaires after each training session about the amount of self-reported mindfulness practices within their dyadic conversations, ranging from low [once a week or less], medium [three times a week or less], and high [at least three times a week].

(4) *Program fidelity*, i.e., the extent to which the delivered program corresponds to the original program will be collected using self-administered digital forms completed by the trainers after each lesson, reporting whether the scheduled activities were delivered (yes or no) and whether the trainers (yes or no) altered any activities. The fidelity forms will list all activities planned for each training session, based on the training manual. Each item will have data on the percentage of activity completeness (i.e., the numerator will be the number of activities delivered, and the denominator will be the total number of activities planned), and percentage of alterations (i.e., the numerator will be the activities instructors reported changing, and the denominator will be the number of activities planned). A fidelity variable for each dyad will be calculated as follows: fidelity = % completeness × (1 − % alteration). Dyads will then be divided into two groups according to the level of fidelity: those that received ≥ 80% of the proposed activities will be considered to have completed the program, whereas those that received < 80% of the activities will be considered to have incomplete implementation.

(5) T*reatment contamination*, i.e., monitoring of the control group, will be measured by an online questionnaire for parents at T0, T2, and T4 with one question: “Did your child attend a mindfulness-based course in the last two or three months, and if yes, please mention the name of the course.”

Trainer measures

T1, T2, T3, T4

These following variables will be measured among the trainers for every dyad: Trainer Coping with Occupational Stress tied to the Context in which they implement the Program will be measured at the end of each lesson of the prevention program, Self-Reported Teaching Competence, Self-Reported Competence Teaching the Course in the Future, Trainers Program Expectations will be assessed at the end of each phase of the prevention program.

Trainers Coping with Occupational Stress tied to the Context in which they implement the Program

Trainers Coping with Occupational Stress tied to the Context in which they implement the Program will be measured using two items adapted from a study by Braun and colleagues (2024). First item, ‘’To what extent did you find this lesson stressful’, will be scored on a dichotomous scale (0 = not stressful, 1 = very stressful). Second item, ‘’How effectively were you able to manage the stress you experienced during this lesson’’, will be rated with two options (0 = not at all well, 1 = very well)

Self-Reported Teaching Competence

Teaching the course will be assessed using a single-item originally designed for a study by Braun and colleagues (2024), ‘’How competently do you feel you delivered the course?’’. This item will be rated on a 9-point Likert scale ranging from 1 (not al all competently) to 9 (very competently).

Self-Reported Competence Teaching the Course in the Future

Trainers' confidence teaching the course in the future will be measured using a single-item originally designed for a study by Braun and colleagues (2024), “How confident would you feel teaching the course again?” The item will be rated on a 9-point Likert scale ranging from 1 (not at all confident) to 9 (very confident).

Trainers Program Expectations

Trainers' expectations about the program will be assessed using an adapted version for this study derived from the Credibility/Expectancy Questionnaire (Borkovec & Nau, 1972). This 5-item measure evaluate the the degree to which trainers believe that the intervention is credible and effective in improving outcomes (e.g. ‘’How important do you think it is to make this training available to other girls?’’). Item scores ranged from 1 (not at all) to 9 (very). This measure has demonstrated a strong reliability ($\alpha > 0.80$ for original measure (Devilly & Borkovec, 2000).

Descriptives

Age (based on date of birth) and gender (male or female) will be registered on the completed participant informed consent forms and this will be checked by the trainers.

T0 measure (parents/main caretakers)

Socioeconomic status

Parental education level will be used as an indicator of socioeconomic status (SES), which has been regarded the most powerful indicator of SES (Davis-Kean, Tighe & Waters, 2021; Tighe & Davis-Kean, 2021; Waters, Ahmed, Tang, Morrison, & Davis-Kean, 2021). To this end, the primary caregiver will report the education level of the mother and the father of each participant. Educational levels will be rated according to the Dutch Standard Education Classifications (Statistics Netherlands, 2021), which corresponds to the International Standard Classification of Education (ISCED; UNESCO, 2011). Following the ISCED classifications, parental education levels will be coded using an 8-point scale, with education levels including the following: 0 = no education/early education, 1 = primary education, 2 = lower secondary education (e.g., junior secondary school, middle school, junior high school), 3 = upper secondary education (e.g., senior secondary school, [senior] high school), 4 = post-secondary non-tertiary education (e.g., technician diploma, primary professional education), 5 = short-cycle tertiary education (e.g., [higher] technical education, higher/advanced vocational training, associate degree), 6 = bachelor's degree or equivalent, and 7 = master's degree, equivalent or higher. Parental education level will be based on the highest completed parental education level per household. That is, if a child has one parent with upper secondary education (i.e., 3) and another parent with a bachelor's degree (i.e., 6), then we will code this child's parental education with bachelor's degree (i.e., 6).

Intervention status will be dummy-coded (0 = control, 1 = Girls United program) and registered by the research assistants in a password protected access file.

T0 measure (trainers)

At baseline these following variables will be measured among trainers:

Qualifications trainers

The trainers' qualifications pertain to their competency in teaching mindfulness and their personal meditation practice. These qualifications will be evaluated through four questions: (1) whether the trainer holds a certification as a mindfulness trainer or as a mindfulness coach for children/adolescents, (2) whether they have completed formal mindfulness training programs, and if so, which ones, (3) the frequency of their meditation practice (e.g. daily, multiple times daily, or weekly on average, and (4) the duration of their meditation sessions (e.g., half an hour or less, half an hour to an hour, or more than an hour).

Trainers General Levels of Self-Reported Global Perceived Stress

Trainers' stress will be measured using 10 items from the *Perceived Stress Scale* (Cohen et al., 1983). Items (e.g., “In the last month, how often have you found that you could not cope with all the things that you had to do?”) will be rated on a 5-point Likert scale (1 = never, 5 = very often; α = 0.85). Reverse scoring is applied to specific items as needed, so that higher scores reflected greater levels of stress. Research on the psychometric properties of this scale in various populations has demonstrated to have an adequate reliability (> 0.70) and validity as it is correlated with related experiences of depression and anxiety symptoms, among others (Cohen et al., 1983; Lee, 2012).

Demographics

Gender will be assessed using a binary scale (0 = male, 1 = female), and age will be measured in decades with the following categories: 1 = 20-30 years, 2 = 31-40 years, 3 = 41-50 years, 4 = 51-60 years, and 5 = 61 years of older.

8.2 Randomisation, blinding and treatment allocation

Dyads will be randomly assigned in a 1:1 ratio to either the intervention group (max 80 dyads; n = max 160 girls) or the control group (TAU; max 80 dyads; n = max160 girls) by an independent researcher using CASTOR EDC, a web-based randomization program compliant with Good Clinical Practice (GCP) guidelines. Ideally, randomization will occur on a single day after completing the screening phase. If this is not feasible (e.g., due to time constraints), randomisation will proceed in batches of 50 dyads (100 girls) and on classroom level. The median of the screening scores will be calculated, and dyads where one or both girls above the median will be included. These dyads will then be randomly assigned to the intervention or control group using a block randomisation procedure (50% allocated to each group). Allocation will be concealed through a computer-generated list in a secure web-based application. However, due to the organisational structure of the prevention program, participants, parents, schools, and researchers will be aware of group assignments. As the trial follows an open-label design, unblinding will not occur.

8.3 Study procedures

Measures

Questionnaires T0, T1, T2, T3, T4 and one-year follow-up T5

For the dyad girls, filling out the T0 questionnaires will take place via BigBlueButton, so that the girls the first time that they have to fill out the questionnaires will be able to ask questions about the items and the researchers will be able to assist. Both girls of a dyad will receive a link to the BigBlueButton environment via email. Via BigBlueButton it is possible to deliver the questionnaires via the chat-function. Both girls of a dyad will fill out their own questionnaires independently.

Girls, parents/main caretakers, and trainers will receive online questionnaires via email at the follow-up timepoints (T1, T2, T3, T4), and one-year follow-up (T5). A trained PhD student or senior research assistant will be responsible for distributing all questionnaires via Qualtrics. If participants do not respond within one week, a reminder email will be sent. Three days later, those who still have not completed the questionnaire will receive a follow-up phone call from the trained PhD student or senior research assistant. Teacher-mentors will assist by sending the reminder emails, while the trained staff will handle the phone calls. The estimated time burden for completing the questionnaires is detailed in Table 1 for girls, Table 2 for parents/main caretakers, and Table 3 for trainers.

Table 1. Specified duration: girls.

Questionnaire	Duration (min)
Screening	
Co-rumination Questionnaire – CRQ short	2
Total	2
T0 t/m T4 and follow-up primary outcome measures	
Co-rumination Questionnaire – CRQ short	2
Total	2
T0 t/m T4 secondary outcome measures	
RCADS (Subscale Generalized Anxiety Disorder)	2
CDI-2	10
PANAS-C	5
CoDEQ	5
NRI	10
CBSK	6

Total	38
T0 t/m T4 and follow-up: moderator	
Total	2
T0 t/m T4 and follow-up: mediators	
MAAS-A	5
CAMM	5
DERS	10
Total	20
T1 t/m T4 implementation variables* only for girls in the intervention condition	
Participant responsiveness	14
Practice outside of the training session	7
Total	21.5
Total Screening (min.)	2
Total T0 t/m T5 (min.)	60 x 6 = 360
Total implementation measures. only for girls in the intervention condition (min)	21.5

Table 2. Specified duration: parents/caretakers.

Questionnaires	**Duration (min)**
T0	
Descriptives (SES)	2
Total	2
T0 en T4	
Parental health care use of their child/family	3
Total	3
T0, T2 en T4 : Implementation variables	
Treatment contamination	1
Total	1
Total T0	7
Total T2	1
Total T4	4

Table 3. Specified duration: trainers.

Questionnaires	Duration (min)
T0: Before training starts	
Demographics	0.2
Qualifications trainers	1
General levels of self-reported global perceived stress	2
Total	3.2
T1, T2, T3 and T4: Implementation variables	
Program dosage for each girl	7
Program fidelity for each girl	56
Trainers Coping with Occupational Stress tied to the Context in which they implement the Program	7
Self-Reported Teaching Competence	1
Self-Reported Competence Teaching the Course in the Future	1
Trainers Program Expectations	4
Total	76
Total for each participating girl*	76

***Total amount of min. depends on the *n* of girls a trainer supports with the online training sessions.**

8.4 Withdrawal of individual subjects

Parents/main caretakers, the girls, and their best friend may withdraw from the study at any time and for any reason without facing any consequences. This is explicitly stated in the participant information sheet provided to parents/main caretakers. It will be emphasized that withdrawing from the study will not affect their treatment at school or in any other setting. If withdrawal occurs, no further information will be collected from the girl or her best friend from that point forward. Additionally, data collected in prior waves will be removed upon explicit request by the girl or her parents. Withdrawal is expected to be minimal due to the minimal burden placed on participants. Furthermore, good coaching by the Principal Investigator (PI) and the full-time availability of researchers aim to reduce withdrawal wherever possible. We take three measures during the study to minimize the chance of drop-out due to participating in the experimental condition: (1) In case of a (planned) drop-out, which (in our experience) is either made known to the trainers by the dyads during a lesson or told to the researchers, the PI will contact the parents/guardians and the girl in question (the girls are informed about this in advance by the researchers). The PI will explain/reassure that stopping without providing a reason is okay and will inquire if it is an option to continue with the lessons later in the school year. If that is not the case, then the dyad will stop. (2) If a dyad stops after the first lesson,

and one of the girls wants to continue the lessons with another friend, this can be done provided that the girl has a higher score on the co-rumination screener. We will then start the consent procedure with the new friend, carry out the T0 measurement with the 'new' dyad, and after that, the lessons for this dyad can begin, starting with the first lesson. (3) We include new dyads in case of a drop-out. This is possible because we are working with two cohorts. . No follow-up will be conducted for participants who withdraw from the study.

8.4.1 Specific criteria for withdrawal (if applicable)

Not applicable.

8.5 Replacement of individual subjects after withdrawal

Please see paragraph 8.4.

8.6 Follow-up of subjects withdrawn from treatment

No follow-up will be conducted with girls who withdrawn from the study.

8.7 Premature termination of the study

Previous studies on co-rumination (Rose et al., 2014; Schwartz-Mette et al., 2014) have demonstrated minimal risks associated with participation. Similarly, research on mindfulness-based interventions, including app-based mindfulness training for study purposes, has reported minimal risks (e.g., Baer et al., 2021). To address potential expected or unexpected unpleasant experiences and mitigate any potential harm to participants, we will adhere to the framework recommendations outlined by Baer and colleagues (2019), as detailed in the following section. Consequently, no specific criteria have been established for the premature termination of the study.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of subject safety

In accordance with Section 10, Subsection 4, of the Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO), the sponsor will suspend the study if there is sufficient evidence that continuation could jeopardize the health or safety of the participants. In such cases, the sponsor will promptly notify the accredited Medical research ethics committee

(METC) of the temporary halt, providing the reasons for this decision. The study will remain suspended until a positive decision to resume is issued by the accredited METC. The PI will ensure that all participants are kept informed throughout the process.

9.2 AEs, SAEs and SUSARs

9.2.1 Adverse events (AEs)

In accordance with section 10, subsection 1 of the WMO, the PI will inform the participating schools, school professionals, parents/main caretakers and girls and the METC once the study is interfering with the subjects' health or safety. Study continuation will be frozen at that point and the METC will be informed accordingly and until further notice. The PI will ensure that all participants and involved parties remain informed during this process.

9.2.2 Serious adverse events (SAEs)

The sponsor will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

Negative and serious adverse events

Participation in the measurements and intervention condition: general measures
Criteria for identifying significant deterioration on the basis of which participation is discontinued (measurements and participation in the intervention condition).

1. Criteria for identifying significant deterioration

A girl may be considered to be experiencing significant deterioration if any of the following are observed or reported:

- Marked increase in distress levels during training sessions (e.g., sustained worsening of anxiety, depression, stress).

- Frequent emotional overwhelm or persistent distress beyond what is typically expected during following mindfulness training sessions and filling out questionnaires.

- Signs of avoidance or disengagement from the training session due to distress (e.g., repeated absences, withdrawal from activities, lack of responsiveness).

- Expression of hopelessness or thoughts of self-harm—in such cases, immediate intervention and referral to appropriate support services will be prioritised.

- Feedback from trainers indicating observable emotional or behavioural decline.

2. Conditions for reconsidering participation or withdrawal

Participation in the intervention condition may be reconsidered if:

- A girls' distress is assessed as improving or as significant.

- The nature of the distress suggests that the current structure of the program will be beneficial.

- Girls express a clear desire to withdraw, and this is supported by their well-being needs.

- In cases where withdrawal is considered, this will be done with sensitivity, ensuring that the participant is supported in transitioning out of the program. Support pathways for participants require additional assistance from the PI and Per Norrgren.

3. To safeguard participant well-being, we will ensure:

- Regular well-being check-ins facilitated by trainers.

- Access to a support contact within the program for concerns or guidance. - Signposting to appropriate professional support services as appropriate (e.g., school-based counsellors, external mental health resources) if additional intervention is required.

Participation in the CDI-2 measures at T0 to T5

The PI will inform parents or main caretakers by phone if the girls score above 12 on the CDI-2 (the cutoff score for possible depression). They will be advised to contact their family doctor or the independent Health Care Professional for further guidance.

Participation in the RCADS-measures at T0 to T5

The PI will inform parents or caretakers by phone if the girls have a T-score greater than 65 on the RCADS (the cutoff score for possible anxiety disorder). They will be advised to contact their family doctor or the independent Health Care Professional for further guidance.

Participation in the intervention condition

1. *Participating in the online training sessions*

In this study, following psychotherapy literature, the potential for harm is defined as sustained deterioration in a girl's functioning that is *attributable to the prevention program* (Duggan et al., 2014). Evidence-based mindfulness programs are commonly described as educational or skills training programs, rather than forms of psychotherapy, but are often used to reduce psychological symptoms and stress in (sub)clinical populations. The literature on harmful effects of mindfulness programs is sparse. To be able to manage (potential) harm caused by the online training sessions skillfully and in a protocolled manner, we developed a risk management protocol to provide a consistent approach to the identification, reporting and follow-up of risks related to participation in the intervention condition. Before the first training session starts, the trainers explain that the girls are not allowed to talk about suicide, self-injury, sexual or physical abuse or eating disorders because of safety reasons. When girls talk about suicide, self-injury, sexual or physical abuse or eating disorders during the online training sessions, the trainer will stop the session. In these cases, the coordinating researcher will immediately (by no contact within 24 hours) contact the PI. The PI will contact the independent health care professional in case of severe problems. Depending on the situation, parents/main caretakers of both participants of the dyad or the school-mentor will be informed by the PI, depending on the specific topic. The PI will inform parents/main caretakers in situations of non-family related acute problems and will advise them to contact the family doctor or the independent health care professional. In case of severe family-related problems, the PI will call inform the school-mentor. We will inform the mentor in case of family-related acute problems, so that the school will be able to decide to use the Veilig Thuis Protocol. In severe cases the independent health care professional will also be consulted by the PI. In all situations, we protect the privacy of all participants. This implies that we only should inform parents/main caretakers or the mentor more in-depth when the participant initiated the conversation about suicide, self-injury, sexual or physical abuse, substance abuse or eating disorders. The training sessions will be continued after this procedure. All reported difficulties and support provided will be logged in the research team logbook. This part of the intervention protocol will be discussed and agreed with the headteachers/teacher-mentors of the participating dyads and will be explained in the participant information sheets for parents and girls. Moreover, following

study procedures of Baer and colleagues (2021; MYRIAD Mindfulness study), several questions will follow each training session and relating to unpleasant experiences during the sessions, perceived harm from the sessions, and support for any difficult experiences. Some used Likert scales whereas others requested free-text responses. A written introduction to these questions noted that the practice of mindfulness can increase awareness of the full range of human experiences, including difficult thoughts, emotions, and sensations. Girls then will be asked how often they had such experiences during the course (with response options ranging from "*never*" to "*daily or almost daily*") and how upsetting these experiences will be (response options ranging from "*not at all*" to "*extremely*"). An open text response question will ask the girls to describe their unpleasant experiences during the mindfulness training in more detail. Next, harm will be defined for girls as being "worse off, in any way, after the course, then you would have been if you hadn't done the course". Girls will be asked how harmful the course is for them (response options ranging from "*not at all*" to "*extremely*") and a free-response question will ask them to describe the harm in more detail. Finally, they will be asked if they had sought support for any difficult experiences and, if so, from whom and how helpful the support was. After each training sessions, trainers will send the questionnaires to the PI and she will contact girls who reported difficulties during the sessions within max. three days after the session, and she will provide appropriate support, eventually after consulting the independent Health Care Professional.

It is also possible that there will be possible deteriorations in girls' functioning resulting from *frictions with the dyad friend* during the intervention period. The training program consists of fourteen online meetings in which the dyads participate together. Each dyad has its own trainer who provides all meetings. Every meeting the trainers discuss with the dyads how the cooperation with the app and the homework assignments went in the previous practice period. These discussions have a signaling function: trainers will invite the girls to share all their experiences. We assume that girls will share any problems regarding, for example, their motivation and any frictions or disagreements with the trainers (or that these are observable by the trainers based on verbal and non-verbal behavior during the meetings), so that solutions can be found together. If necessary, trainers may also seek general advice from the teacher-mentors. These possible problems, solutions and results are shared by the trainers during the intervisions, so that trainers can offer uniform advice as much as possible.

The use of the app is monitored at the individual level twice a week by the researchers. When girls write about suicide, self-injury, sexual or physical abuse or eating disorders in their Diary, the coordinating researcher will immediately (by no contact within 24 hours) contact the PI. The PI will contact the independent health care professional in case of severe problems.

Depending on the situation, the parents/main caretakers of the participant or the school-mentor will be informed by the PI, depending on the specific topic. The PI will inform parents/main caretakers in situations of non-family related acute problems and will advise them to contact the family doctor or the independent health care professional. In case of severe family-related problems, the PI will call inform the school-mentor. We will inform the mentor in case of family-related acute problems, so that the school will be able to decide to use the Veilig Thuis Protocol. In severe cases the independent health care professional will also be consulted by the PI. In all situations, we protect the privacy of all participants. This implies that we only should inform parents/main caretakers or the mentor more in-depth when the participant disclosed about suicide, self-injury, sexual or physical abuse, substance abuse or eating disorders. All reported difficulties and support provided will be logged in the research team logbook. This part of the intervention protocol will be discussed and agreed with the headteachers/teacher-mentors of the participating dyads and will be explained in the participant information sheets for parents and girls

When girls do not fill in the Diary and Moodtracker for more than three days in a row, the researchers will pass this on to the trainers, because this may indicate motivation problems, and whether this is caused by mutual friction. But girls may also be sick, for example, which causes them to lose track of the app for a while. During the next meeting, the trainers will discuss the causes of non-response with the dyads and jointly look for solutions. This information, possible solutions and results will also be shared by the trainers during the intervisions.

2. Using the app

Because the App yourself Happy app will collect high-risk personal (health) data in order to monitor the program fidelity and to supervise the trainers (this process will be the responsibility of the PI), the Chief Privacy Officer of the Rotterdam University of Applied Sciences (Mr. Dominique Booms) and a Data Steward (Elly Katoen) conducted a Data Protection Impact Assessment, which was finalized in December 2022 with an approved addendum for the current study in January 2023. Rotterdam University of Applied Sciences and YipYip (the company who is leading on the technical development and design of the App yourself Happy app) have conducted a 'Data Verwerkersovereenkomst'. In sum: all risks have been analyzed and this process resulted in several mitigating measures. The only identified residual risk with moderate risk status concerns the following: 'Appropriate agreements have been made with YipYip and Rotterdam University of Applied Sciences about the processing of personal data recorded in a processing agreement. YipYip has an ISO/IEC27001:2017 and NEN 7510-1:2017 certification. YipYip uses the 'subverwerker' Google Cloud Platform. The company is

located in the United States, but data storage takes place in the Netherlands. YipYip has indicated to have appropriate agreements with Google and is Google ISO 27001 and Netherlands Norm 7510 certified. Any residual risk at American cloud providers cannot be ruled out.

9.2.3 Suspected unexpected serious adverse reactions (SUSARs)

Not applicable.

9.3 Annual safety report

Not applicable.

9.4 Follow-up of adverse events

Not applicable.

9.5 Data Safety Monitoring Board (DSMB) / Safety Committee

Not applicable.

10. STATISTICAL ANALYSIS

10.1 Primary study parameter(s)

To test the primary hypothesis, the following statistical analyses will be conducted:
Hypothesis 1 “Girls in the intervention group will have a greater reduction in co-rumination (primary outcome) about distress and difficult emotions and feelings, (and thereby) internalizing symptoms (depression/anxiety, secondary outcomes) and negative affect (secondary outcome) during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition” will be tested via a multi-level (within level = girls within dyads; between level = dyads) parallel process, dual latent growth curve model (with co-rumination measured via self-report).

For analysis with co-rumination measured via self-report (T0 to one-year follow up T5), we will use multi-level parallel process, dual latent growth curve (LGM) models, with intervention arm as the exogenous predictor variable, growth rate of co-rumination (primary outcome) as the mediating variable and growth rate of internalizing symptoms as (correlated) secondary outcome variables. The mediator and primary and secondary outcome variables will be

modelled on both the individual (within) level and on the dyadic (between) level. This way, the between-level intervention effects will be adjusted for variation between individuals in co-rumination (primary outcome) and internalizing symptoms (depression/anxiety, secondary outcomes) at the within-level. Note that we have no a priori hypotheses regarding the nature of the growth patterns of the mediator and outcome variables and that they may be best captured by either a linear or a non-linear slope. We will adjust the analyses accordingly. For a (simplified) visual representation of this model, please see Figure 2. For a more technical description of this model, see Preacher, Zyphur, & Zhang, 2010; Preacher, Zhang, & Zyphur, 2011).

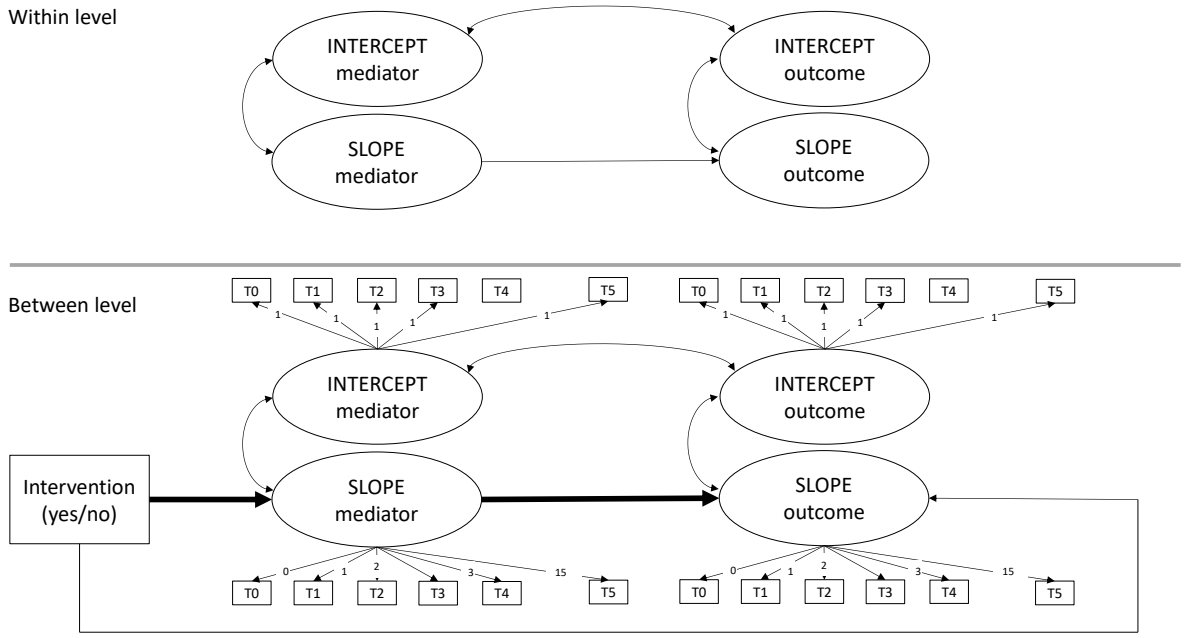

Figure 2. Simplified visual representation of a multilevel, duals process latent growth model with a predictor (e.g., intervention condition), mediator (e.g., co-rumination, primary outcome) and secondary outcomes (e.g., anxiety/depression). Ovals represent latent variables; squares represent observed variables. Double headed arrows represent (residual error) correlations, single headed arrows represent regression paths. Paths of interest are in bold.

10.2 Secondary study parameters

Hypothesis 2 *"*Girls in the intervention group will have less dyadic depression contagion during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition" will be tested using discrete-time survival analysis and via actor-partner interdependence modeling (Cook & Kenny, 2005), respectively.

We will use prospective change, actor-partner interdependence modeling (APIM) to investigate whether dyads in the intervention condition will experience less dyadic depression contagion compared to dyads in the control arm from T0 – one-year after follow up APIM allows to test the effects of each girl's predictor variables (here: depressive symptoms) on her own outcomes (actor effects) and on her friend's outcomes (partner effects), while controlling for similarities between dyad-members. If the actor effect is non-significant, this indicates stability in depression symptoms. If the actor effect is significant, this indicates contagion between girls in the dyad. We will use multi-group comparisons to test whether contagion effects are less strong in the intervention arm compared to the control arm. Specifically, a model is which the actor and partner effects will be estimated freely for the intervention and control arm (unconstrained model) versus a model where the actor and partner effects will be constrained to be equal will be specified. If constraining the parameters to be equal results in poorer model fit, this indicates that effects are not similar in the two conditions.

Hypothesis 3 "Girls in the intervention group will demonstrate b) less dyadic anxiety contagion during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition" will be tested using LGM, DTSAs and multi-group APIM, respectively.

Multi-group (i.e., intervention versus control condition) APIM will be used to investigate whether dyads in the intervention condition will experience less anxiety contagion compared to dyads in the control arm from T0 to one-year after follow-up. For a more detailed description of this model, please see the model description in hypothesis 2.

Hypothesis 4 *"*Girls in the intervention group will experience better friendship quality, higher levels of positive affect and higher levels of interpersonal responses to positive affect during the intervention period, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition" will be tested using multi-level LGMs for each outcome, respectively.

Three multi-level LGMs with intervention arm as the exogenous predictor variable and growth rate of friendship quality, positive affect and interpersonal responses to positive affect as the (potentially correlated) outcome variables, will be used to test whether girls in the intervention arm experience more improvements in friendship quality, a faster growth in positive affect and faster growth levels of interpersonal responses to positive affect, compared to girls in the control arm. The outcome variables will be modelled on both the individual (within) level and

on the dyadic (between) level. This way, the between-level intervention effects will be adjusted for variation between individuals in the outcome measures on the within-level. Note that we have no a priori hypotheses regarding the nature of the growth patterns of the outcome measures and that it may best captured by either a linear or a non-linear slope. We will adjust the analysis accordingly.

Hypothesis 5 **"**The hypothesized intervention effects on co-rumination (primary outcome) will be mediated by the development of mindfulness and emotion regulation skills during the intervention period, immediately after the intervention period and after one-year follow-up" will be tested using a multi-level parallel process LGMs for self-reported co-rumination.

For the model where co-rumination is measured via self-report, a multi-level (LGM) model, with intervention arm as the exogenous predictor variable, growth rate of mindfulness and emotion regulation skills as the mediating variables and growth rate of co-rumination as the primary outcome variable. The mediator and primary and secondary outcome variables will be modelled on both the individual (within) level and on the dyadic (between) level. This way, the between-level intervention effects will be adjusted for variation between individuals in co-rumination (primary outcome), internalizing symptoms (depression/anxiety, secondary outcomes) and negative affect (secondary outcome) on the within-level. Note that we have no a priori hypotheses regarding the nature of the growth patterns of the mediator and outcome variables and that they may be best captured by either a linear or a non-linear slope. We will adjust the analysis accordingly.

Hypothesis 6 "Girls in the intervention group will experience greater feelings of self-worth and will show less health care use, immediately after the intervention period and after one-year follow-up, relative to girls in the control condition" will be tested using multi-level LGMs for each outcome, respectively.

Two multi-level LGMs with intervention arm as the exogenous predictor variable and growth rate self-worth and health care use as the (potentially correlated) outcome variables, will be used to test whether girls in the intervention arm experience more feelings of self-worth and less health care use over time, compared to girls in the control arm. The outcome variables will be modelled on both the individual (within) level and on the dyadic (between) level. This way, the between-level intervention effects will be adjusted for variation between individuals in the outcome measures on the within-level. Please note that health care use will be modelled as a categorical LGM due to the nature of the data (dichotomous). Furthermore, note also that we have no a priori hypotheses regarding the nature of the growth patterns of the outcome

measures and that it may best captured by either a linear or a non-linear slope. We will adjust the analysis accordingly.

Statistical software

All analyses will be conducted in structural equation modeling program Mplus (v 8.7 or higher; Muthén and Muthén, 1998-2017). Model fit will be determined using the comparative fit index (CFI, critical value ≥ .95), the root mean square error of approximation (RMSEA, critical value ≤ .06) and the standardized root mean square residual (SRMR, critical value <. 08; Hu & Bentler, 1999). When appropriate, standard errors will be adjusted for clustering of dyads within schools using a sandwich estimator (Williams, 2000). For hypotheses that include mediation analysis (hypothesis 1 & 5) we will use 10.000 bootstrap resamples with replacement and bias-corrected 95% confidence intervals to test these indirect effects (Preacher and Hayes, 2004). When appropriate, differences in (indirect) pathways between the intervention and the control arm will be estimated using the DIFFtest option in Mplus (when using the WLSMV estimator) or the Satorra Bentler chi-square difference test (Satorra & Bentler, 2001; when using the MLR estimator).

Handling of protocol non-adherence and missing data

The way the questionnaires are administered online makes it impossible to skip a question. Participants who do not complete a questionnaire will receive one or more reminders. Missing data during the follow-up period (e.g., due to unavailability during a certain measurement wave or due to dropout) will be handled using Full Information Maximum Likelihood (FIML) estimation.

10.3 Other study parameters

Not applicable.

10.4 Interim analysis

No interim analysis or stopping guidelines will be applied.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

The study will be conducted in accordance with the principles of the Declaration of Helsinki (current version, 2008) and complies with the Medical Research Involving Human Subjects Act (WMO, Section 4 for minors). It also adheres to the guidelines outlined in “Toetsing van

onderzoek met minderjarige proefpersonen" (CCMO, 2017) and the Code of Conduct regarding expressions of objection by minors participating in medical research (CCMO, 2017).

11.2 Recruitment and consent

The study will take place at regular primary schools of the study consortium partners RiBA, BLICK op onderwijs, and Scholenetwerk BSI, as well as at schools that are involved in the study through our social media channels and webinars. When schools express interest in participating to the PI or lead researchers, the PI will provide an online or in-person presentation about the study to the teachers of grades 7 and 8, and possibly other involved or interested school professionals, such as internal coordinators. After this information session, when schools agree to participate, they will inform the parents/caregivers of the girls in grades 7 and 8 in writing via their regular communication channels about the study and the upcoming study procedures, such as the date and an invitation for classroom visits and the consent procedures. This step provides parents/caregivers with the opportunity to inform the teacher if their daughter should not attend the classroom visit. A few weeks later, the girls and their parents/caregivers in grades 7 and 8 will receive information from two trained lead researchers about the goal of the study and what participation entails, and they will have the opportunity to ask questions. Girls will not be allowed to form dyads during the classroom visits, and it will be explained that the teacher will be available for support when the girls experience challenges during dyad formation. After the classroom visits, teachers will send the information letters and digital consent forms (for parents/caregivers and girls) to the parents/caregivers via email. Parents/caregivers will have fourteen days to consider. After fourteen days, the teacher will send a friendly reminder to the parents/caregivers via email. The only exception is when the consent forms for a dyad are incomplete. In that case, the researchers will approach the teacher with a request to ask the respective family for permission to share their contact details with the researchers, so the lead researchers can complete the consent procedure for the respective dyad. After that, the girls will receive a digital invitation via email to fill out the screener.

11.3 Objection by minors or incapacitated subjects

The study targets female adolescents aged 10-12 years. Parents or main caretakers must provide written consent, but only if their child is willing to participate. Twelve-year-olds must also sign an IC form, in addition to obtaining consent from their parents or main caretakers. Signed IC from both parents or main caretakers is essential for participation. Participants are free to withdraw from the study at any time, without any further consequences. Special attention will be given to addressing any resistance or objections during the assessments

with minors. In cases of resistance, study participation will be terminated. Examples of resistance include (1) the adolescent or her best friend becoming upset, (2) the adolescent or her best friend arguing, or (3) the adolescent or her best friend requesting to stop the video recording or to end their participation in the study. Researchers will adhere to the Code of Conduct for resistance in minors (CCMO, 2017).

11.4 Benefits and risks assessment, group relatedness

The burden and risks for girls participating in the study are considered minimal, as the study does not interfere with their regular education and focuses on naturally occurring interactions and activities within their close friendships. This study offers girls the opportunity to contribute to research that seeks to enhance our understanding of preventing excessive co-rumination and internalizing problems in adolescent girls.

11.5 Compensation for injury

For the girls participating in the cRCT, a subject insurance policy has been taken out with CNA Netherlands (certificate number 10580637).
The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO.

11.6 Incentives

Screening
Girls who participate in the screening will receive a gift valued at €2.50.

T0 - T5 measures
Girls will receive €10.00 upon completing each measurement.

Intervention
To encourage the use of the dyadic app during the prevention program period, friendship dyads will earn a weekly credit of €2.50 if both participants complete daily monitoring (three times a day) and journaling (three times a day) for at least six out of the seven weekdays in a period starting the first day after the first lesson until the date of the last lesson (holiday days are excluded). Study personnel will email parents and participants after each phase (please see Figure 1) to update them on the number of times the girls used the app that week and whether they have earned the weekly credit.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Table 4 presents an overview of the data collection.

Table 4. Overview of data collection.

TYPE	DESCRIPTION	INFORMANT	N	FORMAT	VOLUME
.APPLICATION DATA (APP)	Test of the intervention app used on personal smartphone	Girls in 5th and 6th grade of primary education	160 (80 dyads)	.csv	100MB - 500MB
OBSERVATIONAL DAYA	Videotapes of Problem talk task	Girls in 5th and 6th grade of primary education	160 (80 dyads)	Not yet available	Not yet available
QUESTIONNAIRES	Questionnaires during T0. T1. T2. T3. T4 and Follow-up T5.	Girls in 5th and 6th grade of primary education	320 (160 dyads)	.sav (.dat possible)	200MB - 1000MB
QUESTIONNAIRES	Questionnaires during T0, T2 and T4.	Parents/caretakers of participating girls	320	.sav (.dat possible)	100MB - 500MB
QUESTIONNAIRES	Questionnaires about implementation	Trainers	160 (80 dyads)	.sav (.dat possible)	100MB - 500MB

1. Application App yourself Happy app

   The App yourself Happy app collects personal data. YipYip has developed the app. YipYip is a Dutch company but engages a sub-processor where personal data collected by the app is hosted: Google Cloud Platform. The company is based in the United States, but the servers where the data is are hosted in the Netherlands. YipYip has made appropriate agreements with Google regarding the processing of personal data. To be able to monitor the implementation of the training program, the PI and both PhD-students will receive a login link with a personal login-code to access this data file. Data will be stored under a

pseudonym. The keyfile which links the participants to their pseudonyms will only be accessible by the PI and the PhD-students.

2. Questionnaires. Questionnaire data will be collected using Qualtrics. No physical data (e.g., paper questionnaires) will be collected, used, or stored. All data will be stored on Research Drive.
3. The training sessions will be recorded with BigBlueButton for training and intervision purposes but only when the parents/main caretakers provided their approval on the informed consent form. The videorecordings will be automatically transported to Research Drive by BigBlueButton. Nobody but the PI, the two coordinatingresearchers and the trainer of the girls have access to the videorecordings.

The data will be accompanied by a short overview of the instruments and constructs used (.pdf format) for each of the phases of the study. This gives an at-a-glance overview of the available data. (instrument names, constructs, scales and subscales, admitted waves, expected N, etc.). For a more in-depth overview of the data, a codebook (.pdf format) will be created (instruction text, variable labels, value labels, variable info, calculated variables, syntax, references, etc.). Data gathered for the implementation study will be accompanied by a digital logbook per person per training session. This logbook contains general information (name, date, schoolId/classId, etc.) and a checklist (checklists for all tasks, and open text fields to allow the trainers to write down comments). This data will be transported to an encrypted MS Access database (.accdb) and the digital files will be removed after ten years.

Data minimization and anonymization

Identifying data will be pseudonymized before they are analyzed, so: no names will be used, only an artificial identifier (string of digits). Furthermore, other identifying data, age and education are de-identified, by not using absolute values, but broader categories, which prevent an inference attack from revealing disclosed information, but generalizing the identifying information.

Anonymization/pseudonymization and storage

Collection and processing of personal data for the purpose of the research project will be carried out exclusively by the PI, the data-manager and PhD-students. The keys will be known only to the PI and the PhD-students. De-anonymization may occur only for the purpose of assessment of scientific integrity and upon a request thereto by a competent authority (CA). All research data is stored on Research Drive.

Sharing during research

In order to facilitate co-operative research over long-distance and only if necessary, with regard to the purpose of the research project, research data including personal data may be shared among the PI and all researchers (including the data manager). Data linked to published papers will be made openly available minus any data that can be considered personal data (video data). For the purpose of sharing pseudonymized research data over distance, researchers will use ResearchDrive or the Dutch cloud service SURFdrive. SURFdrive is designed especially for higher education and research purposes and offers researchers and staff an easy way to share and synchronize files within a secure community cloud with ample storage capacity. All SURFdrive information security protocols meet high standards. The Dutch Legal Framework for Cloud Services serves as a guideline for all service-related agreements. SURFdrive complies with Dutch and European privacy legislation. In addition, access to SURFdrive is password protected and designated folders can be password protected. Communication to and from SURFdrive is encrypted. If shared via SURFdrive, files that contain personal data are placed in designated and password protected folders. In addition, such shared files will be encrypted. Keys to encrypted shared files are held by the PI and secondary researchers.

Sharing after research

When the study is completed, the underlying research data may be shared with third parties for the purposes of reproduction, reuse or assessment of scientific integrity. The sharing of research data connected to a publication is subjected to contractual obligations with the publisher. Data linked to published papers will be made openly available minus any data that can be considered personal data. The sharing of research data with third parties will be carried out with the use of Dataverse.nl. Dataverse is certified with Data Seal of Approval and World Data System and uses persistent identifiers to make data FAIR. Files that contain personal data will not be stored on y unless they are anonymized d. Files that contain personal data will be stored in DarkStore, an offline archive for storing sensitive information/data without a persistent identifier. Files stored in DarkStore will not be shared with third parties, unless the purpose of reproduction, reuse or assessment of scientific integrity justifies otherwise. In that event such files may be released subject to identification of the requestor accompanied by a purpose statement and approval by the CA of Rotterdam University of Applied Sciences.

12.2 Monitoring and Quality Assurance

Not applicable.

12.3 Amendments

Not applicable.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The end of the study is defined as the last measurement (T5) of the final dyad. The PI will promptly notify the MEC-U of any temporary halt to the study, along with the reason for such an action. In the event of premature termination, the investigator will inform the MEC-U within fifteen days, providing the reasons for the early termination. Within one year after the study's conclusion, the PI will submit a final study report with the results, including any publications or abstracts related to the study. The data will be retained for ten years after the termination of the study .

12.6 Public disclosure and publication policy

After the study is completed, the research data will be stored for ten years at the national data repository of Data Archiving and Networked Services (DANS), which is the Academy/NWO-funded provider of research data archiving. Requests for access to anonymized datasets will be granted to academic and non-profit researchers through the application of a Creative Commons Attribution-Non-commercial or comparable license.

13. STRUCTURED RISK ANALYSIS

13.1 Potential issues of concern

Not applicable.

13.2 Synthesis

Not applicable.

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