

# Dyadic-based targeted prevention of maladaptive co-rumination and internalizing problems and disorders in Dutch early adolescent girls: A Cluster Randomized Controlled Trial on the effectiveness of the blended school-based mindfulness prevention program Happy Friends, Positive Minds.

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The objective of the Happy Friends, Positive Minds Cluster Randomized Controlled Trial is to evaluate the effectiveness of Happy Friends, Positive Minds prevention program, delivered by experienced mindfulness health professionals, on self- and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON55907

### Source

ToetsingOnline

### Brief title

Prevention of maladaptive co-rumination and internalizing problems.

### Condition

- Mood disorders and disturbances NEC

**Synonym**

Internalizing symptoms and disorders (depression/anxiety)

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Rotterdam University of Applied Sciences

**Source(s) of monetary or material Support:** NRO Gedrag en Passend Onderwijs; SIA KIEM; Citylab010.

**Intervention**

**Keyword:** Cluster Randomized Controlled Trial, Co-rumination, Girls, Internalizing problems

**Outcome measures****Primary outcome**

Participant-level self- and teacher-reported risk for (early onset) depression and anxiety, self-reported and observed co-rumination, self- and friend-reported friendship quality, self-reported positive and negative affect, self-reported interpersonal responses to positive affect and self-reported anhedonia symptoms will be the primary outcomes.

**Secondary outcome**

Secondary outcomes will be self-reported anhedonic symptoms, self-reported mastery, self-reported academic motivation, self-reported concentration, parent-reported health care use and teacher-reported emotional and behavioral problems and academic competence.

**Study description****Background summary**

A growing literature indicates that adolescent girls who talk with friends about interpersonal problems or worries in a way that is excessive, speculative, and negatively focused, with an intense focus on distress and uncertainty about whether problems will be manageable or solved (i.e., co-rumination) are at heightened risk for early onset internalizing symptoms and disorders. However, to date, there are no prevention programs available that target co-rumination in adolescent girls. Given the emphasis on the cultivation of present moment awareness, practicing appreciation and gratitude and meta-awareness of the dynamics between thoughts, emotions, body sensations and impulses, mindfulness-training may be particularly beneficial for girls who engage excessively together in repetitive, negative, and judgmental interactions. As such, we developed an app-based mindfulness training program that will be available via schools after the Cluster Randomized Controlled Trial phase, and that focuses on teaching mindfulness skills on the dyadic level and that supports excessive co-ruminating girls to integrate these skills in their everyday lives: the Happy Friends, Positive Minds (HFPM) secondary school-edition prevention program. We will include 160 friendship dyads who are primarily characterized by high levels of co-rumination within their daily interaction patterns. The goal of this program is to train dyads to shift dyadic maladaptive emotion regulation patterns to more adaptive emotion regulation strategies within their dyadic interactions, while continuing to reap the benefits of their close, intimate friendships and exploring healthy, new alternatives for excessive co-rumination.

## **Study objective**

The objective of the Happy Friends, Positive Minds Cluster Randomized Controlled Trial is to evaluate the effectiveness of Happy Friends, Positive Minds prevention program, delivered by experienced mindfulness health professionals, on self- and teacher-reported mental health outcomes in a sample of 320 Dutch girls from age 13 to 15 years old, and to unveil the mechanisms of change of the program.

## **Study design**

The HFPM Cluster Randomised Controlled Trial has two arms: (1) an intervention condition in which 80 girls\* friendship dyads (n = 160 high-risk girls) will receive the training program HFPM between November 2023 and July 2024, and (2) a control condition in which 80 girls\* friendship dyads (n = 160 high-risk girls) will receive teaching-and-care-as-usual (TAU). To prevent contamination across the two trial arms, friendship dyads will be the unit of randomisation. The 14-week prevention program will be delivered in four phases between November 2023 and June 2024 (phase 1: November 2023; phase 2: January 2024; phase 3: March 2024, and phase 4: May/June 2024). The T0 baseline measure will take place in September and October 2023, followed by a T1 measure (December 2023), a T2 measure (February 2024), a T3 measure (April 2024), a T4 measure

(July 2024) and a one-year follow-up measure in July 2025 (T5 measure).

## **Intervention**

The Happy Friends, Positive Minds prevention program is designed to train social-emotional-behavioral self-regulation within the supportive close friendship context by facilitating dyadic as well as individual experiential learning. This program was developed between 2020 and 2022 using the Intervention Mapping Approach for planning health promotion programs (Bartholomew et al., 2016) and the Template for Intervention Description and Replication (TIDieR) checklist and guide for reporting complex interventions (Hoffmann et al., 2014). The program comprises 14 guided, weekly online lessons with mindfulness practices and psychoeducation, guiding the dyadic use of the eMental health application App je Happy. The goal of this program is to train 160 Dutch (80 dyads) high risk girls between ages 13 to 15 to shift dyadic maladaptive emotion regulation patterns to more adaptive emotion regulation strategies within their dyadic interactions, while continuing to reap the benefits of their close, intimate friendships and exploring healthy, new alternatives for excessive co-rumination.

## **Study burden and risks**

The burden and risks for girls associated with participation in the study are seen as minimal given that the study does in no way interfere with regular education of the girls and is focused on natural occurring interactions and activities within girls\* close friendships. The current study offers girls the opportunity to join a study focused on gaining more knowledge about the prevention excessive co-rumination processes and internalizing problems in adolescent girls.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)

Adults (18-64 years)

### **Inclusion criteria**

To be eligible for inclusion, a participant/meisje must meet the following five inclusion criteria:

- (1) Aged 13 to age 15 years.
- (2) Visiting a secondary school of Samenwerkingsverband Koers VO.
- (3) Attending second or third grade of mainstream secondary education in academic year 2023/2024.
- (4) \*Assigned female at birth, being a female transgender or being a nonbinary adolescent.
- (5) Having a mutual same gender (\*assigned female at birth, being a female transgender or being a nonbinary adolescent) good or best friend at the same school.

To be eligible for inclusion, a dyad must meet the following inclusion criterium:

- (1) At least one of the two girls of one friendship dyad, or both girls, should have a score of at least one standard deviation above the mean co-rumination screening score on the Co-rumination Questionnaire Short (Hankin et al., 2010).

### **Exclusion criteria**

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

- (1) Not having a headteacher in academic year 2023/2024.
- (2) Judged as 'inadequate\*' during most recent school inspection by the Dutch Inspectorate of Education.
- (3) Implementing another mindfulness-based intervention in academic year 2023/2024.

Exclusion criterium at the individual girl level:  
(1) Following an/participating in an individual or group-based mindfulness-based training in academic year 2023/2024.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	14-08-2023
Enrollment:	1000
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	14-08-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	14-02-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL82696.078.23