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The Happy Friends, Positive Minds cluster randomized controlled trial

Submission date
01/02/2023

Recruitment status
No longer recruiting

Registration date
24/02/2023

Overall study status
Ongoing

Last Edited
12/01/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
A growing literature indicates that adolescent girls (13-15 years old) 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 of 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 a blended school-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 (called the Happy Friends, Positive Minds (HFPM) secondary school-edition prevention program). The main aim of the Happy Friends, Positive Minds Cluster Randomized Controlled Trial is to evaluate this program 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.

Who can participate?
We will include 160 friendship dyads who are primarily characterized by high levels of co-rumination within their daily interaction patterns.

What does the study involve?
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). Involvement in the study requires participation in the measurements (all) and participation in the prevention program (girls).

What are the possible benefits and risks of participating?
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.
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.

Where is the study run from?
Rotterdam University of Applied Sciences (Netherlands)

When is the study starting and how long is it expected to run for?
October 2022 to July 2026

Who is funding the study?
Stichting Innovatie Alliantie SIA (Netherlands)

Who is the main contact?
Dr Patricia Vuijk, p.vuijk@hr.nl

Contact information

Type(s)
Principal investigator

Contact name
Dr Patricia Vuijk

ORCID ID
https://orcid.org/0000-0002-6307-9153

Contact details
P.O. Box 25035
Rotterdam
Netherlands
3001 HA
+31 615959704
p.vuijk@hr.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
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.

Acronym
HFPM

Study objectives
The main study aim of the Happy Friends, Positive Minds Cluster Randomized Controlled Trial is to evaluate the effectiveness of the blended, school-based mindfulness program Happy Friends, Positive Minds on self-reported mental health outcomes in a sample of 320 Dutch girls aged between 13 to 15 years, and to unveil the mechanisms of change of the program.

The research question is: To what extent does the app-based mindfulness prevention program Happy Friends, Positive Minds impact mental health, well-being, and school functioning in Dutch 13-to-15-year-old girls?

Hypotheses:
1. Girls in the intervention group will have a greater reduction in co-rumination about distress and difficult emotions and feelings, (and thereby) internalizing symptoms and negative affect 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 a later onset of depressive symptoms or a later onset of depressive disorder and 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 anxiety problem talk, a later onset of anxiety symptoms or a later onset of anxiety disorder and 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 of the dyad friend, 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 skills, emotion regulation skills and problem-solving skills during the intervention period, immediately after the intervention period and after one-year follow-up.
6. The hypothesized intervention effects on co-rumination will be moderated by self-control: girls with more developed self-control skills will demonstrate greater intervention effects immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
7. Girls in the intervention group will experience less anhedonic symptoms, will experience greater feelings of mastery, will show less emotional and behavioral problems, will show greater

school motivation, will experience more concentration, and 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.
8. Girls in the intervention group will demonstrate a change in topics discussed: girls will demonstrate less problem talk about interpersonal problems and shorter periods of interpersonal problem talk immediately after the intervention period and after one-year follow-up, relative to girls in the control condition.
9. The hypothesized intervention effects on (the onset) of depression and anxiety symptoms or disorders and depression contagion and anxiety contagion are differently related to changes in the conversation-topics between girls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/08/2023, Medical Ethics Review Committee Erasmus MC (PO Box 2040, 3000 CA Rotterdam, Netherlands; + 31 10 704 0 704; metc@erasmusmc.nl), ref: MEC-2023-0116

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of excessive co-rumination and related internalizing symptoms and disorders.

Interventions
Current interventions as of 07/12/2023:
The HFPM cRCT 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 February 2023 and June /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 randomization.

Randomization, blinding and treatment allocation
Sequence generation. Girls will be randomly assigned in a 1:1 ratio to the intervention group (80 dyads; n = 160 girls) or to the control group (CAU; 80 dyads; n = 160 girls) by an independent researcher, using CASTOR Electronic Data Capture (EDC), a web-based electronic case record form and randomisation program that is compatible with the GCP guidelines. Ideally, randomization takes place on one day, after the screening phase has been completed. However, when this is not possible (e.g., due to time limitations), we will follow the following procedure: We will randomize dyads in batches of 50 dyads (100 girls). For the first batch, the mean and standard deviation (SD) will be computed and dyads in which one or both girls score 1 SD above the mean will be included in the study and randomly assigned to the treatment or control condition via a block randomization procedure (i.e., 50% of dyads assigned to the intervention arm and 50% assigned to the control arm). Next, the next 50 dyads (batch 2) will be screened, and a new mean and SD will be calculated for the group in total (i.e., 100 dyads). Then, dyads of

batch 2 who adhere to the inclusion criteria are included and randomly assigned to the control or intervention condition. We proceed with this process until 1000 girls are screened and 160 dyads are included in the study.

The Happy Friends, Positive Minds prevention program focuses on teaching mindfulness skills on the dyadic friendships levels and will support excessive co-ruminating girls to integrate these skills in their daily lives: the Happy Friends, Positive Minds (HFPM) secondary school-edition prevention program (Vuijk et al., 2022). This 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. The program comprises 14 guided, weekly online lessons with mindfulness practices and psychoeducation, guiding the dyadic use of the eMental health application App yourself 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.

The 14-week HFPM program will be delivered in two cohorts (cohort 1: academic year 2023-2024; cohort 2: academic year 2024-2025) in four phases between February 2024 and May 2025 for both cohorts. The T0 baseline measurements for both cohorts will take place from October 2023 (cohort 1) and from October 2024 (cohort 2), followed by T1 measurements (from February 2024 for cohort 1 and from December 2024 for cohort 2), T2 measurements (from April 2024 for cohort 1 and from February 2025 for cohort 2), T3 measurements (from June 2024 for cohort 1 and from April 2025 for Cohort 2), T4 post-intervention measurements (from September 2024 for cohort 1 and from Juli 2025 for cohort 2) and a one-year long-term follow-up measurement (T5) from July 2025 and 2026.

Participant-level self-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 outcome variables.

Previous interventions:
The HFPM cRCT 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 June /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 randomization.

We use MS Excel to randomize the dyads by sorting a list of Dyad Identification numbers with the RANDOM function. After sorting, the first half of the list will be the intervention group and the second half will be the control group. This is the full random way of sorting.

The Happy Friends, Positive Minds prevention program focuses on teaching mindfulness skills on the dyadic friendships levels and will support excessive co-ruminating girls to integrate these skills in their daily lives: the Happy Friends, Positive Minds (HFPM) secondary school-edition prevention program (Vuijk et al., 2022). This 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. The program comprises 14 guided, weekly online lessons with mindfulness practices and psychoeducation, guiding the dyadic use of the eMental health application App yourself 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.

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). 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.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 07/12/2023:
The 14-week HFPM program will be delivered in two cohorts (cohort 1: academic year 2023-2024; cohort 2: academic year 2024-2025) in four phases between February 2024 and May 2025 for both cohorts. The T0 baseline measurements for both cohorts will take place from October 2023 (cohort 1) and from October 2024 (cohort 2), followed by T1 measurements (from February 2024 for cohort 1 and from December 2024 for cohort 2), T2 measurements (from April 2024 for cohort 1 and from February 2025 for cohort 2), T3 measurements (from June 2024 for cohort 1 and from April 2025 for Cohort 2), T4 post-intervention measurements (from September 2024 for cohort 1 and from Juli 2025 for cohort 2) and a one-year long-term follow-up measurement (T5) from July 2025 and 2026.

All data will be collected via Qualtrics at T0, T1, T2, T3, T4 and 1-year follow-up measures T5 (girls)
1. Self-reported negative affect: co-rumination (girls; questionnaire; Co-Rumination Questionnaire-Short, Hankin et al., 2010)
2. Observed regulation of negative affect: co-rumination (Problem Talk Task; Rose et al., 2014; Dutch version; Vuijk et al., 2022)
3. Self-reported (early onset risk for) depressive symptoms/disorder (girls; questionnaire; Child Depression Inventory; CDI-2; Bodden, Braet, & Stikkelbroek, 2016)

Previous primary outcome measure:
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):
1. Self-reported negative affect: co-rumination (girls; questionnaire; Co-Rumination Questionnaire-Short, Hankin et al., 2010);
2. Self-reported (early onset risk for) depressive symptoms/disorder (girls; questionnaire; Child Depression Inventory; CDI-2; Bodden, Braet, & Stikkelbroek, 2016);
3. Self-reported (early onset risk for) generalized anxiety symptoms/disorder (girls/ questionnaire; subscale Generalized Anxiety Disorder (GAD) of the Revised Children's Anxiety and Depression Scale; RCADS, Chorpita et al., 2000);
4. Self-reported problem anxiety talk (girls/ questionnaire; Problem Anxiety Talk Scale; PATS, Herzig, Steward, & Treadwell, 2022);

5. Self-reported positive and negative affect (girls/ questionnaire; Dutch version of the Positive and Negative Affect Schedule for Children; PANAS-C, Laurent et al., 1999; De Bolle, De Fruyt, & Decuyper, 2010);
6. Self-reported interpersonal responses to positive affect (girls/ questionnaire; Co-Dampening and Co-Enhancing Questionnaire; CoDEQ, Bastin et al., 2019);
7. Self-reported quality of the friendship with the dyad-friend and investments in the interpersonal relation (girls/ questionnaire; Network of Relationships Inventory; NRI, Furman & Buhrmester, 1992);
8. Regulation of negative affect: co-rumination (girls/ observations; Dutch version of the standardized Problem Talk task (Rose et al., 2014; Vuijk, Bul, & Amesz, 2021).

Key secondary outcome(s))

Current secondary outcome measures as of 07/12/2023:
Collected at T0, T1, T2, T3, T4 and 1-year follow-up measures T5 (girls):
1. Self-reported (early onset risk for) generalized anxiety symptoms/disorder (girls/ questionnaire; subscale Generalized Anxiety Disorder (GAD) of the Revised Children's Anxiety and Depression Scale; RCADS, Chorpita et al., 2000)
2. Self-reported problem anxiety talk (girls/ questionnaire; Problem Anxiety Talk Scale; PATS, Herzig, Steward, & Treadwell, 2022)
3. Self-reported positive and negative affect (girls/ questionnaire; Dutch version of the Positive and Negative Affect Schedule for Children; PANAS-C, Laurent et al., 1999; De Bolle, De Fruyt, & Decuyper, 2010)
4. Self-reported interpersonal responses to positive affect (girls/ questionnaire; Co-Dampening and Co-Enhancing Questionnaire; CoDEQ, Bastin et al., 2019)
5. Self-reported quality of the friendship with the dyad-friend and investments in the interpersonal relation (girls/ questionnaire; Network of Relationships Inventory; NRI, Furman & Buhrmester, 1992)
6. Regulation of negative affect: co-rumination (girls/ observations; Dutch version of the standardized Problem Talk task (Rose et al., 2014; Vuijk, Bul, & Amesz, 2021)
7. Self-reported anhedonic symptoms (girls/ questionnaire; Leuven Anhedonia Self-report Scale, LASS, Nelis et al., 2015)
8. Self-reported mastery (girls/ questionnaire; Dutch version of the Pearling Mastery Scale, PMS, Pearling & Schooler, 1998)
7. Parental health care use of their child/family (parents/ questionnaire; Parental health care use of their child/family will be measured by three questions about whether the child and/or family received health care for psychosocial, emotional or behavioral problems of the child in the last 12 months and about the underlying cause(s) and about the duration of the care.

Previous secondary outcome measures:
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):
1. Self-reported interpersonal reactivity to dyad friend personal distress (girls/ questionnaire; Interpersonal Reactivity Index for Personal Distress; IRI-PD, Davis, 1983);
2. Self-reported anhedonic symptoms (girls/ questionnaire; Leuven Anhedonia Self-report Scale, LASS, Nelis et al., 2015);
3. Self-reported mastery (girls/ questionnaire; Dutch version of the Pearling Mastery Scale, PMS, Pearling & Schooler, 1998);
4. Self-reported academic motivation (girls/ questionnaire; the Dutch version of the Academic Motivation Scale (AMS; Vallerand et al., 1992);
5. Self-reported concentration (girls/ questionnaire; participants will be asked to what extent

they had been able to complete the online questionnaires with concentration (without being distracted);
6. Self-reported academic competence (girls/ questionnaire; subscale School skills of the Dutch questionnaire Competentie Belevingsschaal voor Adolescenten, CBSA, Treffers et al., 2002);
7. Parental health care use of their child/family (parents/ questionnaire; Parental health care use of their child/family will be measured by three questions about whether the child and/or family received health care for psychosocial, emotional or behavioral problems of the child in the last 12 months and about the underlying cause(s) and about the duration of the care;
8. Teacher-reported behavioral and emotional problems (teachers/ questionnaire; Dutch version of the Teacher Report Form, TRF, Achenbach & Rescorla, 1991; Verhulst, van der Ende, & Koot 1997).

Moderator
9. Self-reported self-control (girls/ questionnaire; Dutch version of the 5-item Self-Control Measure, Tangney, Baumeister, & Boone, 2004; De Vries & van Gelder, 2013).

Mediators
10. Self-reported trait mindfulness (girls/ questionnaire; Dutch adolescent version of the Comprehensive Inventory of Mindfulness Experiences; CHIME-A, Johnson, Burke, Brinkman, & Wade, 2017; Kock, Kuppens, van der Gucht, & Raes, 2021);
11. Self-reported emotion regulation (girls/ questionnaire; Dutch version of the Difficulties in Emotion Regulation Scale, DERS; Gratz & Roemer, 2004; DERS-NL; Neumann, van Lier, Gratz, & Koot, 2010).

Completion date
31/07/2026

Eligibility

Key inclusion criteria
To be eligible for inclusion, a participant/girl 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/girls must meet the following inclusion criterion:
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).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Child

Lower age limit
13 years

Upper age limit
15 years

Sex
Female

Key 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 criteria at the individual girl level:
1. Following an/participating in an individual or group-based mindfulness-based training in academic year 2023/2024.

Date of first enrolment
16/08/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Koers VO
Schiekade 34
Rotterdam
Netherlands
3032 AJ

Sponsor information

Organisation
Rotterdam University of Applied Sciences

ROR
https://ror.org/0481e1q24

Funder(s)

Funder type
Government

Funder Name
Stichting Innovatie Alliantie SIA

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 07/12/2023:
In order to facilitate co-operative research over long-distance and only if necessary, 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 (e.g., 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 specifically for higher education and research purposes and offers researchers and staff an easy and safe 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.

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The repository that will be used for archiving is DataverseNL (https://dataverse.nl/dataverse/vuamsterdam) using CC BY-NC or a comparable license. Data that will be shared will be raw data, cleaned data, syntaxes, transcripts and logbooks. This data will be accompanied by a codebook which can be referred to interpret the data. The data will be archived after the project is finished and will be retained for 10 years. Where possible, data will be openly shared, but since the data concerns human subjects, it is likely an approved data request form will be required before data is issued (encrypted files will be sent via SurfDrive or similar secure transfer methods). Data issued will not include personal data unless it is absolutely required. Either way, steps will be taken to ensure the data is recoded (age instead of birthdate, no open questions, etc) or anonymised.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/01/2024	12/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes