A randomised controlled trial of the Happy Lessons approach: a school-based programme to strengthen psychosocial wellbeing and prevent depression in pre-vocational school pupils

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Determine if HL meets the criteria for the higher DEI designation of effectiveness. We will investigate the effectiveness of HL in terms of an increase in well-being and a reduction of depressive symptoms after 6 months compared to care as usual.

Ethical review	Approved WMO
Status	Completed
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON51002

Source
ToetsingOnline

Brief title
RCT Happy Lessons

Condition

- Mood disorders and disturbances NEC

Synonym
depression; depressive symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: adolescents, Depression prevention, pre-vocational school-based program, Randomized Controlled Trail

Outcome measures

Primary outcome

The primary study parameters are well-being and depressive symptoms. These will be measured by pupils self-reports at all four assessment points (e.g., T0-T3).

The primary outcome measurement will be the 6-months follow-up measurement (T3). Depressive symptoms will be measured with the Dutch version of the self-report questionnaire Center for Epidemiologic Studies Depression Scale (CES-D) (Bouma et al., 2012; Schroevers et al., 2000). Well-being will be measured with the Dutch translation of the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) (Ikink, Lamers, & Bolier, 2012; Tennant et al., 2007).

Secondary outcome

Life satisfaction will be assessed with the Cantril Ladder (Cantril, 1965).

demographic characteristics (i.e., gender, age, immigration background) and questionnaires measuring the pupils perceived school climate (i.e., classmate support, teacher support, bullying involvement, bullying victimization, school connectedness, and perceived schoolwork pressure). The mental health professionals who deliver HL will fill in an online questionnaire after the final individual consultation session on how many pupils the referred to

additional help and what type of help they referred the pupils too (e.g., some additional individual sessions with the mental health professional themselves or other appropriate local care). We will also evaluate the implementation of HL to gain insight in the results of the study and warrant successful future implementation for scale up of HL.

Study description

Background summary

Happy Lessons (HL) is a school-based program to promote well-being and prevent depression among young people. It is specifically developed for young people in lower education. HL has been thoroughly evaluated and optimized and is recognized as theoretically sound by the Dutch Recognition System for Interventions (DEI). In the DEI a proven effective school-based depression program is missing yet for lower educated young people.

Study objective

Determine if HL meets the criteria for the higher DEI designation of effectiveness. We will investigate the effectiveness of HL in terms of an increase in well-being and a reduction of depressive symptoms after 6 months compared to care as usual.

Study design

The objective will be addressed in a cluster Randomized Controlled Trail in two parallel groups comparing an experimental condition (receiving HL during the study) and a control condition (CAU waitlist condition, with HL not delivered until after the final follow-up assessment).

Intervention

HL is a school-based program to promote well-being and prevent depression among young people. It is specifically developed for young people in lower education and provided by a mental health professional. It consists of: (a) four classroom lessons, two face-to-face lessons and two e-lessons, (b) an online HL test that includes two well-being scales and a depression scale that is administered at the beginning and end of the classroom lessons, (c) an individual consultation session with the mental health professional who

delivers HL for each pupil, and (d) an additional help offer for high-risk pupils.

Study burden and risks

Previous research concerning the various aspects of our study has shown no risk for pupils: pilot studies of the HL classroom sessions (without control group) have shown promising results, with depressive symptoms reduced and well-being enhanced; the largest effects were found in pupils with elevated depression level. Pupils have also given positive ratings to both the classroom-delivered HL and the subsequent individual advice sessions. In this study both the experimental and control groups will have access to HL. The only differences is that the experimental condition receives HL earlier than the control condition. Moreover, all participants have access to standard usual care delivered at their schools.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

In order to be eligible to participate in this study, recruited schools must meet all of the following criteria: both (1) the school authorities and (2) the community or mental health service whose duty it is to provide services for the school must agree to adhere to the HL protocol. In addition, (3) each school should include at least two school classes within at least one school year (e.g., either school year one or two).

In order to be eligible to participate in this study, students must meet all of the following criteria:
1. Enrolment in either the first or second school year of pre-vocational education.
2. Informed consent of the parent(s).
3. Informed consent of the pupil.
4. Sufficient command of the Dutch language

Exclusion criteria

1. No informed consent from the parent(s)
2. No informed consent from the pupil

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-10-2021

Enrollment:	1050
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-06-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24100
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77336.041.21

Study results

Date completed: 29-01-2024

Summary results
Trial ended prematurely