

Evaluation study to examine the effectiveness of Longlivelove-4, a teacher-delivered sexual health program

Submission date 23/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/11/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Compared to other Western countries contraceptive use and condom use is high among young people (aged 12-24) in the Netherlands. Nevertheless, early starters and low educated young people are more likely to be at risk for unprotected sex, and the risk for unprotected and unsatisfactory sex is higher when first time sexual intercourse is unexpected.

This study aims to evaluate the effectiveness of a teacher-delivered comprehensive sexual health education program, LongLiveLove (LLL4, fourth edition).

Who can participate?

Students and teachers in the second class at participating schools

What does the study involve?

Schools are randomized to one of three intervention conditions:

1. The control condition, where learners would receive regular sexual education
2. The LLL4 experimental condition
3. The LLL4 condition + Teacher coaching

LLL4 is a newly developed teacher-led comprehensive sexual health curriculum. In six lessons learners are taught about different sexual health themes: sexual maturation, sexual preferences and boundaries, sexual transmitted diseases, pregnancy and safer sexual practices, sexual diversity. Three types of materials are used as part of the lessons: A magazine for students consisted of 6 chapters, each representing a lesson. The magazine was developed to provide students with information about themes that are discussed during the lessons. It contains role model stories with personal experiences, photo's, a photo story, quizzes, recommendations and a cartoon geared to the students' perception of their environment. A digital manual for teachers consists of a set-up and style example for each lesson. Both the magazine for students and the manual for teachers had two versions, one for theoretical pre-vocational secondary education, senior general secondary education and pre-university education, and one for practical training and practical pre-vocational secondary education. The second version contains less text, bigger letters and more practical tasks. A DVD for pupils contained 6 episodes of 7 minutes, one for

each lesson. An additional episode discussed teenage motherhood. The DVD was developed to stimulate discussion and to teach skills. Each episode consists of a docudrama, animations, statements of adolescents about themes and interviews with adolescents.

Teacher coaching

The teachers in the teacher coaching conditions were offered additional support via a website (Teachinglove.nl) that addressed common challenges of teachers in delivering sexual health education.

What are the possible benefits and risks of participating?

There are no direct benefits or risk for participants.

Where is the study run from?

1. TNO, Research Group Child Health (Netherlands)
2. 59 participating schools

When is the study starting and how long is it expected to run for?

September 2011 to November 2013

Who is funding the study?

Netherlands Organisation for Health Research and Development (Netherlands)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

051.90051

Study information

Scientific Title

Effectiveness of the Long Live Love 4, a comprehensive sexual health program for 13- and 14-year-old secondary school students in the Netherlands: a cluster-Randomized Controlled Trial

Study objectives

It is hypothesized that students exposed to Long live love 4, compared to the control group, will result in improved sexual health outcomes.

At teacher-level: It was expected that teachers that receive the LLL+eCoach (LLL4+) compared to the teachers that only received LLL4 (without eCoach) would show higher quality of implementation of LLL4.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Psychology Ethics Committee (ECP) of Maastricht University, 06/01/2012, ref: ECP 109 8_12_2011

Study design

Cluster-randomised controlled trial with three arms

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Sexual health

Interventions

There are three intervention arms:

1. Control condition (receives conventional sex education)
2. Long live love (without eCoach) experimental condition: receives the newly developed comprehensive sexual health program, which include six lessons; it consists of a magazine and DVD for adolescents, a teachers manual, condoms, posters and a question box.
3. LLL4 with eCoach condition: LLL4 program, but in addition a website with e-coaching material is developed for teachers (Teachinglove.nl) that addresses common challenges of teachers in delivering sexual health education.

LLL4 is a series of six lessons; it consists of a magazine and DVD for adolescents, a teachers manual, condoms, posters and a question box. Teachers can choose between 1-2 lessons per week (lessons are one class hour (i.e., 50 minutes). Hence, total duration is 3-6 weeks (total duration approximately 5 hours).

Themes discussed within the different lessons:

Lesson 1) Sexual maturation: what happens to you? Puberty, being in love, sexual identity, influence of parents and friends, and homosexuality;

- Lesson 2) Sexual maturation: which stage have you reached? Making eyes, courting, breaking up, love sickness, choices in relationship and ways for intimacy;

- Lesson 3) Preferences and boundaries: what are your boundaries? Discovering and communicating your and others' preferences and boundaries, safe internet use, unpleasant experiences, loverboys;

Lesson 4) Preferences and boundaries: how to make the best out of sex? First time having sex, conditions for having safe, preferable and pleasant sex, dealing with sexual problems, information and help seeking;

Lesson 5) Safe sex: what is it? Preventing pregnancy and STI's, (un)safe sex and what to do;

Lesson 6) Safe sex: how to do it? Use of contraception, condom use, communication about it and dealing with resistance against condom use.

The lessons were developed to transfer knowledge, to promote a positive attitude towards sex and to practice with skills.

As part of the intervention the following materials were available:

- The magazine for students consisted of 6 chapters, each representing a lesson. The magazine was developed to provide students with information about themes that will be discussed during the lessons. It contained role model stories with personal experiences, photo's, a photo story, quizzes, recommendations and a cartoon geared to the students' perception of their environment.

- A digital manual for teachers consisted of a set-up and style example for each lesson. Both the magazine for students and the manual for teachers had two versions, one for theoretical pre-vocational secondary education, senior general secondary education and pre-university education, and one for practical training and practical pre-vocational secondary education. The second version contained less text, bigger letters and more practical tasks.

- The DVD for pupils contained 6 episodes of 7 minutes, one for each lesson. An additional episode discussed teenage motherhood. The DVD was developed to stimulate discussion and to teach skills. Each episode consisted of a docudrama, animations, statements of adolescents about themes and interviews with adolescents.

eCoach (Teachinglove.nl)

Teachinglove.nl contains video's, hands-on examples and recommendations of other teachers, a teachers manual and worksheets, and teachers could participate in a quiz, ask questions and exchange experiences. It specifically addresses 7 challenges:

1. creating a safe and trusted environment for the provision of sexual health lessons,

2. teaching about sexual health without shame,
3. protecting boundaries in sharing personal information and questions between teachers and students and among students themselves,
4. identifying personal problems of students,
5. integrating social media,
6. integrating homosexuality as self-evident during the lessons of LLL and dealing with negative reactions to homosexuality
7. anticipating differences in culture and levels of sexual experience in the classroom.

Randomization takes place at school level. Schools were stratified with the aim to ensure a match in terms of educational level, religious background, and region. In order to assess the differences between the two LLL4 conditions, twice as many schools are allocated to these conditions, as compared to the control condition (with a ratio of 2:2:1). The experimental intervention is delivered by (trained) teachers. The teachers in the LLL4+ condition are offered a web-based eCoach ('Teachinglove.nl'). Quality of implementation, between the two experimental conditions is also compared at teacher-level.

Intervention Type

Behavioural

Primary outcome measure

Determinants of sexual health related behaviors of the students are measured using previously validated paper-and-pencil questionnaires at baseline, and 1 month and 8 months after delivery of LLL4:

- 1.1. Condom use (attitude, subjective norms, self-efficacy expectations and intention)
- 1.2. Contraceptive pill use (attitude, girls perceived social influence, girls self-efficacy expectations, girls intention, boy's self efficacy expectations)
- 1.3. Prevention of sexual pressure (attitude towards students preferences, other preferences and self-efficacy expectations towards boundaries)
- 1.4. Attitude towards homosexuality
2. Self-reported completeness and (guideline) adherence of LLL4 of the teachers is measured using a paper and pencil questionnaire at baseline and at post-test (2 weeks after delivery of LLL4).

Secondary outcome measures

1. Knowledge regarding sex and perceived risk including STI and unwanted pregnancy is assessed using a previously validated paper-and-pencil questionnaire at baseline, 1 month and 8 months.
2. Teacher level: Determinants of LLL4 usage (Curriculum-related teacher benefits, subjective norms, perceived social support, and self-efficacy expectations)

Overall study start date

01/09/2011

Completion date

01/11/2013

Eligibility

Key inclusion criteria

Students:

1. Students from the second class of secondary vocational school
2. Aged 13-14 years

Teachers:

1. Teaching 2nd class of secondary vocational school

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

59 schools agreed to participate. control condition: 12 schools (848 students), LLL4 condition : 18 schools (1.484 students and 26 teachers), LLL4+ condition: 18 schools (1575 students and 41 teachers)

Key exclusion criteria

No exclusion criteria

Date of first enrolment

09/01/2012

Date of final enrolment

01/05/2013

Locations**Countries of recruitment**

Netherlands

Study participating centre

TNO, Research Group Child Health

Schipholweg 77-89

Leiden

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Sponsor information**Organisation**

TNO

Sponsor details

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Sponsor type

Research organisation

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ROR

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Funder(s)

Funder type

Research council

Funder Name

ZonMw (Netherlands Organisation for Health Research and Development), funding number 12427 0003

Results and Publications

Publication and dissemination plan

Publication of the study results is planned in a high-impact peer reviewed journal

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/06/2018	23/11/2020	Yes	No