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Evaluation of the Long Live Love sex education program for students in special secondary education

Submission date
20/02/2023

Recruitment status
No longer recruiting

Registration date
10/03/2023

Overall study status
Completed

Last Edited
12/03/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Students with psychiatric and/or severe behavioral problems in special secondary education (formerly known as cluster 4: VSOc4) are at increased risk for unintended pregnancy. Compared to regular secondary education (VO), they engage in unsafe sex practices more often and at an earlier age than their peers. Characteristics of students in VSOc4 include, for example, attention deficits, attachment problems, emotion regulation problems, child abuse or (sexual) trauma. This makes them extra vulnerable to unintended pregnancy.
To prevent unintended pregnancy among VSOc4 students, evidence-based programs are essential for this target group. Currently, as indicated by the knowledge synthesis (Jansma & Sondeijker, 2019), there is no program specifically suitable for VSOc4 students. Because VSO schools are overloaded with programs on a variety of themes, it is essential to depart from already used, evidence-based interventions. Long Live Love (LLL) is the only comprehensive sex education program that has proven long-term effects on risk factors for unintended pregnancy among VO students in the Netherlands. It has already been implemented in over 50% of schools in diverse settings (e.g., VO, practical education), but needs to be adapted to meet the specific needs of VSOc4 students.
This project aims to prevent unintended pregnancy by adapting LLL to the needs and characteristics of VSOc4 students and schools; we will focus on adaptations (i.e,. content and intervention strategies) specifically needed to prevent unintended pregnancy. In addition, we will evaluate program feasibility and effectiveness in preventing risk factors of unintended pregnancy in a small-scale intervention study.

Who can participate?
The study population exists of students in special secondary education (VSO) with psychiatric and/or severe behavioral problems (formerly known as cluster 4; VSOc4), and their teachers.

What does the study involve?
Schools willing to participate in the study will be randomly assigned to the experimental or control condition. The waiting list control group will receive access to the adapted Long Live Love program (LLL VSOc4) after the post-test evaluation among students and teachers. The

experimental group will receive access to LLL VSOc4 after the baseline survey among students. LLL is a school-based, comprehensive sexual health program aimed at promoting sexual health and preventing unintended pregnancies, STI/HIV infections and sexual coercion. It consists of a series of lessons addressing sexual health challenges of adolescents: sexual development, assertiveness and boundaries, and skill development for having safe sex. LLL VSOc4 consists of 3 modules; each module consists of 6 lessons about relations, the body and puberty, sexual wishes and boundaries, and safe sex. The approximate duration per lesson is 30 to 45 minutes. The modules can be subsequently used, they suit different learning levels, and a subsequent module provides repetition as well as more in-depth information. Schools in the experimental condition will be asked to select the appropriate module for their students and provide the 6 lessons within a module. The LLL program consists of a teacher manual, student magazines and a digital environment containing materials (working forms, videos and tasks) that can be used in the lessons. Students and teachers will receive a post-test after the lessons are provided.
Schools in the control condition will conduct the same pre- (among students) and post-test (among students and teachers) as the experimental condition, but they will receive the LLL VSOc4 program after the post-test.

The pretest will be conducted approximately 2 weeks before the start of the LLL program, the program will last approximately 2 months, and will be followed by a posttest approximately 2 weeks after the program. The RCT will take approximately 4 months time.

The LLL VSOc4 programs are provided within schools to students by the teacher. The online surveys (pre- and posttest) are provided to students by teachers or research assistants at school during or outside the class; the individual interviews at posttest will be provided to a subsample of students at school outside the class. The online survey (posttest) for teachers will be sent to teachers via e-mail.

What are the possible benefits and risks of participating?
Possible benefits of participation are contributing to an improved educational program about relations and sexuality for VSOc4 schools, teachers and students, and increased practical (communication and technical) skills to avoid unintended pregnancy.
Participating in the study has the following risks:
- The survey of students contains sensitive questions about sexuality. This may trigger emotions and/or feelings for exclusion, questions or the need for help among students. We will provide students with information about whom to reach out to for their questions within or outside the school in the study information as well as in both the surveys (pre- and post-test).
- Because of the sensitive data, the data needs extra protection. The data protection methods taken are described in a data-protection plan, and students, their parents and teachers are informed about the study, the confidentiality of their data, and how their data is protected, so that they can decide for themselves whether they want to participate in the study information, and where to ask questions about the study. After this, they are asked to provide active informed consent to participate in the study (for students, this includes consent from themselves and their parents).
- Participating in the study costs time, approximately 1.5 hours for students to complete both surveys, and 20-30 minutes for teachers to complete the survey, besides providing the program when they are part of the experimental group. We will inform students and teachers about the study time in the study information, and will provide them with surveys as brief as possible to answer the research questions.

Where is the study run from?
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

When is the study starting and how long is it expected to run for?
May 2021 to March 2024.

Who is funding the study?
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZonMw 554002011

Study information

Scientific Title
A small-scale study to examine the feasibility and effectiveness of a school-based comprehensive sex education program for students in special secondary education

Acronym
LLL VSOc4

Study objectives
The optimized Long Live Love program is more effective in increasing knowledge, attitude, self-efficacy expectations, behavioral willingness and intention towards safe sex and communication about sexual preferences and boundaries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/02/2023, Institutional Review Board TNO (Anna van Buerenplein 1, 2595 DA Den Haag, Netherlands; +31 888668464; toetsing_Mensgebondenonderzoek@tno.nl), ref: 2023-003A.

Study design
Cluster randomized controlled trial with a pre-post-test waiting list control group

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
See additional files in Dutch

Health condition(s) or problem(s) studied
Prevention of unintended pregnancy among students with psychiatric and/or severe behavioral problems in special secondary education (formerly known as cluster 4: VSOc4).

Interventions
Schools willing to participate in the study will be randomly assigned to the experimental or control condition by means of a computer program (R). We will stratify schools on the number of participating student classes before randomization. The control group will receive access to the optimized Long Live Love program after the posttest, the experimental group will receive access to the optimized Long Live Love program after the pretest.

Intervention - Schools in the experimental group will receive Long Live Love (LLL VSOc4). LLL is a school-based, comprehensive sexual health program aimed to promote sexual health and prevent unintended pregnancies, STI/HIV infections and sexual coercion. It consists of a series of lessons addressing sexual health challenges of adolescents: sexual development, assertiveness and boundaries, and skill development for having safe sex. The LLL program for students with severe behavioral or psychiatric problems in special secondary education (formerly known as cluster 4) consists of 3 modules; each module consists of 6 lessons about relations, the body and puberty, sexual wishes and boundaries, and safe sex. The approximate duration per lesson is 30 to 45 minutes. The modules can be subsequently used, they suit to different learning levels, and a subsequent module provides repetition as well as more in-depth information. Schools in the

experimental condition will be asked to select the appropriate module for their students and provide the 6 lessons within a module. The LLL program consists of a teacher manual, student magazines and a digital environment containing materials (working forms, videos and tasks) that can be used in the lessons.
Waiting list Control - Schools in the control condition will receive the LLL VSOc4 program after the data collection (i.e., the post-test).
We will use a cluster-randomized waiting group-controlled design. Schools willing to participate in the study will be randomly assigned to the experimental or control condition by means of a computer program (R). We will stratify schools on number of participating student classes before randomization.
The pretest will be conducted approximately 2 weeks prior to the start of the LLL program, the program will last approximately 2 months, and will be followed by a posttest approximately 2 weeks after the program. The cluster-RCT will take approximately 4 months time.

Intervention Type
Behavioural

Primary outcome measure
To identify the contribution of the LLL program on the prevention of unintended pregnancy, we will evaluate program effects on key risk factors. Primary outcomes will be measured at pre- (approximately 2 weeks prior to the intervention) and post-test (approximately 2 weeks after the intervention) via an online survey.
1. Knowledge regarding safe sex will be measured with 10 items (untrue/true/don't know; Van Fulpen et al., 2002).
2. Attitude towards safe sex will be measured with 2 items, and towards sexual preferences and boundaries with 4 items (Van Fulpen et al., 2002) on a 5-point likert scale (1 = very unimportant, to 5 = very important).
3. Self-efficacy expectations will be measured with 4 items for safe sex and 8 items for communication about sexual preferences and boundaries on a 5-point likert scale (1 = certainly not, to 5 = certainly yes; Van Fulpen et al., 2002).
4. Behavioral willingness will be measured with 4 items for safe sex on a 5-point likert scale (1= certainly not, to 5 = certainly yes; Van Empelen & Kok, 2006).
5. Intention towards safe sex will be measured with 2 items on a 5-point likert scale (1= certainly not, to 5 = certainly yes; Van Fulpen et al., 2002).

Secondary outcome measures
1. Secondary outcome measures are attitude and perceived skills regarding safe sex and communication about sexual preferences and boundaries measured by means of individual interviews (open ended questions) with a subsample of students at the post-test (approximately 2 weeks after the intervention). These will be measured by 2 role model stories regarding safe sex and 2 role model stories regarding communication about sexual preferences and boundaries. For each of these stories, students are asked how they would feel, what their opinion is/with whom they agree (attitude) and what they would say or do (perceived skills). There is an additional scenario about teen pregnancy in which students are asked their attitude towards teen pregnancy and knowledge regarding options they have and what is needed to take care for a baby.
2. Secondary outcome measures among teachers are program use and acceptability of LLL VSOc4; they will be measured via an online survey at the same time the post-test among students is conducted (approximately 2 weeks after the intervention). Program use is measured by asking teachers if they have provided lessons about relations and sex in the past two months, and if so, the amount of lessons, which working methods were used, which topics discussed, and

which educational program has been used (Van Fulpen et al., 2002). For teachers in the experimental condition, this also includes questions about which module was used and which lessons were provided, whether they used the student magazines, the digital environment and videos from LLL VSOc4. Acceptability of the LLL VSOc4 program in general, and specifically for the videos, student magazines and digital environment is measured with a report mark (10-point scale; 1 = very bad, to 10 = excellent), and for the program in general, the videos and students magazines with 5 items on a 5-point likert scale (1 = certainly not, to 5 = certainly yes) regarding importance, understandability, fun, instructiveness, and fit with the students experiences.
3. Acceptability of the digital environment was measured with 4 items on a 5-point likert scale (1 = certainly not, to 5 = certainly yes) regarding user-friendliness, attractiveness of the design, ease of navigating through the digital environment, and pleasure of use. Acceptability of LLL VSOc4 was also measured by asking teachers whether they would use it in the future, and whether they would recommend it to other colleagues on a 5-point likert scale (1 = certainly not, to 5 = certainly yes).

Overall study start date
01/05/2021

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. Students in special secondary education (VSO) with psychiatric and/or severe behavioral problems (formerly known as cluster 4; VSOc4).
2. Teachers of students in VSOc4.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
We will include a minimum of 6 schools for the feasibility and effectiveness study (3 schools per condition), 12 classes (6 classes per condition, assuming 2 classes per school) and 120 students (60 per condition, assuming 10 students per class) at baseline. This includes the possibility for drop-out (up to 40%).

Key exclusion criteria
1. Students who do not follow special secondary education (VSO) and/or have psychiatric and/or severe behavioral problems (formerly known as cluster 4; VSOc4).
2. Teachers who do not teach students in VSOc4.

Date of first enrolment
09/02/2023

Date of final enrolment
15/12/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
TNO Child Health
Sylviusweg 71
Leiden
Netherlands
2333 BE

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development

Sponsor details
Laan van Nieuw Oost-Indië 334
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Sponsor type
Other

Website
http://www.zonmw.nl/en/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. We will facilitate access to data by using the repository of ZENODO (https://zenodo.org).
The following end products we will make available for further research and verification after the project has ended:
Documentation of the research process, documentation of data, syntaxes and raw data. Data descriptions will be published. We will further specify which software and which version thereof was used. All data and end products will be made available in an anonymous form.
Data description will be made available after closing of the project, and data itself will be made available based on restricted access.
Our data will comply with the FAIR guidelines as the data description will be publicly accessible. The data itself will be available under a set of terms of use. These terms may be related to publications, purpose of re-use and handling fee.
During the project, pseudonymous data will be kept separate from personal data (e.g. name) and linked by means of a unique participant code until people filled out the posttest and the pre- and posttest data is coupled. After this period of time, the personal data will be deleted so that there will not be the possibility to trace back individuals. Thus, personal data will be deleted within eight weeks after the last questionnaire of phase 2 is filled in, the separated anonymous data will be kept for 10 years in accordance with ZonMw recommendations.
During the project, access to the personal data is limited to the researchers of the project on a need to know basis.
Consent was obtained from all participants (i.e., students, their parents and teachers; for students we will ask informed consent from students themselves and their parents) before participation.
This study received approval (Approval 08/02/2023) from the TNO Institutional Review Board

(ref: 2023-003A).
The full data management plan has been approved by ZonMw (https://www.zonmw.nl/en/).

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	for parents (in Dutch)	09/02/2023	21/02/2023	No	Yes
Participant information sheet	for students (in Dutch)	09/02/2023	21/02/2023	No	Yes
Participant information sheet	for teachers (in Dutch)	09/02/2023	21/02/2023	No	Yes