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Does an electronic patient-reported outcome improve early identification of health-related problems in young people visiting a youth health clinic in Sweden?

Submission date
01/07/2022

Recruitment status
No longer recruiting

Registration date
16/08/2022

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Many young people in Sweden come to a Youth Health Clinic (YHC) to discuss their health. YHCs admit young people between the ages of 13 and 23, to ensure young people's right to good health, detect mental illness at an early stage and support personal identity development. Research results show that young people's reporting of psychosocial problems increases their reporting of health-related risk behaviors. The reporting makes it easier for young people to convey things that make them feel vulnerable. Young people describe that reporting their health before the visit gives more time to talk about what is most important to them and has been experienced positively by both young people and staff. Activities that develop health interventions to accommodate the recipient’s needs have the potential to streamline care and improve the health of the care recipient, which can lead to health benefits individually and in society.

There is currently no uniform way of mapping young people's health or health risks at YHCs, nor digital services to identify health-related problems in young people who visit YHCs. The development of an electronic patient-reported outcome (ePRO), tailored for a specific cause, can increase the understanding of the care recipient's needs and lead to treatment that has the potential to contribute to behavior change, improved health, quality of life and an increased sense of being able to influence one's own life.

The study aims at evaluating the effects of using an ePRO early identification of health-related problems intervention in young people visiting a YHC in Sweden. The primary outcome measure's focus is mental health and the secondary outcome measures foci are physical and sexual health and social support.

Who can participate?
Young people aged from 15 to 23 years old who attend 1 of the 17 participating YHCs in Sweden

What does the study involve?
The included 17 YHCs will be randomly allocated to cross-over from the initial control phase to the intervention phase. Young people who book an appointment at the YHC, that will include a conversation about their general health, can join the study. They will be invited to receive study information and give consent to the study and will be part of either a control group or an intervention group, depending on if the YHC is in the control- or intervention phase. All young people will answer background questions and the electronic scientific outcome questionnaires, including the General Health Questionnaire 12. The questions are designed as 12 statements and participants are asked to rate their symptoms on a 4-point Likert scale from "less than usual" (0) to "much more than usual". The answers enable a summarized index score. High response values indicate mental illness and disability.

Control group participants will respond to health questions in a patient-reported electronic scientific outcome questionnaire. The intervention group participants will respond to health questions in the patient-reported electronic scientific outcome questionnaire and directly afterwards, to the ePRO.

The results from the ePRO inform the staff of the young people´s health status prior to the meeting between the healthcare provider and the young person. The answers form a report that has the potential to guide the health consultation towards what the young person has said is important and further affects the treatment plan and actions.

The healthcare provider will report the content of the health consultation to the young person, and what plans for continued care are made.

After six months, all participants will again respond to the patient-reported electronic scientific outcome questionnaire. They will gain access to the questionnaire through a short message service (SMS) with a digital link.

What are the possible benefits and risks of participating?
Replying to the questions may cause young people to feel uncomfortable or vulnerable. However, the use of electronic outcome measures for the identification of health-related problems has the potential to identify health risks in young people at an early stage. This can lead to early preventive and adequate treatments and management based on the young people's actual needs. This has the potential to increase young people's mental health, quality of life, physical, and sexual health and social support. It also means the opportunity to streamline society's resources which can reduce costs. National implementation of the new patient-reported outcome for early identification of health-related problems can provide structure to how YHCs develop and provide opportunities for equal care and national comparison. Hence, it is important to study the effects of the electronic patient-reported outcome for the early identification of health-related problems in young people visiting the YHC.

Where is the study run from?
Mälardalen University (Sweden)

When is the study starting and how long is it expected to run for?
June 2018 to August 2023

Who is funding the study?
Regional Research Council in Uppsala-Örebro Region (Sweden)

Who is the main contact?
Ms Petra Lostelius (Sweden)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RFR-967585

Study information

Scientific Title
Does an electronic patient-reported outcome (ePRO) for the identification of mental, physical, sexual health and social support improve mental well-being, physical and sexual health, ability to manage life and social support, and relationships in young people visiting a youth health clinic (YHC), compared with traditional assessments, at follow-up after six months: a stepped wedge cluster randomized trial at YHC

Study objectives
Primary hypothesis: The electronic patient-reported outcome (ePRO) for early identification of health-related problems in young people visiting a youth health clinic (YHC) leads to improved mental health compared with traditional assessments at follow-up after six months

Secondary hypothesis:
1. Young people using the ePRO and visiting the YHC will:
1.1. Experience improved physical and sexual health, ability to manage life and obtain social support compared with traditional assessments at follow-up after six months

1.2. Experience improved quality-of-life, compared with traditional assessments at follow-up after six months.
1.3. Will have their health-related problems identified and be offered treatment
2. The ePRO provides health economic benefits in the form of costs being set in relation to quality-adjusted life years, compared with traditional assessments at follow-up after six months

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 10 475 08 00; registrator@etikprovning.se), ref: 2020-01921

Study design
20-week multicenter interventional non-blinded stepped-wedge-cluster randomized study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Early identification of health-related problems regarding mental, sexual, physical health and social support in young people

Interventions
Young people visiting any of the 17 included youth health clinics (YHCs) for any health-related issue will be presented with written information about the ongoing trial upon arrival at the YHC. The young people are allocated to the control group or intervention group in this study, depending on the study period during which they have their visit to the YHC.

For further information and participation, they will be instructed to scan a QR code from the written information. This will lead to an IT environment with an information film about the study, a link to detailed written study information, digital consent to study participation and consent to GDPR. Upon consenting, the young people will be asked to register their name, personal identification number and telephone number in the IT system. They will then get access to an electronic research outcome evaluation questionnaire. After finishing the research outcome questionnaire, the control group will receive traditional assessments at the YHC.
The participants in the intervention will go through the same procedure but upon finishing the research outcome questionnaire, the participants in the intervention group will get access to an ePRO, with questions about lifestyle and mental health, physical- and sexual health, social support, a question about what health area the respondent preferable would like to talk about during the visit and a self-efficacy question about the propensity to change.

One YHC represents a cluster. Clusters that are randomized to start the intervention phase (intervention group) at the same time are part of the same cluster group. Randomization takes place at cluster group level to reduce the risk of bias and is performed before the start of studies by research staff with the help of a computer-generated list. Each cluster group will contain four to five clusters. According to the randomization, the cluster groups transition from the control phase (control group) to the intervention phase in a specific period interval. In this

study, every study period will last for four weeks. This process continues until all cluster groups have transitioned to the intervention phase. The length of the study period in the control and intervention phase has been calculated and adjusted depending on the results from a previous pilot study and participating YHCs.

1. Weeks 1-4: Study period 1 - corresponds to the control phase. All included YHCs (n=17) start the study on the same date and in the control phase. Thus, all consenting young people are therefore in the control group. They receive a traditional assessment at the YHC, in a meeting with either a midwife, therapist or a medical doctor.

2. Weeks 5-8: Study period 2 - corresponds to the first intervention phase. One cluster group (four to five YHCs), crosses over from the control phase to the intervention phase, leaving three cluster groups (12-13 YHCs) in the control phase. After scanning the QR-code, consenting and finishing the electronic research outcome questionnaire, young people are presented with the ePRO. Before meeting with the healthcare provider, the young people in the intervention group respond to the questions in the ePRO, including the reason for their visit.

3. Weeks 9-12: Study period 3 - corresponds to the second step for cross-over from control phase to intervention phase. Another cluster group of four to five YHCs crosses over from the control phase to the intervention phase. Half of the participating YHCs are still in the control phase (n=8-9) and half are in the intervention phase (n=8-9).

4. Weeks 13-16: Study period 4 - corresponds to the third step for cross-over from the control phase to the intervention phase. An additional cluster group of YHCs crosses over from the control phase to the intervention phase. Now, less than half of the participating YHCs are still in the control phase (n=4-5) and more than half are in the intervention phase (n= 12-13).

5. Weeks 17-20: Study period 5 - corresponds to the final step for cross-over from the control phase to the intervention phase. The last cluster group of YHCs crosses over from the control phase to the intervention phase. Now, all YHCs are in the intervention phase (n=17).

Intervention Type
Other

Primary outcome(s)
Mental health measured using the General Health Questionnaire 12 at baseline and 6 months

Key secondary outcome(s))
1. Physical activity level measured using the International Physical Activity Questionnaire (IPAQ) at baseline and at 6 months
2. Sexual health measured using three questions, showing young people's self-perceived image of their ability to act in a sexually healthy way at baseline and at 6 months
3. The experience of handling life measured with the Sense of Mastery Scale in seven questions, using a four-point Likert scale at baseline and at 6 months.
4. Social support measured using the Oslo Social Support scale (OSS-3) in three questions at baseline and at six months
5. Relationships measured in eight statements regarding friendship relationships, with five answer options, at baseline and at six months
6. Incidence of health-related problems measured using descriptive and inferential statistics at baseline and at six months
7. Incidence of treatment offers measured using descriptive and inferential statistics at baseline

and at six months
8. Proportion of girls and people who belong to the group homosexual, bisexual, trans, queer and other sexualities (HBTQ+), with worse mental health compared to boys in the population, measured using the GAD-7 (Generalized Anxiety Disorder 7-item scale), and PHQ-9 (Patient Health Questionnaire) at baseline and six months

Completion date
02/08/2023

Eligibility

Key inclusion criteria
1. Aged 15 to 23 years old
2. Visit a participating youth health clinic with health-related requests
3. Understand and speak Swedish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Aged 15 years old and under
2. Not understanding and speaking Swedish

Date of first enrolment
15/09/2022

Date of final enrolment
02/02/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Ungdomsmottagningen Falun
Myntgatan 8

Falun
Sweden
791 51

Study participating centre
Ungdomsmottagningen Mora
Badstugatan 1
Mora
Sweden
792 32

Study participating centre
Ungdomsmottagningen Rättvik
Centralgatan 1
Rättvik
Sweden
795 30

Study participating centre
Ungdomsmottagningen Malung
Stogatan 47
Malung
Sweden
782 30

Study participating centre
Ungdomsmottagningen Vansbro
Kapellgatan 1
Vansbro
Sweden
780 50

Study participating centre
Ungdomsmottagningen Ludvika
Landstinget i Dalarna, Carlavägen 34
Ludvika
Sweden
771 30

Study participating centre
Ungdomsmottagningen Västerås
Munkgatan 20B
Västerås
Sweden
722 12

Study participating centre
Ungdomsmottagningen Köping
Glasgatan 27
Köping
Sweden
731 30

Study participating centre
Ungdomsmottagningen Fagersta
Dalavägen 32
Fagersta
Sweden
737 47

Study participating centre
Ungdomsmottagningen Hallstahammar
Storgatan 4
Hallstahammar
Sweden
734 30

Study participating centre
Ungdomsmottagningen Sala
Norrbygatan 18
Sala
Sweden
733 31

Study participating centre
Ungdomsmottagningen Uppsala City
S:t Olofsgatan 21
Uppsala
Sweden
753 21

Study participating centre
Ungdomsmottagningen Tierp
Liljevägen 2
Tierp
Sweden
815 37

Study participating centre
Ungdomsmottagningen Enköping
Västra Ringgatan 16-18
Enköping
Sweden
745 31

Study participating centre
Ungdomsmottagningen Bålsta
Centrumleden 2
Bålsta
Sweden
746 32

Study participating centre
Ungdomsmottagningen Gimo
Gimo Torg 6
Gimo
Sweden
747 02

Study participating centre
Ungdomsmottagningen Heby
Brogatan 16
Heby
Sweden
744 32

Sponsor information

Organisation
Mälardalen University

ROR
https://ror.org/033vfbz75

Organisation
Centrum för klinisk forskning, Västmanlands (Center for Clinical Research, Västmanlands)

Funder(s)

Funder type
Research council

Funder Name
Regionala Forskningsrådet Uppsala/Örebro (Regional Research Council Uppsala/Örebro)

Alternative Name(s)
Regional Research Council in Uppsala-Örebro Region, Uppsala-Örebro Regional Research Council, RFR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Centrum för klinisk forskning, Västmanlands (Center for Clinical Research, Västmanlands)

Funder Name
Mälardalens högskola (Mälardalen University)

Alternative Name(s)
Mälardalen University, Mälardalen University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The Swedish ethical legal regulations do not currently allow medical and health related raw-data to be openly available. Collected data will be stored in a confidential research register. All information will be processed coded by storing collected data without a name or social security number, with an ID number and separate from the digital consent form. The code key to the research register is stored separately from the collected data, locked at the Center for Clinical Research, Västerås. Only the system administrator, responsible researcher, and project managers for the study will have access to the data. All data will be saved for 10 years after the end of the study. Thereafter, the code key to the research register will be destroyed and the entire register will be deidentified. Data and results will be processed so that unauthorized persons cannot access them.

The results of the study will be presented coded and at group level, which means that data will not be able to be traced to a person when the results are presented in an international scientific journal and at scientific conferences. Responsible for personal data is Region Västmanland. According to the EU Data Protection Regulation, participants have the right to access the data handled in the study free of charge, and if necessary to have any errors corrected. Participants can also request that data be deleted and that the processing of personal data be restricted. Reference is made to the project manager and the Region's Data Protection Officer in the information to the participants. The information also states that in the event of dissatisfaction with how their personal data is processed, the participants have the right to submit a complaint to the Swedish Data Inspectorate.

IPD sharing plan summary
Stored in non-publicly available repository