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Early identification of health-related problems in Swedish young people – a feasibility study on using an Electronic Patient-Reported Outcome tool

Submission date
15/09/2020

Recruitment status
No longer recruiting

Registration date
17/09/2020

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many young people in Sweden come to the Youth Health Clinic (YHC) to discuss their health. YHCs admit young people between the ages of 13-23, to ensure young people's right to good health, to 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. The young people describe that reporting on 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 recipients' needs have the potential to streamline care and to 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 digital solutions, tailored for a specific cause, can increase the understanding of the care recipients' 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 life.
In order to inform a planned full study, this pilot study will examine the feasibility of implementing a composed digital support for the early identification of health-related problems in young people visiting a YHC.

Who can participate?
Young people from 15 -23 years of age and staff who attend/work at a Youth Health Clinic in Borlänge, Sweden

What does the study involve?
Young people who book an appointment at the YHC that will include a conversation about their

general health will be included in either the control group or the intervention group, depending on the study period for their appointment. All young people will answer background questions and scientific outcome questionnaires. The intervention group will respond to questions from the experimental composed digital support. The results from the digital support will inform the staff of the young people's health status before the visit at the YHC. After 6 months, both the control group and the intervention group will receive a new digital link for responding to the outcome questionnaires. The study also involves YHC staff interviews on the possible utility of the experimental composed digital support.

What are the possible benefits and risks of participating?
Replying to the questions may cause young people to feel uncomfortable or vulnerable. Staff may feel that any dissenting opinions may stand out in relation to the others' and feel uncomfortable speaking their minds. However, the use of digital support 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 young people's actual needs. This has the potential to improve young people's mental health and quality of life. It also means the opportunity to streamline society's resources which can reduce costs. National implementation of the composed digital support for early identification of health-related problems can provide structure in how YHCs develop, and provide opportunities for equal care and national comparison. Hence, it is important to study the feasibility of this experimental composed digital support for the early identification of health-related problems in young people visiting the YHC.

Where is the study run from?
Mälardalen University, Clinical Research Centre Region Västmanland, and the YHC in Borlänge (Sweden)

When is the study starting and how long is it expected to run for?
November 2018 to January 2022

Who is funding the study?
1. Uppsala-Örebro Regional Research Council (Sweden)
2. Centre for Clinical Research, Region Västmanland (Sweden)

Who is the main contact?
Petra V Lostelius
petra.lostelius@regionvastmanland.se

Contact information

Type(s)
Scientific

Contact name
Ms Petra V Lostelius

Contact details
Södra Ringvägen 2D
Västerås
Sweden
722 12

+46 (0)708 442454
petra.lostelius@regionvastmanland.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
274723

Study information

Scientific Title
An Electronic Patient-Reported Outcome tool for early identification of health-related problems in young people visiting a Swedish youth health clinic: a feasibility study in preparation for a stepped wedge cluster randomized controlled trial

Study objectives
The pilot study will examine the feasibility (process, resource, management and scientific aspects) of implementing an experimental composed digital support for the early identification of health-related problems in young people visiting a Youth Health Clinic (YHC) in order to inform a future stepped wedge cluster randomized trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2020, The Ethics Review Authority (Box 2110, 750 02 Uppsala, Sweden; +4610-475 08 00; registrator@etikprovning.se), ref: 2020/01921

Study design
Single-center feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

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
Health-related problems with regards to sexual, mental, physical health and social support

Interventions
Current intervention as of 16/03/2022:
After young people book an appointment at the YHC, a digital link will be sent by short text message or email. The link will lead to an information video about the study, digital consent to participate in the study and the digital outcome evaluation questionnaires. For the intervention group, the link will also lead to the experimental composed digital support for early identification of health-related problems.

The young people are allocated to the control or intervention group in this feasibility study, depending on the study period during which they have their visit at the YHC.

Week 1-2: Study period 1 - corresponds to the control phase. The control group receive the usual care at UM, including the regular identification of health problems in a meeting with either a midwife, therapist or doctor.

Week 3-10: Study period 2 - corresponds to the intervention phase. Prior to their visit at the YHC, the young people in the intervention group respond to the questions in the experimental composed digital support for early identification of health-related problems. This includes the reason for their visit, followed by questions about lifestyle, mental and sexual health and social support. Finally, a question about propensity to change will be answered.

Previous intervention:
After young people book an appointment at the YHC, a digital link will be sent by short text message or email. The link will lead to an information video about the study, digital consent to participate in the study and the digital outcome evaluation questionnaires. For the intervention group, the link will also lead to the experimental composed digital support for early identification of health-related problems.

The young people are allocated to the control or intervention group in this feasibility study, depending on the study period during which they have their visit at the YHC.

Week 1-3: Study period 1 - corresponds to the control phase. The control group receive the usual care at UM, including the regular identification of health problems in a meeting with either a midwife, therapist or doctor.

Week 4-15: Study period 2 - corresponds to the intervention phase. Prior to their visit at the YHC, the young people in the intervention group respond to the questions in the experimental composed digital support for early identification of health-related problems. This includes the reason for their visit, followed by questions about lifestyle, mental and sexual health and social support. Finally, a question about propensity to change will be answered.

Intervention Type
Other

Primary outcome measure

Feasibility measures:
1. Processes: data concerning dropout and recruitment potential will be retrieved from the contracted IT company's database at 6 months after final participant recruitment
2. Resources: focus group interviews with staff about resources (i.e. administration for sending digital link, number of tablets, technical problems, time to answer digital outcome questionnaires and fill in the questions in the new experimental composed digital support, time and resources required to help young people answer the questions in the composed digital support on-site, opportunity and challenges for staff and young people to participate) conducted after final participant recruitment (i.e. after study period 2)
3. Management: focus group interviews with staff about management (i.e. data transfer from tablet to staff computer, staff interpretation of results, do the results support young people's understanding, unforeseen events) after final participant recruitment (i.e. after study period 2)

Secondary outcome measures

Current secondary outcome measures as of 16/03/2022:
1. The scientific evaluation data is collected before the visit to the YHC and at 6 months after the visit to the YHC. The following instruments are included in the digital outcome evaluation questionnaire:
1.1. Mental well being measured using Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)
1.2. Level of physical activity measured using International Physical Activity Questionnaire (IPAQ)
1.3. Sexual health measured by three questions on propensity to protect oneself from unwanted pregnancy or sexually transmitted disease
1.4. Ability to handle life difficulties measured using Sense of Mastery Scale
1.5. Social functioning measured using the Oslo 3-item Social Support Scale (OSS-3)
2. Data from staff reporting (concerning identified health problems, current health care contacts, and performed/planned measures) collected from the contracted IT company managing the composed experimental digital support at 6 months after final participant recruitment
3. Number of care occasions, level of care and which professions the young person has met, collected from Region Dalarna's database after study period 2 at 6 months after final participant recruitment. Data will be coordinated with the National Board of Health and Welfare's Medicines Register for information on consumption of medicines, and with the National Board of Health and Welfare's Patient Register (outpatient care) for information on care occasions and diagnoses.

Previous secondary outcome measures:
1. The scientific evaluation data is collected before the visit to the YHC and at 6 months after the visit to the YHC. The following instruments are included in the digital outcome evaluation questionnaire:
1.1. Mental well being measured using Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)
1.2. Level of physical activity measured using International Physical Activity Questionnaire (IPAQ)
1.3. Sexual health measured by three questions on propensity to protect oneself from unwanted pregnancy or sexually transmitted disease
1.4. Ability to handle life difficulties measured using Sense of Mastery Scale
1.5. Social functioning measured using the Oslo 3-item Social Support Scale (OSS-3)
1.6. Health-related quality of life measured using EuroQoL-5 Dimension Questionnaire (EQ-5D)
2. Data from staff reporting (concerning identified health problems, current health care contacts, and performed/planned measures) collected from the contracted IT company

managing the composed experimental digital support at 6 months after final participant recruitment
3. Number of care occasions, level of care and which professions the young person has met, collected from Region Dalarna's database after study period 2 at 6 months after final participant recruitment. Data will be coordinated with the National Board of Health and Welfare's Medicines Register for information on consumption of medicines, and with the National Board of Health and Welfare's Patient Register (outpatient care) for information on care occasions and diagnoses.

Overall study start date
01/11/2018

Completion date
31/01/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 16/03/2022:
1. Young people from age 16-23, who visit the YHC and include health-related requests
2. Staff, such as managers, midwives, therapists and doctors at the YHC

Previous participant inclusion criteria:
1. Young people from age 15-23, who visit the YHC and include health-related requests
2. Staff, such as managers, midwives, therapists and doctors at the YHC

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
500 young people and 6 staff

Total final enrolment
104

Key exclusion criteria
1. Young people under 15 years old
2. Young people who do not speak, read or understand the Swedish language

Date of first enrolment
01/04/2021

Date of final enrolment
16/07/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Ungdomsmottagningen Borlänge
Skomakargatan 18
Borlänge
Sweden
78170

Sponsor information

Organisation
Mälardalen University

Sponsor details
Box 883
Västerås
Sweden
721 23 Västerås
+46 (0)21 10 13 00
anne.soderlund@mdh.se

Sponsor type
University/education

Website
http://www.mdh.se/?l=en_UK

ROR
https://ror.org/033vfbz75

Organisation
Centre for Clinical Research, Region Västmanland

Sponsor details
Hospital of Västmanland
Västerås
Entrance 29
Västerås
Sweden

721 89
+46 (0)21 175867
forskning@regionvastmanland.se

Sponsor type
Research organisation

Funder(s)

Funder type
Research council

Funder Name
Uppsala-Örebro Regional Research Council

Funder Name
Centre for Clinical Research, Region Västmanland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. This is a pilot study aimed to inform the upcoming Stepped Wedge Cluster randomized trial, for which the researchers are planning to publish the study protocol. Thus, the current pilot feasibility study does not have a study protocol.

Intention to publish date
01/12/2022

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. Personal data will be handled in accordance with the EU General Data Protection Regulation (GDPR, Article 6). Collected data will be stored in a confidential research register at the Center for Clinical Research, Västerås, Sweden. All data will be saved for 10 years as Swedish regulations for research data state.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/03/2024	09/10/2024	Yes	No