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Preliminary evaluation of a structured support program for young people not in education, employment, or training

Submission date	**Recruitment status**	[X] Prospectively registered
08/10/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/10/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/06/2024	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
School absenteeism and drop-out is a major societal challenge. Young people not in education, employment, or training are at risk for a range of adverse social and health-related long-term outcomes. Effective strategies to support this group to resume their education is therefore of high priority. In Sweden, the municipalities have an obligation to provide support and guidance to help young people complete upper-secondary school. However, current practice differs between municipalities and the support provision has not been systematically evaluated.
The Transition program was originally developed as a structured support program for young adults with autism spectrum disorder or ADHD. The program combines a series of lectures covering seven important life domains, with individual support to help the participants identify values and goals within these domains and to start taking small steps in the valued direction. Preliminary results indicate that the program is well received by young adults and staff and can lead to positive change. This study aims to examine if the Transition program can be helpful also for young people who have not yet completed upper-secondary school and are currently not in education, employment, or training.

Who can participate?
People who are 16 to 20 years of age, have not completed upper-secondary school, and are currently not in education, employment, or training.

What does the study involve?
Participants will be randomly allocated into one of two groups: The Transition program as an add-on to the support currently provided by the municipality, or a control group receiving only the usual support. The Transition program consists of a series of online lectures and individual support for a total of 15 weeks. Participants will rate their quality of life, self-efficacy, health, and functioning before and after the intervention, and 6 months after completion.

What are the possible benefits and risks of participating?
The Transition program can provide participants with structured support to resume their education and prepare for adulthood in general. All specific components of the Transition

program have been derived from well-established approaches previously tested for this age group, including cognitive behavioural interventions and psychoeducation. The program has also been tested with good results in a different target group. As with other interventions, it is unlikely that all participants will benefit from the Transition program. Some transient emotional distress might also be expected as a consequence of new insights and changes in daily living during the program. Negative effects will be closely monitored throughout the study.

Where is the study run from?
Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
September 2020 to June 2024

Who is funding the study?
FORTE: Swedish Research Council for Health, Working Life and Welfare (Sweden)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility, acceptability, and preliminary efficacy of the Transition program for young people not in education, employment, or training: a pilot randomized controlled trial with a support as usual comparator

Study objectives
The aim of this pilot randomized controlled trial is to assess the feasibility, acceptability, and preliminary efficacy of the Transition program for young people not in education, employment, or training. The pilot trial will not be powered for formal hypothesis testing. However, preliminary effects on quality of life, self-efficacy, mental health, and functioning compared with support as usual will be evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/09/2020 and 12/07/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, SE-750 02 Uppsala, Sweden; +46 (0)10 4750800; registrator@etikprovning.se), ref: dnr 2020-03675 and dnr 2021-03796

Study design
Parallel open-label pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Quality of life, mental health, self-efficacy and functioning in young people not in education, employment, or training

Interventions

This pilot trial will employ a parallel-groups design, where participants will be randomly assigned (1:1 allocation rate) by permuted block randomisation to either the Transition program as an add-on to support as usual, or support as usual only. Outcome measures will be collected at baseline, at 15 weeks (post-intervention), and 6 months after completion.

The Transition program consists of two key components:
1. A standardised education program covering information and life skills within seven significant life domains (i.e., work, education, finance, housing, health, participation in society, and relationships)
2. An individualised support program in which values and concrete goals within these life domains are formulated and pursued.

The educational part consists of seven online lectures (approximately 20 minutes each), which the participants can complete at their own pace together with their support worker. However, a minimum of one lecture per week is recommended. Each lecture is followed by questions designed to help the participant consider their own situation. The individualised part will initially run in parallel with the lectures and continue for up to 15 weeks. In conjunction with each lecture, the participants will reflect on their values within each domain and start formulating long-term goals aligned with these values. Each goal will be subdivided into concrete activities using Goal Attainment Scaling. With weekly assistance from the support worker, the participants will thereafter start working on concrete change guided by their values, goals, and activities. Support as usual is defined as the current practice used by support workers for this specific target group. This can include a combination of pedagogical and psychological strategies (e.g., motivational interviewing), but is currently not standardised. The specific content of support as usual will be monitored throughout the study.

Intervention Type

Behavioural

Primary outcome(s)

Feasibility/acceptability:
1. Recruitment rate, intervention uptake, and retention is measured using information collected continuously over the course of the trial
2. Characteristics of the included and retained samples (e.g., diagnoses, age, gender, years of schooling) collected at baseline
3. Participant satisfaction and relevance measured using course evaluations after each of the 8 sessions and post-intervention
4. Participation/involvement measured using the Patient Participation and Rehabilitation Questionnaire post-intervention
5. Negative effects measured using the Negative Effects Questionnaire post-intervention, one free text question included in the course evaluations administered after each session and post-intervention, and spontaneously reported events
5. Feasibility/acceptability overall based on in-depth interviews with participants and staff mid-intervention and post-intervention

Key secondary outcome(s))

Current secondary outcome measures as of 29/10/2021:
Preliminary efficacy:
1. Quality of life measured using Assessment of Quality of Life (AQoL-8D) and EQ-5D-5L at baseline, post-intervention, and 6 months after completion
2. Mental health measured using the General Health Questionnaire (GHQ-12) at baseline, post-intervention, and 6 months after completion
3. Self-efficacy measured using the Generalized Self-Efficacy Scale at baseline, post-intervention, and 6 months after completion
4. Functioning measured using the Social and Self-Direction subscales of the Adaptive Behavior Assessment System (ABAS) at baseline, post-intervention, and 6 months after completion
5. Knowledge within the life domains covered by the Transition program measured using a knowledge test developed for this purpose at post-intervention

Previous secondary outcome measures:
Preliminary efficacy:
1. Quality of life measured using Assessment of Quality of Life (AQoL-8D) and EQ-5D-5L at baseline, post-intervention, and 6 months after completion
2. Mental health measured using the General Health Questionnaire (GHQ-12) at baseline, post-intervention, and 6 months after completion
3. Self-efficacy measured using the Generalized Self-Efficacy Scale at baseline, post-intervention, and 6 months after completion
4. Functioning measured using Adaptive Behavior Assessment System (ABAS) at baseline, post-intervention, and 6 months after completion
5. Knowledge within the life domains covered by the Transition program measured using a knowledge test developed for this purpose at post-intervention

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 29/10/2021:
1. Aged 16 to 20 years
2. Have not completed upper-secondary school and currently not enrolled in education or training
3. Sufficient proficiency in Swedish

Previous participant inclusion criteria:
1. Aged 16 to 20 years
2. Have not completed upper-secondary school and currently not enrolled in education or training

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
20 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Intellectual disability
2. Currently preparing actively for enrolment in education

Date of first enrolment
08/11/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Sweden

Study participating centre
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Sponsor information

Organisation
Karolinska Institute

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Research council

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes