ISRCTN13111047 https://doi.org/10.1186/ISRCTN13111047

Preliminary evaluation of a structured transition program (Transition) compared with usual support for young adults in Sweden with support in daily living

Submission date
19/02/2026

Registration date
19/02/2026

Last Edited
20/02/2026

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Ulf Jonsson

ORCID ID
https://orcid.org/0000-0002-5761-2943

Contact details
Karolinska Institutet
Center of Neurodevelopmental Disorders at Karolinska Institutet (KIND)
Gävlegatan 22B
Stockholm
Sweden
SE-113 30
+46 (0)73 806 43 37
ulf.jonsson@ki.se

Additional identifiers

Study information

Scientific Title
A structured transition program (Transition) compared to usual support for young adults in Sweden with support in daily living: a pilot randomised trial assessing feasibility and initial effects on quality of life and recovery

Study objectives
Young adults in Sweden with disabilities related to mental, behavioural, and neurodevelopmental conditions are increasingly accessing daily living support through social services. This pilot randomised controlled trial evaluates a structured transition program (Transition) as an addition to standard support, compared to standard support alone, for this target group. The aims of the trial are to assess both the feasibility of the program and the evaluation design. Although it is not designed for formal hypothesis testing, the trial will measure and report preliminary effects on quality of life and recovery in comparison to standard support services.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/12/2025, Etikprövningsmyndigheten [The Swedish Ethical Review Authority] (Etikprövningsmyndigheten Box 2110, Uppsala, SE-750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2020-03675, 2021-03796, 2022-02354-02 and 2025-07732-02

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Support for young adults with support needs due to mental, behavioural, and neurodevelopmental conditions.

Interventions
This pilot trial will use a parallel-groups design in which participants are randomly assigned to one of two groups. The allocation ratio is 1:1, and randomisation will occur in blocks of size 10. 1.

The randomisation was computer-generated (sealedenvelope.com). Sealed envelopes will be used. One group will receive the Transition program in addition to usual support, while the other group will receive only the usual support. Outcome measures will be collected at the beginning of the trial (baseline) and again at 15 weeks (the endpoint). Additionally, brief interviews will be conducted with participants after 5 weeks and at the endpoint. Participants assigned to the usual support group will be offered the Transition program after completing the initial phase and will then complete the outcome measures again after 15 weeks of working with the program.
The Transition program consists of two main components:
1. A standardised education part featuring eight online lectures, each lasting approximately 20 minutes. The first two lectures are mandatory; they provide an overview of the program and introduce the behavioural strategies used, such as goal setting, values, and tiny habits. The remaining lectures focus on essential life skills across key domains, including work, education, finance, housing, health, social participation, and relationships. Participants can choose one or more domains to concentrate on. They can complete the lectures at their own pace, with support from their support worker.
2. Individualised work with the support worker, where participants will formulate and pursue goals based on their values within the selected domain(s), while also establishing small health habits. Support as usual refers to the current practices employed by support workers for this specific target group. This may involve a combination of pedagogical and psychological strategies, such as motivational interviewing, though it is not currently standardised. The specific content of support as usual will be monitored throughout the study.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility of the evaluation design measured using recruitment rate, intervention uptake, and retention rates at relevant timepoints over the course of the trial

2. Acceptability measured using interviews with all participants at 5 weeks and at endpoint (15 weeks)

3. User satisfaction measured using course evaluations at completion of each section of the program at endpoint

4. Safety measured using a specific question about negative effects at supervison meetings with staff and during the interviews with participants after 5 weeks and at endpoint

Key secondary outcome(s))
1. Health-related quality of life measured using Assessment of Quality of Life (AQoL-8D) at baseline and after 15 weeks (+ after an additional 15 weeks for those in the support as usual group accessing Transition after completion)

2. Recovery measured using Recovery Assessment Scale - Domains and Stages (RAS-DS) at baseline and after 15 weeks (+ after an additional 15 weeks for those in the the support as usual group accessing Transition after completion)

Completion date
30/04/2028

Eligibility

Key inclusion criteria
1. Aged 18 to 29 years
2. Currently accessing housing support with planned meetings at a frequency of at least once a week
3. Sufficient proficiency in Swedish

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
29 years

Sex
All

Total final enrolment
0

Key exclusion criteria
A diagnosis of intellectual disability.

Date of first enrolment
05/03/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type

Funder Name
Forskningsrådet för 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

IPD sharing plan summary
Not expected to be made available