Effectiveness of a transition program to empower adolescents with congenital heart disease in the transition to adulthood: Rationale and methods of the STEPSTONES-ConHD project

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Ninety percent of children born with congenital heart disease (ConHD) survive into adulthood. To prepare adolescents with ConHD to take on new responsibilities for their health and to anticipate a transfer to adult care, transition programs have been developed. Hard evidence on the effectiveness of transition programs is lacking. We established the STEPSTONES project: Swedish Transition Effects Project Supporting Teenagers with chrONic mEdical conditions, and test the effectiveness in young persons with ConHD.

www.stepstones-project.org

Objective
To describe the rationale and design of STEPSTONES-ConHD.

Hypothesis
Adolescents with ConHD who receive a structured, person-centered transition program over a 2-year period have a higher patient empowerment score than adolescents who receive usual care.

Setting
The study is conducted in 4 ConHD-centers in Sweden: Gothenburg, Lund, Stockholm, Umeå.

Sample size calculation
We target an improved patient empowerment score of 6 points on a scale from 15-75 (i.e. 0.5 standard deviation). For two-sided tests with alpha=0.05 and power=80%, 63 patients are needed in each arm of the RCT. An additional 120 patients are recruited in the control centers.

Participants
Participants are: Aged 16 years, Diagnosed with ConHD, Literate, Swedish-speaking and their parents.

Variables and measurement
Primary outcome
Patient empowerment: Gothenburg Young Persons Empowerment Scale

Secondary outcomes
Transition readiness: Readiness for Transition Questionnaire (RTQ): adolescent version
Knowledge: Knowledge Scale for Adults with Congenital Malformed Hearts
Health behavior: Health Behavior Scale CHD
Patient-reported health: PedsQL 4.0 (generic and cardiac module); EQ-5D
Quality of life: Linear Analog Scale
Transition readiness perceived by parents: Readiness for Transition Questionnaire (RTQ): parent version
Parental uncertainty toward transition: Linear Analog Scale