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Original article

Effectiveness of the STEPSTONES Transition Program for Adolescents With Congenital Heart Disease—A Randomized Controlled Trial

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A B S T R A C T

Purpose: Adolescents with congenital heart disease transition from childhood to adulthood and transfer from pediatric-oriented to adult-oriented care. High-level empirical evidence on the effectiveness of transitional care is scarce. This study investigated the empowering effect (primary outcome) of a structured person-centered transition program for adolescents with congenital heart disease and studied its effectiveness on transition readiness, patient-reported health, quality of life, health behaviors, disease-related knowledge, and parental outcomes e.g., parental uncertainty, readiness for transition as perceived by the parents (secondary outcomes).
Methods: The STEPSTONES-trial comprised a hybrid experimental design whereby a randomized controlled trial was embedded in a longitudinal observational study. The trial was conducted in seven centers in Sweden. Two centers were allocated to the randomized controlled trial-arm, randomizing participants to intervention or control group. The other five centers were

IMPLICATIONS AND CONTRIBUTION

The STEPSTONES transition program was effective in increasing patient empowerment (primary outcome), reducing parental involvement, improving satisfaction with physical appearance, and increasing disease-related knowledge

Conflicts of interest: The authors have no conflicts of interest to declare
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intervention-naïve centers and served as contamination check control group. Outcomes were measured at the age of 16 years (baseline), 17 years, and 18.5 years.

Results: The change in empowerment from 16 years to 18.5 years differed significantly between the intervention group and control group (mean difference = 3.44; 95% confidence interval = 0.27 −6.65; $p = .036$) in favor of intervention group. For the secondary outcomes, significant differences in change over time were found in parental involvement ($p = .008$), disease-related knowledge ($p = .0002$), and satisfaction with physical appearance ($p = .039$). No differences in primary or secondary outcomes were detected between the control group and contamination check control group, indicating that there was no contamination in the control group.

Discussion: The STEPSTONES transition program was effective in increasing patient empowerment, reducing parental involvement, improving satisfaction with physical appearance, and increasing disease-related knowledge.

(secondary outcomes). This trial provides empirical underpinnings for the implementation of transition programs for afflicted adolescents.

Congenital heart disease (CHD) is the most common birth defect, with a global birth prevalence of 8.2 per 1000 newborns [1]. Improvements in the diagnosis and treatment of children with CHD have resulted in improving life prospects, with more than 90% surviving into adulthood in countries where highly specialized care is available [1,2]. To provide expert lifetime care, patients should transfer from pediatric-oriented care to adult-oriented care [3,4]. At the same time, they need to transition from being a dependent child with CHD to becoming an independent adult who is able to manage living with the CHD. During adolescence, patients with CHD need to acquire knowledge and skills to independently manage their health while they simultaneously experience a series of physical, cognitive, and social changes [5]. To facilitate this phase, transitional care is needed.

It is argued that transitional care should be provided in a structured way [3,6,7]. For this purpose, transition programs have been developed which are sets of "coordinated transitional care interventions that are provided in a structured albeit individualized way, in order to support the process of the transition to adulthood and achieve the outcomes of transition" [3]. However, transition programs are poorly implemented in CHD [8,9] and this may be due to the lack of high-level evidence that supports the effectiveness of transition programs [10]. In CHD, the CHAPTER studies (Congenital Heart Adolescents Participating in Transition Evaluation Research) [11–13] are the only clinical trials on transitional care, to date. These studies were conducted in a Canadian health care system and showed that educational sessions improved adolescents' self-management [11,12], knowledge of the condition [11–13], transition readiness [13], and excess time between pediatric and adult care [12]. Until now, most studies of CHD and other conditions have not targeted psychosocial skills that can help foster independence, participation in the decision-making process, or improved communication skills, all of which are important transition outcomes. One particular outcome of transition is empowerment [3,14]. Empowerment can be defined as 'an enabling process or outcome arising from communication with the health care professional and a mutual sharing of resources over information relating to illness, which enhances the patient's feelings of control, self-efficacy, coping abilities, and ability to achieve change over their condition' [15]. Patient empowerment aims at increasing autonomy, patient participation, awareness, and consciousness. As a consequence, higher levels of empowerment are associated with improvements of quality of life (QoL), wellbeing, health status, transition readiness, communication skills and clinical outcomes [3,14] and it is for this reason we conducted the STEPSTONES-CHD trial (Swedish Transition Effects Project Supporting Teenagers with chrONic mEdical conditions—Congenital Heart Disease).

The main aim of STEPSTONES-CHD was to investigate the effectiveness of a structured, person-centered transition program for adolescents with CHD on the level of patient empowerment. It was hypothesized that adolescents with CHD who followed the transition program over a 2-year period would have a higher patient empowerment score than adolescents receiving usual care. The effects on the secondary outcomes of transition readiness, patient-reported health, QoL, health behaviors, disease-related knowledge, and parental outcomes (e.g., parental uncertainty, readiness for transition as perceived by the parents) were also tested.

Methods

Trial design

A hybrid experimental design was used whereby a randomized controlled trial (RCT) was embedded in a longitudinal observational study. This resulted in a three-arm design (Figure 1). The study was conducted in seven CHD centers in Sweden. Two of the centers were allocated to the RCT, where participants were randomly assigned to either the intervention group (IG) or the control group (CG). The other five centers were designated as the "contamination check control group" (CCCG) and represented by intervention-naive centers. This measure was taken, as there is a potential risk of contamination bias when participants in the CG are inadvertently exposed to the intervention. This design allowed to control for the potential contamination of the CG in the intervention centers [16]. The methods used in the STEPSTONES-CHD trial have been described in a protocol paper [16]. The trial has been registered at ClinicalTrials.gov: NCT02675361.

Sample size calculation

Sample size calculation was based on the primary outcome of patient empowerment. The target was an improved patient empowerment score of 5.25 points on a scale from 15 to 75, which corresponded with half a standard deviation, found in a

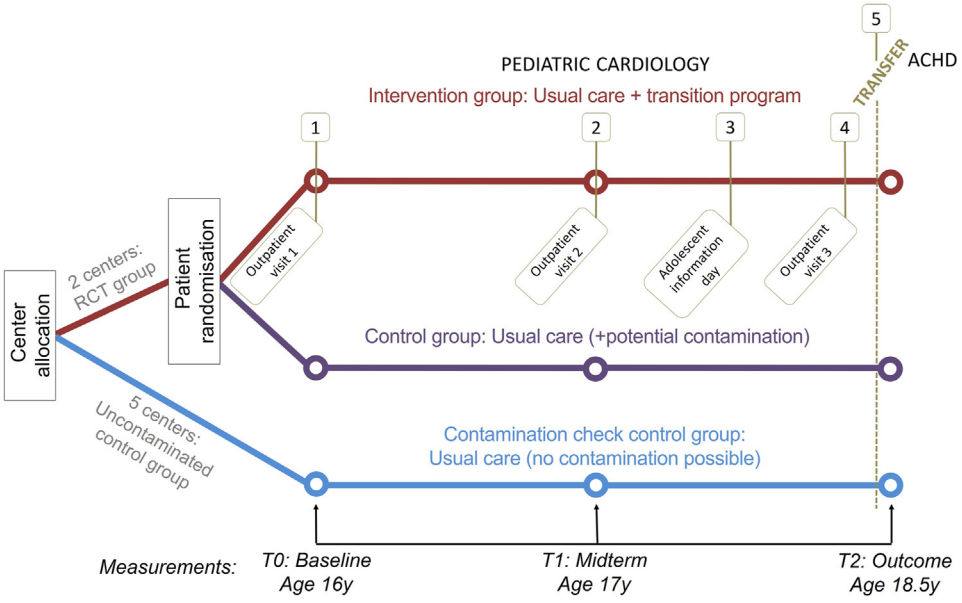

Figure 1. STEPSTONES-CHD study design.

previous study [14]. For two-sided tests with $\alpha = 0.05$ and power = 80%, 63 patients were needed in each arm of the RCT [16]. Anticipating a potential dropout of 10%, 70 patients were targeted in each arm.

Participants and recruitment

Patients were eligible for inclusion if they had CHD (mild, moderate, and severe) [17]; were 16 years of age; Swedish speaking; and literate. The Swedish Registry of Congenital Heart Disease (SWEDCON) [18] was used to retrieve a list of eligible patients. Patients were excluded if they did not have the cognitive capacity to complete the questionnaires; had an acquired or nonstructural heart condition; or were heart transplanted. Parents of the included adolescents were also asked to participate. It was not a requirement that both the adolescent and the parents (dyads) agreed to participate. All eligible participants were recruited by a transition coordinator (TC) or a data collection officer (DCO) [16]. Participants were offered a cinema ticket for each visit.

Randomization

A stratified block randomization with a random variable block size assigned patients of the two RCT centers to the IG or the CG (1:1). Stratification was made by center and disease complexity [16].

Intervention

The STEPSTONES transition program was developed using "intervention mapping", which is a rigorous method that combines theory, findings from literature, and information collected from involved stakeholders [19]. The output is a blueprint of the intervention that visualizes how each component is expected to affect the outcome assessed.

The STEPSTONES transition program is a multi-component intervention comprising eight components: (1) a TC; (2) information and education about the condition and treatment, health behavior, dealing with school and friends; (3) availability by telephone, text message, and email; (4) information about and contact with the adult program; (5) guidance of parents; (6) meeting with peers (once during the study period); (7) person-centered transfer plan; and (8) the actual transfer to the adult program. These components are implemented in five steps [1]: first outpatient visit with TC [2]; second outpatient visit with TC [3]; information day for adolescents and their parents which also included an introduction to the adult health care team [4]; third outpatient visit; and [5] actual transfer (Supplementary figure S1) [16]. The TCs are specialized nurses at the outpatient clinic of pediatric cardiology who have received specific training in performing this intervention. Throughout the intervention, the TCs employ a person-centered care approach which implies that participants are active partners in their care and decision-making process [20]. The content of the visits is individualized, age and developmentally adapted, and it is documented in the transition plan. The TCs, together with the adolescent, are in charge of determining which topics are important to discuss, in establishing goals related to patient empowerment (e.g., in establishing goals related to managing symptoms, communicating with others, and health care planning) [19] and in assessing the need for referral to other services. Support for parents mainly involved information about aspects of importance to their parenting and how they, as parents, could support their youth. The peer support component also involved groups for parents.

Usual care

All participants followed usual care. Usual care included regular check-up visits according to follow-up recommendations

for the different complexity levels of the disease (mild, moderate, and severe) [17]. None of the participating centers had a TC as a part of usual care or had implemented a formal transition program/model. It is common practice in Sweden that patients are transferred to adult care around the age of 18 years.

Blinding

Owing to the nature of the intervention and the study design, it was not possible to blind the participants, TCs or the DCOs. To avoid contamination between the CG and the IG within the RCT centers, TCs were not involved in the delivery of care for the comparison group, and other health care professionals in the participating centers were not informed of the intervention components. The DCOs at the CCCG centers did not participate in discussions of the intervention [16].

Intervention reach, fidelity, and mechanism of impact

Because a transition program is a complex intervention with numerous interacting components, a process evaluation was undertaken simultaneously with the RCT. Such process evaluation helps to understand how the transition program causes change and how outcomes are created, the mechanism of impact and causal pathways. The results of the process evaluation were presented in separate publications, and they showed that the intervention was delivered with high fidelity and was well received by the patients and their parents. Experiences of participation in the transition program were generally positive. Meeting a TC trained in person-centered care and adolescent health and embarking on an educational process based on the adolescents' prerequisites in combination with peer support were considered key change mechanisms. The transition program was delivered to an extent that adhered to the program theory or achieved a high level of fidelity. Moderators affecting the implementation process were the adolescent's and TC's engagement in the intervention, contextual factors, and a lack of standard operating procedures for all components in the program [21,22].

Outcome measurements

Standardized questionnaires were used to assess primary and secondary outcomes. The characteristics and psychometric properties of the questionnaires used are detailed in Supplementary Table 1.

The primary outcome was patient empowerment. This construct comprises five dimensions: identity; knowledge and understanding; personal control; decision-making; and enabling others. Patient empowerment was measured using the Gothenburg Young Persons Empowerment Scale-CHD [15]. This scale comprises 15 items, which is three items for each of the dimensions. The total score ranges from 15 to 75 points, with a higher score reflecting a higher level of patient empowerment [15].

Six secondary outcomes were measured: transition readiness (including responsibility and participation in care and overall transition readiness) [23], health behaviors (e.g., consumption of alcohol and tobacco, dental hygiene, and physical activity) [24], knowledge about CHD [25], QoL (measured using a linear analogue scale, a higher scoring on this scale denotes a better perceived QoL) and patient-reported health (health status in relation to psychosocial and physical health) [26]. In parents, transition readiness (responsibility and participation in their youth's care and overall transition readiness of their youth) [23] and parental uncertainty toward transition were measured [27] (Supplementary Table 1).

Sociodemographic information (sex, age, educational level, size of community, place of birth, number of siblings, birth order, and living situation) was obtained by self-report. Data on the heart defect, other health conditions and medication were derived from the medical records.

Procedure

During the 2.5-year follow-up period, outcome measurements were assessed on three different occasions: baseline at 16 years of age (T0), follow-up one at 17 years of age (T1) and follow-up two at 18.5 years old (T2) (Figure 1). Participants from the IG filled out the set of questionnaires one month before the outpatient clinic visit. If the questionnaires had not been received by the time of the visit, they had the opportunity to complete them while waiting for their appointment. As patients from the CG and CCCG might not have had a scheduled outpatient visit, data collection for these groups was solely undertaken via postal questionnaire at the same time points. To minimize nonresponse, a modified Dillman procedure [28] was used in which up to four reminders were sent out after 2, 4, 6, and 8 weeks.

Approval was received from the Regional ethical review board in Gothenburg, Sweden (No. 931-15, T-417-16, T-435-17). The study was performed according to the Declaration of Helsinki. Participants consented to participation after receiving written and verbal information about the study. As the participating adolescents were over the age of 16 at the time of inclusion, they could give assent without the need for parental consent according to Swedish regulations.

Statistical analysis

Categorical variables were summarized as absolute numbers and percentages. Continuous variables were summarized as means and standard deviations. Analyses on the primary and secondary outcomes were performed on the "full analyses set" (FAS). To be part of the FAS, participants had to have valid data for T0 (baseline) and T2 (end point). The FAS includes all randomized patients in the groups to which they were assigned, regardless of the 'dose' of intervention they had received. For the primary and secondary end points, change in score between T0 and T2 was analyzed using Fisher's nonparametric permutation test, unadjusted between the two groups.

Sensitivity analyses were performed using intention to treat (ITT) analysis and per protocol (PP) analysis. In the ITT, missing data were handled by multiple imputation. In the PP analysis, randomized subjects with no major protocol violations who took part in at least two intervention events (e.g., two meetings with the TC or one meeting with the TC and participated in the adolescent day) were included.

Analyses were performed using SAS, version 9.4. All significance tests were two-sided and conducted at the 5% significance level. For effect sizes, the cutoffs are 0.2–0.5 for small effect; 0.5–0.8 for moderate effect; and >0.8 for large effect.

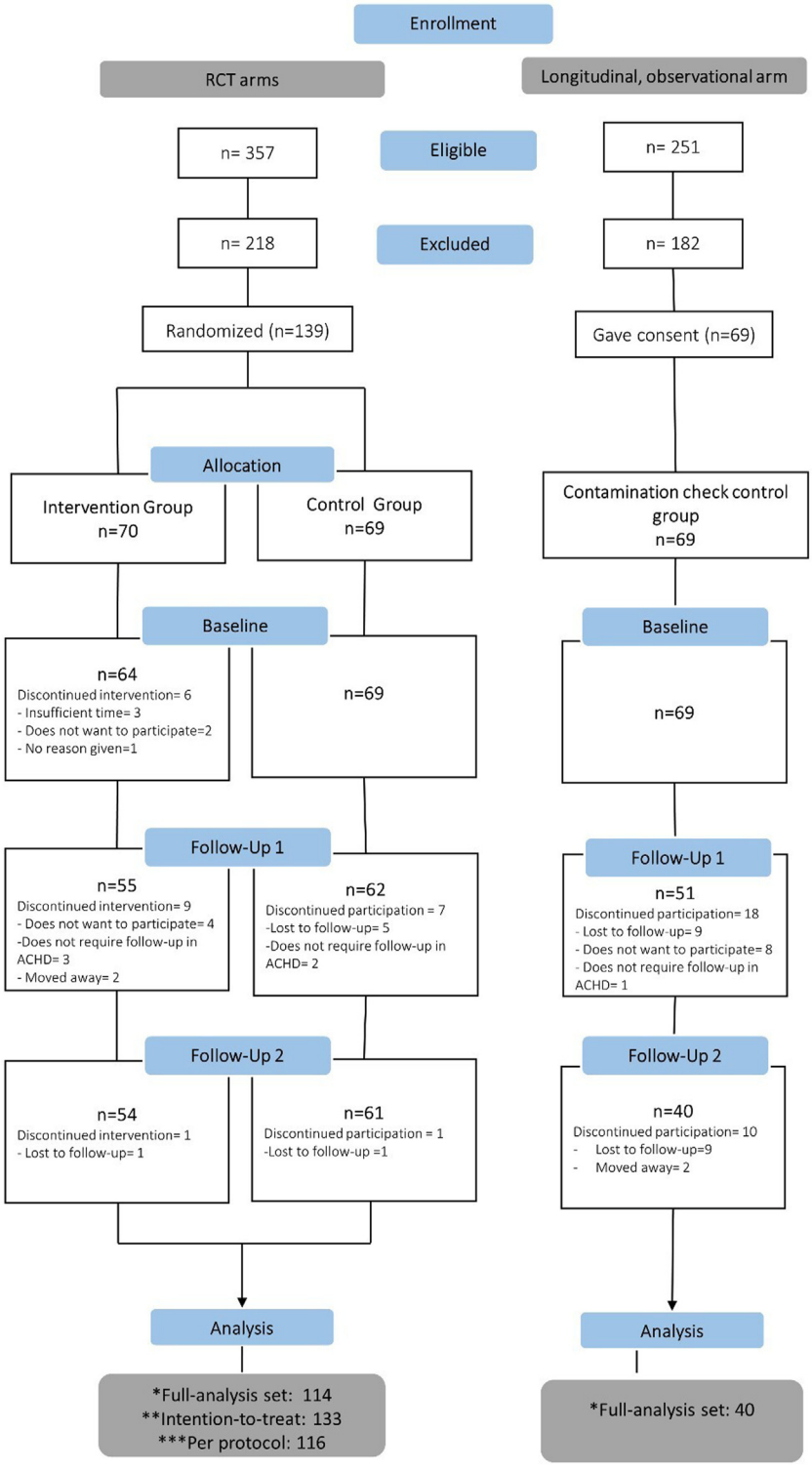

Figure 2. CONSORT flowchart for the STEPSTONES-CHD trial. CONSORT, Consolidated Standards of Reporting Trials.

Table 1
Participants" characteristics (FAS population)

Variables	IG (n = 54)	CG (n = 60)	*p*-value (IG vs. CG)	CCCG (n = 40)	*p*-value (CG vs. CCCG)
Sex			1.00[a]		0. 59[a]
Female	25 (46.3%)	27 (45.0%)		15 (37.5%)	
Male	29 (53.7%)	33 (55.0%)		25 (62.5%)	
CHD complexity[15]			0.25[b]		0.52[b]
Simple	4 (7.4%)	6 (10.0%)		9 (22.5%)	
Moderate	32 (59.3%)	40 (66.7%)		20 (50.0%)	
Complex	18 (33.3%)	14 (23.3%)		11 (27.5%)	
Born in Sweden			0.81[a]		1.00[a]
No	7 (13.2%)	6 (10.0%)		4 (10.0%)	
Yes	46 (86.8%)	54 (90.0%)		36 (90.0%)	
Other congenital disorders			0.70[a]		0.73[a]
No	43 (84.3%)	47 (79.7%)		33 (84.6%)	
Yes	8 (15.7%)	12 (20.3%)		6 (15.4%)	
CHD medication			0.75[a]		0.80[a]
No	39 (73.6%)	46 (78.0%)		28 (73.7%)	
Yes	14 (26.4%)	13 (22.0%)		10 (26.3%)	
Living situation			0.85[c]		0.77[c]
Mother	6 (11.8%)	6 (10.0%)		9 (9.0%)	
Father	2 (3.9%)	1 (1.7%)		1 (1.0%)	
Both parents	37 (72.5%)	47 (78.3%)		81 (81.0%)	
Alternate between parents	6 (11.8%)	6 (10.0%)		9 (9.0%)	

CCCG = Contamination check control group; CG = control group; CHD = congenital heart disease; FAS = full analyses set; IG = intervention group. For comparison between groups Fisher's exact test (2-sided).
[a] was used for dichotomous variables and the Mantel-Haenszel chi square.
[b] test was used for ordered categorical variables. The chi square test.
[c] was used for nonordered categorical variables.

Results

Of 608 potentially eligible patients in the national cohort that were approached for participation, 208 (34%) consented to participate. Statistically significant differences were observed between participants and nonparticipants for primary diagnosis ($p = .023$ effect size = 1.46) and disease complexity ($p = .017$; effect size = 0.54). A larger proportion of participants had a more complex CHD than nonparticipants. No other statistical differences were found. A comprehensive presentation on nonparticipants and dropout analysis is published in a separate article [29].

Seventy patients were randomized to the IG and 69 to the CG (Figure 2). For the CCCG group, 69 patients were enrolled. Over the course of the trial, 53 participants withdrew from the study: 16 in the IG, eight in the CG, and 29 in the CCCG. Patient characteristics are summarized in Table 1. No differences between the IG, CG, and CCCG were found.

Contamination check

No differences in primary or secondary outcomes were detected between the CG and the CCCG. In line with this finding, there was no difference in the change of empowerment from T0-T2 between the CG and the CCCG ($p = .59$). This indicates that there is no evidence for contamination in the CG.

Primary outcome

At baseline, the level of patient empowerment was similar in both groups (IG: 52.2 ± 10.1; CG: 52.0 ± 10.1; $p = .89$) (Table 2). At T2, the empowerment level was significantly higher in the IG (58.6 ± 8.9) than in the CG (54.9 ± 10.7; $p = .048$). The change in empowerment from T0-T2 was 6.41 ± 9.64 in the IG and 2.97 ± 7.67 in the CG. This change in empowerment differed significantly between the groups, with a mean difference of 3.44 (95% confidence interval [CI]: 0.27–6.65; $p = .036$) and an effect size of 0.397 (Table 2). The effect was already demonstrable at T1 (Figure 3). In the sensitivity analyses, these findings were confirmed. The ITT-analysis showed a mean difference of 3.74 (95% CI: 0.93–6.55; $p = .009$) and the PP analysis a mean difference of 3.44 (95% CI: 0.27–6.65; $p = .036$).

Secondary outcomes

Analysis on secondary outcomes showed that the change in scores from T0 to T2 differed significantly between IG and CG for perceived parental involvement, knowledge level, and satisfaction with physical appearance (Table 2). Indeed, the transition program had an effect on decreasing perceived parental involvement (effect size = 0.58), increasing patients' level of knowledge (effect size = 0.74), and improving satisfaction with their physical appearance (effect size = 0.39). No effect of the transition program on other secondary outcomes or parental outcomes was found (Table 2).

Discussion

Transition program for adolescents with CHD aim to empower patients, which in turn will lead to improvements in more distal outcomes (e.g., clinical outcomes, continuity of care, appropriate health care consumption, and disease control) [3]. The STEPSTONES-CHD trial demonstrated that a person-centered transition program was effective in increasing patient empowerment. Furthermore, the transition program was effective in increasing patient knowledge about the condition, and improving satisfaction with physical appearance (feeling more comfortable about their body, e.g., scars) and in reducing parental involvement. This trial provides first-time evidence on

Table 2
Effectiveness of the transition programme on primary and secondary endpoints (FAS population)

	Baseline (T0)			Follow-up 2 (T2)			Change between T0 and T2	
	Intervention group (n = 54) Mean ± SD	Comparison group (n = 60) Mean ± SD	*p*-value	Intervention group (n = 54) Mean ± SD	Comparison group (n = 60) Mean ± SD	*p*-value	Difference between groups	*p*-value
Primary Outcome								
Patient empowerment	52.2 ± 10.1	52.0 ± 10.1	.89	58.6 ± 8.9	54.9 ± 10.7	.048	3.44 (0.27; 6.65)	.036
Secondary Outcomes								
Overall readiness	5.2 ± 1.6	5.0 ± 1.7	.61	6.9 ± 1.2	6.3 ± 1.5	.0095	0.48 (−0.17; 1.12)	.15
Adolescent responsibility	2.3 ± 0.7	2.3 ± 0.7	.81	3.3 ± 0.6	3.1 ± 0.7	.095	0.24 (−0.08; 0.57)	.14
Parental involvement	3.6 ± 0.6	3.5 ± 0.5	.28	2.9 ± 0.9	3.2 ± 0.8	.048	−0.54 (−0.94; −0.14)	.008
Knowledge of CHD	3.7 ± 1.6	4.4 ± 1.5	.03	5.0 ± 1.3	4.5 ± 1.5	.045	1.22 (0.60; 1.82)	.0002
Health behaviors	13.0 ± 10.8	13.2 ± 15.4	.92	14.3 ± 12.6	15.7 ± 13.5	.54	−0.28 (−6.40; 5.93)	.95
Patient-reported health	82.1 ± 15.0	82.2 ± 13.9	.95	84.4 ± 12.3	84.5 ± 12.2	1.00	0.15 (−4.31; 4.58)	.93
Heart problems	78.0 ± 18.9	76.1 ± 17.7	.59	83.1 ± 16.5	81.0 ± 14.5	.47	0.22 (−5.27; 5.66)	.94
Physical appearance	77.3 ± 25.2	78.5 ± 23.4	.83	84.4 ± 19.1	76.7 ± 25.3	.07	8.90 (0.57; 17.45)	.039
Treatment anxiety	82.6 ± 24.5	85.7 ± 19.4	.48	87.3 ± 21.6	80.6 ± 29.9	.19	9.73 (0.00; 19.58)	.056
Cognitive problems	63.0 ± 26.2	67.9 ± 22.1	.27	67.9 ± 26.0	69.2 ± 23.9	.80	3.68 (−5.00; 12.37)	.40
Communication skills	75.3 ± 22.5	78.8 ± 21.7	.42	83.3 ± 19.1	83.9 ± 17.9	.90	2.89 (−5.45; 11.21)	.51
Quality of life	80.9 ± 13.6	80.6 ± 21.3	.95	81.9 ± 13.9	79.3 ± 15.4	.34	1.82 (−4.50; 8.11)	.57
Parental outcomes								
Overall readiness	4.41 ± 1.98	4.43 ± 1.81	.99	6.51 ± 1.43	6.18 ± 1.81	.39	0.433 (−0.421; 1.294)	.35
Adolescent responsibility	1.89 ± 1.18	2.30 ± 1.14	.16	3.07 ± 01.01	3.04 ± 0.90	.87	0.296 (−0.605; 1.203)	.51
Parental involvement	3.77 ± 0.40	3.69 ± 0.34	.34	2.94 ± 1.09	3.26 ± 0.81	.14	−0.483 (−1.034; 0.067)	.083
Parental uncertainty	54.4 ± 28.6	48.3 ± 30.9	.42	27.1 ± 26.5	35.8 ± 32.1	.20	−14.5 (−32.8; 4.0)	.13

For comparison between groups, the Fisher's Non Parametric Permutation Test was used for continuous variables. The confidence interval for the mean difference between groups is based on Fisher's non parametric permutation test.
CHD = congenital heart disease; CI = confidence interval; SD, standard deviation.

the effectiveness of the person-centered STEPSTONES transition program for youths with CHD.

Empowerment is a highly relevant transitional outcome because through empowerment, young persons with CHD can develop psychosocial skills (e.g., goal setting and problem-solving), actively participate in care, and become aware of the need to remain in follow-up [30,31]. For this reason, the global consensus article on transition to adulthood and transfer to adult care in adolescents with CHD highlighted the importance of empowerment as an outcome of transitional care [3]. Interventions aiming to increase the level of patient empowerment have been found to result in improvements in quality of life and well-being and increased patient knowledge of the disease [31]. In the longer term, clinical outcomes are better when patient empowerment is enhanced. Empowerment in this regard should be considered as a proximal outcome that has the potential to affect distal outcomes such as health care consumption, continuation of care, and morbidity [3].

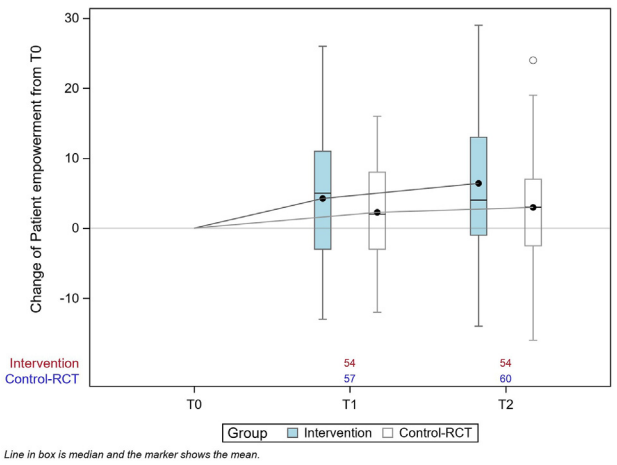

Figure 3. Change in empowerment in the intervention group and control group (FAS population).

The strongest effect of the transition program was seen in the increase of CHD-related knowledge. Indeed, when undergoing a transition program, patients learn more about their condition and better understand what to do to avoid complications. Patients also learn about the importance of continuing follow-up and how to navigate the health care system [32]. This result corroborates findings from previous trials which showed that patients' knowledge of their condition increased when they received educational sessions during transition [11–13].

A reduction in perceived parental involvement during transition was another effect of the STEPSTONES transition program. It is important to realize that parents are important partners in making the transition happen [3,4] but they need support from health care professionals to gradually let their child go. As a result, the adolescent's autonomy increases while parental involvement decreases.

Some of the secondary outcomes were not impacted by the transition program, one possible reason being that these are more distal outcomes. For instance, if adolescent responsibility is measured at a later time point, once the participants have experienced adult care and are faced with more responsibilities, that change will probably become noticeable. Another reason could be that some outcomes, e.g., baseline scores for quality of life and patient-reported health, were already high at baseline level, and these could therefore not improve substantially. Prior

studies have also found quality of life and patient-reported health to be good in adolescents with CHD [33,34]. The present study also found no effect on the parents' uncertainties and perceived transition readiness. This can be explained by the process evaluation, which indicated only a low proportion of parents sought extra support from the TC (6.8%) [22]. It can also be argued that these outcomes were not significant because the intervention did not target specific aspects of health status and quality of life that the instruments measure.

It is possible that the primary and secondary outcomes that were found to be significant in this study interact with and synergize each other. For instance, there is no doubt that adolescents with CHD need knowledge and understanding about their condition in order to feel in control of their health and life, and to be able to take well-founded decisions. Increased knowledge and understanding also enhances the feeling of personal control over the transfer and transition, which are dimensions of empowerment. Moreover, empowerment involves changes in relationships, behaviors, and self [21], which may explain why the adolescents' perception of their physical appearance improved and may be connected to the dimension of identity.

Methodological Considerations

The STEPSTONES-CHD trial has several strengths. Firstly, the hybrid RCT design allowed us to exclude potential contamination in the CG of the intervention centers. Secondly, the RCT was conducted in two centers in Sweden. We applied a block randomization to ensure that the TCs in the two centers had a relatively continuous exposure to the intervention over time, which allowed them to keep their skills up to date and to warrant fidelity of the intervention. This approach decreased variability within centers and reduced the risk for bias and confounding. Thirdly, the trial was accompanied by an extensive process evaluation. Rigorous monitoring of the intervention increases transparency and insight on the fidelity of the intervention and mechanism of impact [21,22]. However, some methodological limitations have to be considered when interpreting the findings. Firstly, the follow-up period was relatively short. Indeed, we measured the effectiveness of the intervention up to half a year after the transfer to adult care. A longer follow-up period could reveal effects on more distal outcomes e.g., morbidities, health care consumption, ability to work, and employment. Future studies ought to explore the long-term effects of the transition program. Secondly, a relatively large proportion of eligible patients did not want to participate in this trial. This illustrates that recruitment of adolescents to intervention studies is a challenge [29]. The dropout analysis showed that patients with simple heart defects were less likely to participate, and thus a selection bias cannot be completely excluded. A comprehensive dropout analysis is published elsewhere [29]. Qualitative results related to the current RCT suggest that adolescents who declined to participate in the intervention study consider themselves healthy and not in need of a transition program [29]. In line with this, one aspect that may also have an impact is the difference in frequency of follow up visits in usual care between T0 and T2, which is related to the complexity of disease.

Now is the time to implement transition programs as a part of usual care. The scientific foundation for the positive effects is today strong and cannot be neglected [3]. Patient organizations are key stakeholders and the collaboration with clinicians and researchers is of outmost importance in the implementation process. Since health care settings (context) differ between countries and within countries, it is central to identify facilitators and barriers before implementation and to carefully plan the implementation process to increase the possibility of sustainability.

Conclusion

The STEPSTONES-CHD trial demonstrated the effectiveness of a person-centered transition program in empowering adolescents with CHD. Furthermore, parental involvement, satisfaction with physical appearance, and CHD-related knowledge were positively influenced. This trial provides empirical underpinnings for the implementation of transition programs for afflicted adolescents.

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Supplementary Data

Supplementary data related to this article can be found at 10.1016/j.jadohealth.2023.02.019.

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