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Authors: Helen Ronning, Niels Erik Nielsen, Eva Swahn and Anna Stromberg

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Evaluation of a model focusing on computer-based and individualized care by face-to-face psycho-education for adults with congenitally malformed hearts: a randomized controlled trial.

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Abstract

Objective: Evaluate the effects of a psycho-educational model for follow-up in adults with congenitally malformed hearts.

Methods: The study had a randomized controlled design. Usual care was compared with computer-based and individualized care by face-to-face psycho-education by a multidisciplinary team. Knowledge and perceived control regarding the heart condition, symptoms of anxiety and depression was analysed at baseline, 3 and 12-months.

Results: The 114 participants (control group n=58, intervention group n=56) had an average age of 34 years, SD 13.5. The intervention group had significantly higher general knowledge after 3 (effect size (ES) 0.63, \(p\) < 0.01), and 12-months (ES 0.53, \(p\) = 0.02). Knowledge regarding endocarditis was significantly increased at 3 (ES 1.43, \(p\)< 0.001), and 12-months (ES 0.58, \(p\) = 0.02) compared to baseline. There were no changes in knowledge regarding medical treatment, contraceptives and pregnancy, perceived control or anxiety and depression in any of the groups.

Conclusion: The model for follow-up was effective to improve and maintain knowledge about self-management.

Practice implication: Future evaluation of how the improved knowledge will affect health behaviours over-time is needed. Clinical Trials NCT01234753

Keywords: computer program, congenital heart disease, follow-up studies, hospital outpatient clinic, patient education

1. Introduction

Many adults with congenitally malformed hearts can be considered to have a chronic condition and most often in need for regular follow-up in the healthcare system [1]. Risks for complications are related to decreased function of the heart due to the heart defect, previous surgery, which leads to needs of self-management behaviours related to medical treatments, physical activity, preventions of endocarditis, employment and spare time, birth control and pregnancy, but also lifestyle concerns such as smoking and healthy eating [2]. In recent years the survival rates of more complex types of congenital heart malformation has improved [3] but there are still no detailed recommendations for the follow-up in international guidelines. [4]. Evaluations of follow-up and long-
term effects on both physical and psychosocial aspects of living with a congenitally malformed heart are still missing [5]. One requirement for self-management is to have sufficient knowledge to improve self-care [6]. Many adults with congenitally malformed hearts lack sufficient knowledge about their heart condition [7, 8]. Previous studies have confirmed these needs for target education and outline the limited comprehension of knowledge in this group [9, 10]. For instance only 54% to 76% knew their congenital malformation diagnose by name [11-14].

There were knowledge deficiencies regarding medical treatment, prevention of endocarditis, birth control and pregnancy [11-14]. There is known that by using the individual’s personal goals in order to involve the person in the care process achieve a better adherence to self-management behaviours [15]. There are studies pointing out that adults with congenitally malformed hearts have a low level of knowledge regarding their heart condition [7]. Risk for complications impose the need for self-management behaviors [6] such as adhering to medical treatment, prophylacticts of endocarditis or risk reduction in connection with pregnancy. Perceptions, motivation, learning skills and the social environment are key factors influencing behaviour changes [16].

Guidelines recommend follow-up of both medical and psychosocial problems [4]. Today, the availability of structured education to promote self-management behaviours in adults with congenitally malformed hearts varies and knowledge and psychosocial needs are not routinely assessed during follow-up [17]. Healthcare professionals strongly influence behaviour changes [16]. Failure to identify misconceptions or beliefs due to low levels of knowledge may increase the risk of poor self-management [16]. Less prepared person’s with poor levels of knowledge concerning their heart condition will not take an active role in their treatment, and the care plan.

Patient education on its own or combined with computer-based education tailored for the person, has shown to significantly affect knowledge and/or management of the disease in people with chronic condition [18-22].

However no study has evaluated educational models, materials and methods for adults with congenital malformation in a randomized controlled design [9, 11-14, 23, 24]. Moons et al [17] describes the current status of delivery of care in Europe 2010. In totally 50 specialist centres form 18 countries participated in this survey. Forty-seven programs (94%) were located in a university hospital. In 94 % of the centres, cardiologists specialized in adults with congenitally malformed hearts were available and 68% had specialized nurses. One model used in Italy has been described by Chessa et al [25]. They have created a web site for collaboration among different centres in Italy through which patients, nurses, and physicians have access to information without login details. The outcome of this web site has not been presented yet. Another program is Copenhagen Transition Program.
[26], an outpatient nursing clinic for adolescents with congenitally malformed hearts. This program focusing on topics such as increasing knowledge about the heart condition, endocarditis, acute situations, nutrition, contraception, alcohol/drugs, smoking, physical activity, sleep/rest, and education. Parents are asked not to participate. The long-term outcome of this program is also not yet described. In Canada, Reid et al [27] describe a successful transfer from paediatric to adult cardiac care in 15 specialized adult centre for congenitally malformed hearts but evaluations of effects of educational models is missing. We have previously developed and tested feasibility of a model for follow-up [28] including person centred care by face-to-face psycho-education and computer-based education [29] by a multidisciplinary team. The aim of this study was to evaluate the effects of this follow-up model [28] in adults with congenitally malformed hearts. We hypothesized that a complementary visit to a nurse, and if needed other members of the multidisciplinary team, focusing on individualized care by face-to-face psycho-education and computer-based education in addition to the traditional physician outpatient visit would increase knowledge and perceived control of the cardiac condition. We further hypothesized that such a visit would not increase symptoms of anxiety and depression.

2. Materials and methods

2.1 Design, setting and sample

The study used a prospective randomized controlled design and is registered with ClinicalTrials.gov, number NCT01234753. The study is presented according to CONSORT 2010 [30, 31]. Data were collected at 4 sites: Linköping University Hospital, Jönköping County Hospital, Kalmar County Hospital and Malmö University Hospital. Between April 2006 and September 2009, adults aged 18 or above with uncomplicated congenitally malformed hearts (ventricular septal defect, atrial septal defect, coarctation of the aortae, aortic valve stenosis) and complicated congenitally malformed hearts (tetralogy of Fallot, complete transposition of the great arteries, congenitally corrected transposition of the great arteries, Ebstein anomaly and Eisenmenger syndrome, scheduled for a regular medical visit, were consecutively randomized to a control group or intervention group Table I). Exclusion criteria were complicating co-morbidity such as age-related coronary heart diseases, valve diseases, other life-threatening diseases, psychiatric illness or inability to read or understand Swedish. The study was conducted with the approval of the Regional Ethical Review Board in Linköping, no M172-05 and the principles outlined in the Declaration of Helsinki were followed.
2.1.1 Control group

The control group received usual care including a visit to a specialized cardiologist with clinical evaluations and/or echocardiography and/or exercise tests. No structured education program or written educational material was provided since this is not included in usual care for this group.

2.1.2 Intervention group

The intervention group was provided with individualized care by face-to-face psycho-education by the multidisciplinary team. A model for follow-up was used that has previously been described by Rönning et al [28]. Briefly, it consisted of a visit to the physician/nurse and a 1 month follow-up by telephone. The visit to the physician was identical to that of the control group. The visit to the nurse included a computer-based educational program [29] followed by individualized care by face-to-face psycho-education. The model for follow-up [28] is in line with the conceptual model for self-management support developed by Glasgow and colleges [32, 33]. Beliefs and behaviours was assessed by the KnoCoMH [34] instrument and by questions about difficulty in daily life developed by Kampuis et al [9]. Advice and psycho-education was provided by individualized care face-to-face by physician and nurse and by the computer-based education [29]. Agreement was reached through the face-to-face conversation between the participants and the nurse where goals based on the person’s perspectives and needs were set. To evaluate the needs of assist, personal barriers, strategies, problem solving techniques was identified with support from the socio demographic data, the questions about difficulty in daily life [9], and the physicians recommendations. The instruments; HADS [35] and CAS [36] was also used in this stage. Plan for and arrange around the participants needs was carried out from the person’s needs. The psycho-education was individual targeted and could for example include personalized advice and support regarding physical exercise or counselling to deal with insurance issues, economical problems or work-related issues due to the chronic disease. The nurse contacted other healthcare professionals in the multidisciplinary team to organize appointments if needed. This team consisted of a physiotherapist, dietician, hospital social worker, cardiologist, gynaecologist, anaesthesiologist, obstetrician and paediatrician.

2.1.3 Procedures
All presumptive study participants received verbal and written information about the study. The participants provided informed consent before the visit to the physician (Figure 1). The randomization was done between the visit to the physician and the visit to the nurse by unpredictable allocation sequences, concealment until assignment occurred by sequentially numbered and sealed letters, prepared by a third person not involved in the randomization. The reason for doing the randomization accordingly was to guarantee a standard visit in both control and intervention group through avoiding influence on the physician's education and support of the participants.

Baseline data were collected after enrolment and signed informed consent before the visit to the physician in the hospital outpatient clinic. Data at the 3 and 12 months follow-up were collected by mail and telephone interview (Figure 1).

2.1.4 Questionnaires

Three self-administrated questionnaires were used for data collection.

1. The knowledge scale for adults with congenitally malformed hearts (KnoCoMH), developed and psychometric evaluated was used to evaluate knowledge [34]. The questionnaire included 46 items in four domains of knowledge concerning the heart condition. General Knowledge have 22 questions with reliability coefficient, Kuder Richardsson 20 (KR 20) 0.68 in our study. Medical treatment have 8 questions with reliability coefficient; KR 20 0.74 in our study. Endocarditis prophylactics have 13 items with reliability coefficient; KR 20 0.90 in our study. Contraceptives and Pregnancy have 3 items with reliability coefficient; KR 20 0.65 in our study. Scores were calculated by dichotomizing answers (correct/incorrect). Missing answers were treated as incorrect. Twelve items were assessed individually from the medical files and physicians' recommendations. If the participant was not recommended medical treatment, or endocarditis prophylactics these domains were excluded. The domain Contraceptives and pregnancy was not included in males.

2. The Control Attitudes Scale (CAS) is a 4-item questionnaire with a 7-point scale (1 = not at all, 7 = very much) measuring perceptions of personal and family control in the context of cardiac disease [36]. The total score ranges from 4 to 28, higher scores indicate stronger perceptions of control over the disease [37].
scale is translated and psychometric tested under Swedish circumstances [38]. Scores below 16 are considered to indicate low level of control [37]. Reliability coefficient, cronbach’s alpha was 0.81 in this study.

(3) The Hospital Anxiety Depression Scale (HADS) is a well-validated 14-item questionnaire for screening symptoms of anxiety and depression in the general population as well as in somatic patient populations [35]. HADS provides separate scores for anxiety (HAD-A) and depression (HAD-D) [39, 40]. Score 0-7 indicates no symptoms of anxiety or depression respectively, score 8-10 indicates possible case, score 11-21 indicates probable case with symptoms of anxiety or depression. Reliability coefficient, cronbach’s alpha for the anxiety score was 0.82 and 0.76 for depression score in our study.

2.1.5 Socio-demographic variables and clinical status

Socio-demographic variables were obtained from a self-report questionnaire at baseline. Clinical status was collected from the participants’ medical files and by questionnaires filled in by responsible physician.

2.1.6 Statistical analysis

Baseline characteristics of the control and intervention groups were compared using χ2 test for categorical data and independent t-test for continuous variables. To test the effects of the intervention, knowledge, perceived control, and symptoms of anxiety and depression were compared between groups and over time with intention to treat analysis in baseline, 3 and 12 months data. Missing data in CAS and HADS questionnaire respectively were not replaced and the scale/subscale was recorded as missing. If only one item was missing in the four domains respectively in the KnoCoMH, the answer was assessed as incorrect. If more than one item was missing in the same area, the area was recorded as missing for the person. Between groups differences at baseline, 3 and 12-months and differences over time were analysed by t-test. The results are given as frequencies, (mean, standard deviation (SD), difference and mean difference between groups with 95 % confidence interval). Effect size was calculated by dividing the mean difference in score by the population (control group) standard deviation [41, 42]. Small, medium, large effect size were defined as 0.20, 0.50, and 0.80 respectively [42]. All analyses were performed using PASW Statistics 18.0. The statistical level was set at p < 0.05.
3. Results

Of the 218 potential participants scheduled for regular check-ups, 114 were randomized and all available cases were included in the final analysis (Figure 1). Of those, 57 participants (50 %) had a complicated heart diagnosis (14 cases of complete transposition of the great arteries, 8 congenitally corrected transposition of the great arteries, 4 Ebstein anomaly, 4 Eisenmenger syndrome, 2 single ventricle and 25 tetralogy of Fallot). Fifty-seven participants (50 %) had a non-complicated diagnosis (20 cases of aortic valve stenosis, 4 atrial septal defect, 17 coarctation of the aortae and 16 ventricular septal defect).

Reason for excluding 104 (48%) potential participants was denied consent, missed cases or failure to meet the inclusion criteria (Figure 1). Thirty-four (33 %) of those participants had a complicated heart diagnosis (11 cases of complete transposition of the great arteries, 5 congenitally corrected transposition of the great arteries, 1 Ebstein anomaly, 16 tetralogy of Fallot and 1 unknown diagnosis). Seventy participants (67 %) had a non-complicated diagnosis (19 cases of aortic valve stenosis, 6 atrial septal defect, 24 coarctation of the aortae and 21ventricular septal defect).

In total 16 participants (14 % of 114) were lost to follow-up after 3 months, 9 in the intervention group and 7 in the control group, and a total of 17 participants (15% of 114) were lost to follow-up after 12 months, 9 in the intervention group and 8 in the control group. Missing data in instrument varied between 1.7 to 3.5 % in CAS and HADS respectively, in KnoCoMH there were no missing data (Figure 1).

3.1 Demographic and clinical characteristics

The participants were between 18-74 years old with an average age of 34 years (SD = 13.5). Three per cent went to the hospital outpatient clinic for a regular visit every sixth month, 50 % every year, 25 % every second year, 5 % every fifth year and 17 % had other time schedules for regular follow-ups. Thirty-three per cent were on medication due to heart failure, high blood pressure, arrhythmias and/or prevention of thrombosis. In total 68 % had undergone heart surgery and 46 % more than once. According to the physician’s recommendation, 66 % of the participants were prescribed endocarditis prophylactics, 91 % of the females (totally n=51) should contact the physician if pregnant and 64 % before becoming pregnant. There were no differences in baseline characteristics between groups (Table I).

3.2 Study outcomes
3.2.1 Knowledge

The intervention group increased their general knowledge about their heart condition after 3 months and the effect remained at 12 months follow-up (medium effect size) (Table II, III). A total of 37 participants in the intervention group were recommended endocarditis prophylactics and their knowledge regarding endocarditis increased at 3 months follow-up (large effect size). After 12-months there were no differences between the groups (Table II, III), but there was a significant difference of knowledge over time between baseline and 12-months (Table III) pointing out that learning occur over time (medium effect size) (Table II, III). There were no knowledge changes in the domains medical treatment and contraceptive and pregnancy in either of the groups (Table II, III).

The changes in different items of the general knowledge domain are described in Table IV.

3.2.2 Perceived control

There were no differences between the groups at baseline and the perceived control over the heart disease showed normal values (mean 21, SD 5.3 in control group, mean 21, SD 6.1 in intervention group). No change was found between groups over time at 3 months (mean difference -1.0, SD 5.2 in control group, mean difference 0.3, SD 4.5 in intervention group, \textit{p}-value 0.17, effect size -0.13) and 12 months follow-up (mean difference -0.5, SD 4.9 in control group, mean difference -0.9, SD 4.6 in intervention group, \textit{p}-value 0.68 effect size -0.28).

3.2.3 Anxiety and depression

There were no differences between the groups at baseline and symptoms’ of anxiety and depression showed normal values respectively (mean 4.6/2.0, SD 3.6/2.1 in control group, mean 4.8/2.8, SD 3.9/3.4 in intervention group). No change was found between groups over time at 3 months (mean difference in symptoms of anxiety/depression -0.4/0.2, SD 2.2/1.7 in control group, mean difference -1.0/-0.7, SD 2.3/2.8 in intervention group, \textit{p}-value 0.22/0.06, effect size -0.63/-0.53) and 12 month follow-up (mean difference in symptoms of anxiety/depression -0.7/0.2, SD 2.5/2.5 in control group, mean difference -0.5/-0.6, SD 3.1/3.0 in intervention group, \textit{p}-value 0.71/0.20, effect size -0.48/-0.32. The intervention with individualized care by face-to-face psycho-education did not produce symptoms of anxiety and/or depression.
4. Discussion

Today there is a lack of knowledge on how to provide individualized care by face-to-face psycho-education to achieve positive health outcomes in adults with congenitally malformed hearts [5]. This is one of the first randomized trial evaluating an intervention with individualized care by face-to-face psycho-education to this population. Our results showed that the intervention improved knowledge over time in the domains general knowledge and Endocarditis prophylactics in the KnoCoMH scale. For example at baseline only 48 per cent of the participants in the intervention group did know the name, diagnosis of their heart defect which is comparable to other studies [11-14] but after the intervention with computer based and person centred face-to-face psycho-education the percentage of participants now knowing the name increased to 84 per cent with persisting effects after 1 year, see table IV. According to Cohen’s effect size index, the improvement of knowledge over time was between medium to large [42]. But the clinical significance of the increased knowledge and long-term effects regarding health outcomes is not yet known. But to knowing the name of the heart defect are always important knowledge to have independently if it is in contact with healthcare professionals or if it is when seeking information over the internet. And because knowledge is known to influence behavioural changes [6, 15, 16, 43] we choose knowledge as the main outcome of our study. An editorial published earlier in year 2012 in Patient Education and Counselling also highlights the importance of evaluating knowledge and models for improving knowledge and effects on behaviours [44].

This is also the first study evaluating perceived control in adults with heart malformation. Increased knowledge around the heart condition has earlier been found to decrease anxiety and improve the perceived control in people with coronary heart disease [45, 46]. Our data showed low scores of anxiety and high levels of perceived control which indicates that most of the participants were in a stable condition and had adapted to living with their malformed hearts. However, since the intervention was promising in terms of increasing knowledge, further studies are needed to assess long-time effects of self-management behaviours and perceived control.

The knowledge scale used in our study, KnoCoMH [34] are an new developed and tested scale, and the results can therefore not directly be compared with previously studies but by presenting the results per item and in per cent (table IV) the results are feasible to compare. Our study showed that adults with congenitally malformed hearts have a need for knowledge regarding their heart condition. Previous studies underlining the importance of preparation of structured educational programs regarding the heart condition for this population [6, 8-10]. Until
know there has been a lack of knowledge regarding the design of a structured program in order to improve required knowledge.

The strength of the computer-based education used in the intervention is that it is based on clinical experience, research literature and developed in close collaboration with formal users (adults with congenitally malformed hearts) [29]. The education theory of constructivism was used with the intention to support deeper knowledge both in the computer-based and individual face-to-face psycho-education [47, 48]. According to studies of learning, one of the most important aspects to consider in order to reach understanding and knowledge, is relevant content and illustrations [47, 48]. The objective of the computer-based educational program was to visualize the relationships between the congenital heart defects and the normal heart, what has happened since childhood or can happen in the future. The purpose with individualized care by face-to-face psycho-education education was to assess needs and provide personal advice and agreements in order to emphasize the person’s own role in caring for themselves [33]. Both the computer-based and individual care by face-to-face psycho-education in this study focused on developing an understanding of the heart condition. Whether the increased level of knowledge also led to behaviour changes was not evaluated.

There is always a risk that the participants in the control group in response to the fact that they are studied improve or modify their behaviours and we found some learning effects also in the control group (table II-IV). This is known as a non-specific effect which is difficult to control [49]. Further, there were many adults with congenitally malformed hearts declining participation. These individuals are in the middle of life busy with studying, making a career or starting a family [50]. The main reason for not participating in the study was often lack of time but if this is the correct reason of it or if it is a defence we can never know [43].

4.1 Conclusion

The model for follow-up was effective in improving and maintaining knowledge about self-management in adults with congenital malformed hearts.

4.2 Practice implications

The model for follow-up can now be used in clinical practice. But future research is also needed to determine the long-term effects of self-management behaviours and perceived control.
4.3 Conflict of interest

The authors declare that they have no conflicts of interest. All rights to the computer-based educational program belong to Linköping University and Linköping University Hospital, Sweden. Earlier development and evaluation of the program were undertaken independently of the funding sources and there are no conflicting interests.

4.4 Acknowledgements

This study was supported by grants from The Research Council in South-East Sweden (FORSS), Heart-Lung Foundation and Östergötland County Council. The authors acknowledge the Cardiology clinics in Linköping, Jönköping, Kalmar and Malmö.

5. Article Summary

Strengths and limitations of this study

- A strength is that this study it is one of the first randomized trial evaluating an intervention with individualized care by face-to-face psycho-education to this population.

- The intervention improved knowledge over time in the domains general knowledge and Endocarditis prophylactics in the KnoCoMH scale.

- Both the computer-based and individual care by face-to-face psycho-education in this study focused on developing an understanding of the heart condition.

- A limitation are that evaluation of whether the increased level of knowledge also led to behavior changes was not done. This was not possible to do due to one year follow up.
References

[34] Rönning H, Franzen Årestedt K, Nielsen N.E, Swahn E, A. S. Development and psychometric evaluation of the Knowledge scale for adults with Congenitally Malformed Hearts: KnoCoMH. Accepted for publication. 2011.

Figure 1. Flow chart of the participants in the enrollment, allocation, follow-up and analysis

Assessed for eligibility (n = 218)
- Excluded (n = 104) 48%
  - Not meeting inclusion criteria (n = 7)
  - Declined to participate (n = 74)
  - Other reasons (n = 23)

Visit to the physician

Randomised (n = 114)

Allocated to Intervention group (n = 56)
- Visit to the nurse
- Received allocated intervention (n = 55)
  - (1 did not receive allocated intervention)

Allocated to Control group (n = 58)
- Received in Control group (n = 58)

Follow-up
- Lost to follow-up (3-month)
  - No reply to mail (n = 9) 16%
  - No reply by telephone, KnoCoMH (n = 6) 11%

- Lost to follow-up (12-month)
  - No reply to mail (n = 9) 16%
  - No reply by telephone (n = 6) (KnoCoMH) 11%

Analysis
- KnoCoMH Analyzed
  - Baseline (n = 56) 100%
  - 3-month (n = 50) 89%
  - 12-month (n = 50) 89%
- Perceived Control Analyzed
  - Baseline (n = 55) 98%  (1 missing data)
  - 3-month (n = 47) 84%
  - 12-month (n = 47) 84%
- HAD-A Analyzed
  - Baseline (n = 56) 100%
  - 3-month (n = 47) 84%
  - 12-month (n = 46) 82%  (2 missing data)
- HAD-D Analyzed
  - Baseline (n = 56) 100%
  - 3-month (n = 47) 84%
  - 12-month (n = 46) 82%  (1 missing data)

- Lost to follow-up (3-month)
  - No reply to mail (n = 7) 12%
  - No reply by telephone, KnoCoMH (n = 1) 2%

- Lost to follow-up (12-month)
  - No reply to mail (n = 8) 14%
  - No reply by telephone, KnoCoMH (n = 4) 7%

- KnoCoMH Analyzed
  - Baseline (n = 58) 100%
  - 3-month (n = 57) 98%
  - 12-month (n = 54) 93%
- Perceived Control Analyzed
  - Baseline (n = 58) 100%
  - 3-month (n = 50) 86%  (1 missing data)
  - 12-month (n = 49) 84%  (1 missing data)
- HAD-A Analyzed
  - Baseline (n = 58) 100%
  - 3-month (n = 51) 88%
  - 12-month (n = 49) 84%  (1 missing data)
- HAD-D Analyzed
  - Baseline (n = 58) 100%
  - 3-month (n = 51) 88%
  - 12-month (n = 50) 86%
Table I. Socio-demographic and clinical characteristics

<table>
<thead>
<tr>
<th>Patient characteristics, n (%)</th>
<th>Total (n=114)</th>
<th>Intervention (n=56)</th>
<th>Control (n=58)</th>
<th>p-value</th>
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<td>14 (13)</td>
<td>8 (14)</td>
<td>6 (11)</td>
<td>ns</td>
</tr>
<tr>
<td>Congenital cardiac malformation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complicated</td>
<td>57 (50)</td>
<td>27 (48)</td>
<td>30 (52)</td>
<td>ns</td>
</tr>
<tr>
<td>Non-complicated</td>
<td>57 (50)</td>
<td>29 (52)</td>
<td>28 (48)</td>
<td>ns</td>
</tr>
<tr>
<td>NYHA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>81 (71)</td>
<td>42 (75)</td>
<td>39 (67)</td>
<td>ns</td>
</tr>
<tr>
<td>II</td>
<td>19 (17)</td>
<td>5 (9)</td>
<td>14 (24)</td>
<td>ns</td>
</tr>
<tr>
<td>III</td>
<td>10 (9)</td>
<td>7 (12)</td>
<td>3 (5)</td>
<td>ns</td>
</tr>
<tr>
<td>Not classified</td>
<td>4 (3)</td>
<td>2 (4)</td>
<td>2 (4)</td>
<td>ns</td>
</tr>
<tr>
<td>Medical treatment at baseline, yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergone heart surgery, yes</td>
<td>78 (68)</td>
<td>35 (62)</td>
<td>43 (74)</td>
<td>ns</td>
</tr>
<tr>
<td>&gt; 1 heart operation</td>
<td>23 (21)</td>
<td>9 (14)</td>
<td>14 (25)</td>
<td>ns</td>
</tr>
<tr>
<td>Smoking, yes</td>
<td>12 (10)</td>
<td>5 (9)</td>
<td>7 (12)</td>
<td>ns</td>
</tr>
<tr>
<td>Do regular physical activity every week, yes</td>
<td>95 (83)</td>
<td>44 (80)</td>
<td>51 (86)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends endocarditis prophylactics, yes</td>
<td>75 (66)</td>
<td>37 (67)</td>
<td>38 (64)</td>
<td>ns</td>
</tr>
<tr>
<td>Only general prevention without antibiotics, yes</td>
<td>9 (8)</td>
<td>6 (5)</td>
<td>5 (4)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends avoiding all regular physical activity, yes</td>
<td>2 (2)</td>
<td>0</td>
<td>2 (3)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends choosing employment without physical demands yes</td>
<td>43 (38)</td>
<td>20 (36)</td>
<td>23 (39)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends avoiding some contraceptives, yes</td>
<td>2 (2)</td>
<td>1 (3)</td>
<td>1 (4)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends contacting the physician if the women want to become pregnant, yes</td>
<td>36 (34)</td>
<td>16 (55)</td>
<td>20 (74)</td>
<td>ns</td>
</tr>
<tr>
<td>Recommends contacting the physician if pregnant, yes</td>
<td>51 (45)</td>
<td>26 (90)</td>
<td>25 (93)</td>
<td>ns</td>
</tr>
</tbody>
</table>

n = Number.
% = Percent
NYHA= New York Heart Association.
1. Complicated = Congenitally malformed hearts such as complete transposition of the great arteries, congenitally corrected transposition of the great arteries, Ebstein anomaly, Eisenmenger syndrome, single ventricle, tetralogy of Fallot
2. Non-complicated = Congenitally malformed hearts as aortic valve stenosis, atrial septal defect, coarctation of the aortae, ventricular septal defect.
3 According to medical files.
4 According to participants’ statements.
5 According to responsible physician (Recommendations due to the congenitally malformed heart).
6 Percentage of female patients (Experimental group n=29, Control group n=27, Totally female n=56).
Table II. Knowledge of the four areas in KnoCoMH

<table>
<thead>
<tr>
<th>KnoCoMH</th>
<th>Interv. mean (SD)</th>
<th>Control mean (SD)</th>
<th>Effect size</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>n</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>19</td>
<td>-0.61</td>
<td>0.189</td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>37</td>
<td>-0.05</td>
<td>0.487</td>
</tr>
<tr>
<td></td>
<td>34</td>
<td>37</td>
<td>0.87</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>37</td>
<td>0.34</td>
<td>0.146</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>27</td>
<td>-0.5</td>
<td>0.118</td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>26</td>
<td>0</td>
<td>0.783</td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>25</td>
<td>0.25</td>
<td>0.516</td>
</tr>
</tbody>
</table>

\*In total, 37 individuals underwent medical treatment at baseline, 18 participants in the intervention group, and 19 in the control group. There were no treatment changes in the 3-month data. After the 12-month follow-up, 5 new participants in the control group underwent medical treatment.

Contr.= Control group
Interv.= Intervention group
SD= Standard Deviation
n= Number
Table III. Differences in knowledge between 3-month/baseline and 12-month/baseline

<table>
<thead>
<tr>
<th>KnoCoMH</th>
<th>Mean diff. (SD) n</th>
<th>Mean diff. (SD) n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Knowledge</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Max score 22)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interv.</td>
<td>5.4 (3.3) 50</td>
<td>4.9 (3.8) 50</td>
</tr>
<tr>
<td>Control</td>
<td>2.9 (3.2) 57</td>
<td>3.0 (3.5) 54</td>
</tr>
<tr>
<td>(95 % CI)</td>
<td>-2.4 (-3.7 to -1.2)</td>
<td>-1.8 (-3.3 to -0.4)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt; 0.001</td>
<td>0.011</td>
</tr>
<tr>
<td>Effect size</td>
<td>0.78</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>Medical treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Max score 8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interv.</td>
<td>0.2 (1.9) 18</td>
<td>-0.2 (2.7) 18</td>
</tr>
<tr>
<td>Control</td>
<td>-0.1 (2.2) 19</td>
<td>-1.0 (2.7) 19</td>
</tr>
<tr>
<td>(95 % CI)</td>
<td>-0.2 (-1.6 to 1.2)</td>
<td>-0.8 (-2.6 to 1.0)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.752</td>
<td>0.358</td>
</tr>
<tr>
<td>Effect size</td>
<td>0.04</td>
<td>-0.29</td>
</tr>
<tr>
<td><strong>Endocarditis prophylactics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Max score 13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interv.</td>
<td>6.0 (4.0) 34</td>
<td>4.3 (3.9) 32</td>
</tr>
<tr>
<td>Control</td>
<td>1.0 (3.5) 37</td>
<td>2.2 (3.6) 37</td>
</tr>
<tr>
<td>(95 % CI)</td>
<td>-5.0 (-6.7 to -3.1)</td>
<td>-2.1 (-3.9 to -0.3)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt; 0.001</td>
<td>0.021</td>
</tr>
<tr>
<td>Effect size</td>
<td>1.43</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>Contraceptives and Pregnancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Max score 3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interv.</td>
<td>0.4 (1.2) 26</td>
<td>0.8 (1.2) 26</td>
</tr>
<tr>
<td>Control</td>
<td>0.1 (0.8) 26</td>
<td>0.0 (1.0) 25</td>
</tr>
<tr>
<td>(95 % CI)</td>
<td>-0.3 (-0.9 to 0.2)</td>
<td>-0.8 (-1.4 to -0.2)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.273</td>
<td>0.014</td>
</tr>
<tr>
<td>Effect size</td>
<td>0.37</td>
<td>0.80</td>
</tr>
</tbody>
</table>

Contr.= Control group
Interv.= Intervention group
SD= Standard Deviation
CI= Confidence Interval
n= Number
Table IV: KnoCoMH: Changes in items in domain General Knowledge

<table>
<thead>
<tr>
<th>Item</th>
<th>Baseline</th>
<th>3-month</th>
<th>12-month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interv (n=56)</td>
<td>Control (n=58)</td>
<td>Interv (n=56)</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Right score/n</td>
<td>n</td>
</tr>
<tr>
<td>What is the correct name of your congenitally malformed heart?</td>
<td>48%</td>
<td>59%</td>
<td>84%</td>
</tr>
<tr>
<td></td>
<td>27/56</td>
<td>34/58</td>
<td>42/50</td>
</tr>
<tr>
<td>How has your congenitally malformed heart been treated to date?</td>
<td>93%</td>
<td>93%</td>
<td>88%</td>
</tr>
<tr>
<td></td>
<td>52/56</td>
<td>54/58</td>
<td>44/50</td>
</tr>
<tr>
<td>Please answer this question even if you are not currently on medication. If you experience side-effects of your medication, is it indicated that you stop taking the medication?</td>
<td>68%</td>
<td>78%</td>
<td>88%</td>
</tr>
<tr>
<td></td>
<td>38/56</td>
<td>45/58</td>
<td>44/50</td>
</tr>
<tr>
<td>When do you have to contact your cardiologist?</td>
<td>25%</td>
<td>24%</td>
<td>46%</td>
</tr>
<tr>
<td></td>
<td>14/56</td>
<td>14/58</td>
<td>23/50</td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shortage of breath</td>
<td>41%</td>
<td>36%</td>
<td>86%</td>
</tr>
<tr>
<td></td>
<td>23/56</td>
<td>21/58</td>
<td>43/50</td>
</tr>
<tr>
<td>Palpitations</td>
<td>52%</td>
<td>48%</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>29/56</td>
<td>28/58</td>
<td>45/50</td>
</tr>
<tr>
<td>Chest pain</td>
<td>73%</td>
<td>69%</td>
<td>94%</td>
</tr>
<tr>
<td></td>
<td>41/56</td>
<td>40/58</td>
<td>47/50</td>
</tr>
<tr>
<td>Unknown fewer</td>
<td>16%</td>
<td>15%</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td>9/56</td>
<td>9/58</td>
<td>24/50</td>
</tr>
<tr>
<td>Reduced fitness</td>
<td>21%</td>
<td>17%</td>
<td>66%</td>
</tr>
<tr>
<td></td>
<td>12/56</td>
<td>10/58</td>
<td>33/50</td>
</tr>
<tr>
<td>Fainting?</td>
<td>41%</td>
<td>41%</td>
<td>66%</td>
</tr>
<tr>
<td></td>
<td>23/56</td>
<td>24/58</td>
<td>33/50</td>
</tr>
</tbody>
</table>
5.8  Tiring more quickly  
   32%  18/56  
   31%  18/58  
   74%  37/50  
   53%  30/57  
   78%  39/50  
   56%  30/54  
5.10  Swollen feet and legs  
   25%  14/56  
   29%  17/58  
   70%  43/50  
   51%  29/57  
   68%  34/50  
   61%  33/54  

6  If the cardiologist informs you that everything is alright, does that mean that you do not need further follow-up?  
   84%  47/56  
   76%  44/58  
   84%  42/50  
   79%  45/57  
   78%  39/50  
   89%  48/54  

7  Why do you have a congenital cardiac malformation?  
   39%  22/56  
   50%  29/58  
   86%  43/50  
   46%  23/50  
   74%  37/50  
   57%  31/54  

8  Is your congenital cardiac malformation hereditary?  
   30%  17/56  
   43%  25/58  
   46%  23/50  
   49%  28/57  
   50%  25/50  
   50%  27/54  

9  Did your cardiologist recommend endocarditis prophylaxis, antibiotics when visiting the dentist to extract teeth for example?  
   68%  38/56  
   64%  37/58  
   74%  37/50  
   72%  41/57  
   80%  40/50  
   65%  35/54  
14  As you have a congenital cardiac malformation, you should take antibiotics immediately if you have a temperature (without consulting a doctor).  
   77%  43/56  
   79%  46/58  
   92%  46/50  
   77%  44/57  
   86%  43/50  
   89%  48/54  
15  Should you go for a dental check-up at least once a year, prophylaxis to endocarditis?  
   23%  13/56  
   12%  7/58  
   44%  22/50  
   32%  18/57  
   50%  25/50  
   30%  27/54  
19  You should avoid all regular physical activity/training because of your congenital cardiac malformation?  
   91%  51/56  
   91%  53/58  
   96%  48/50  
   93%  53/57  
   94%  47/50  
   94%  51/54  
20  You should choose an occupation that is not too physically demanding, as you should be careful not to over-exert yourself.  
   64%  36/56  
   59%  34/58  
   64%  32/50  
   67%  38/57  
   58%  29/50  
   57%  31/54  
21  Could sexual activity deteriorate your cardiac condition?  
   66%  37/56  
   79%  46/58  
   90%  45/50  
   89%  51/57  
   90%  45/50  
   87%  47/54  
22  What is the risk that your children will have a congenital heart malformation?  
   16%  9/56  
   17%  10/58  
   40%  20/50  
   21%  12/57  
   44%  22/50  
   18%  10/54