Adult Congenital Heart Disease – Coping And REsilience (ACHD-CARE): Intervention Development and Feasibility Trial Protocol

Running title: ACHD-CARE

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ABSTRACT

Background and Aim: As a result of significant advances in diagnosis and treatment, approximately 90% of infants born with congenital heart disease (CHD) are now expected to reach adulthood. However, an increased risk of cardiac sequelae necessitates lifelong cardiac surveillance and can significantly impact psychosocial development. One-third of North American adults with CHD have diagnosable mood or anxiety disorders and most do not receive appropriate mental health treatment. There are currently no published trials investigating psychological interventions for this unique patient population. It is thus important to establish the feasibility of conducting a psychological intervention trial in this population. In this methods paper, we describe (1) the development of a group psychosocial intervention aimed at improving the psychosocial functioning, quality of life, and resilience of adults with CHD, and (2) the design of a study to determine the feasibility of a future full-scale randomized controlled trial.

Methods: Based upon quantitative and qualitative (focus group) research, we developed an 8-session Adult CHD – Coping And REsilience (ACHD-CARE) Program. We subsequently designed a 2-parallel arm non-blinded pilot randomized trial with a 1:1 individual patient allocation ratio. Inclusion criteria are documented CHD, age $\geq$ 18 years, English-language proficiency, no planned surgery, and clinically-elevated score (i.e., >8) on the Hospital Anxiety and Depression Scale depression (HADS-D) or anxiety (HADS-A) subscale. Exclusion criteria are current psychotherapy, reported suicidal intent, or significant cognitive impairment, psychosis, or personality disorder. Patients from a single tertiary centre are randomized to the ACHD-CARE intervention or Usual Care. The intervention is delivered during 90-minute sessions held weekly in small groups. Feasibility is assessed in the following five domains: (i) process (e.g., participant recruitment and retention), (ii) resources, (iii) management, (iv) scientific outcomes, and (v) acceptability of the intervention.

Results: Our initial experiences indicate that the study design is feasible and acceptable to stakeholders. We have been able to successfully recruit and retain participants, although travel distance and competing time demands are barriers for many potential study participants. There have been no insurmountable challenges in study management. At the conclusion of the study, we will be poised to make one of three determinations: (1) a full-scale RCT is feasible, (2) a full-scale RCT is feasible with modifications, or (3) a full-scale RCT is not feasible.

Conclusions: This study underscores the importance of carefully developing and testing the feasibility of psychosocial interventions in medical populations before moving to full-scale clinical trials. Feasibility outcomes from this study will guide the future evaluation and provision of psychological treatment for adults with CHD.

Key words: adult congenital heart disease, anxiety, depression, feasibility, intervention

INTRODUCTION

Congenital heart disease (CHD) is characterized by structural defects of the heart and/or great vessels, and is present in almost 1% of infants at birth. The management of CHD often necessitates multiple surgeries and hospitalizations and typically leads to early mortality in those with defects of moderate or great complexity.[1, 2] As a result of significant diagnostic and treatment advances in recent decades, the rate of survival to adulthood is now estimated to be 90%.[3] For the first time in history, there are now more adults living with CHD than children.[4]

Despite increased survival rates, adults with CHD remain at increased risk of cardiac complications including arrhythmias, endocarditis, heart failure and premature death; hence, lifelong medical follow-up is critical.[3, 5, 6] The experience of living with a chronic illness and undergoing regular cardiac surveillance and treatment can also significantly impact psychosocial development.[7-9] Specific challenges include the potential for family overprotection, impaired peer relationships, delayed progression into independent adulthood, and unique considerations for educational, career, and family planning.[10-16] Our focus group research revealed that both intra- and inter-personal psychosocial challenges are common within this patient population, yet these are rarely addressed within routine health care.[17]

Indeed, one in three North American adults with CHD have diagnosable mood or anxiety disorders,[13, 18, 19] a prevalence which is greater than that documented in the general population.[20] Unfortunately, most adults with CHD and comorbid depression or anxiety do not receive appropriate mental health treatment.[13, 18, 19]

The rationale for a psychosocial intervention

Psychological interventions have been shown to be effective at lowering distress and improving social support and quality of life (QOL) in patients with acquired heart disease.[21] Emerging evidence also suggests that interventions can improve resilience,[22-24] which has been negatively associated with symptoms of depression and anxiety in the general population and among patients with heart disease.[25-27] Canadian, American, and European guidelines for the care of adults with CHD also emphasize the importance of psychological care for this unique subgroup of cardiac patients.[28-30] However, despite an increasing awareness of the psychosocial needs of adults with CHD, there have been no interventions developed to promote psychosocial functioning for adolescent or adult CHD populations.[31]

With the aim of systematically developing and evaluating a psychosocial intervention for adults with CHD, we turned to the Medical Research Council's methodological framework for the development of complex interventions. The Medical Research Council's phases of evaluation include: (i) development of the intervention, (ii) feasibility and piloting, (iii) evaluation (effectiveness, change process, cost effectiveness), and (iv) implementation (dissemination and long term follow-up). In this methods paper, we describe the first two phases, namely the development of a group psychosocial intervention aimed at improving the psychosocial functioning, QOL, and resilience of adults with CHD, and the design of a study to determine the feasibility of a future full-scale randomized controlled trial (RCT).

PHASE ONE: DEVELOPMENT OF THE INTERVENTION

Patient engagement

The elevated incidence of psychological problems and their gross under-treatment among adults with CHD clearly point to the need for evidence-based treatment programs to be developed for these patients. However, we recognized that it was also of critical importance to obtain the patient perspective regarding their psychological treatment needs to inform intervention development. In our quantitative study of patient interest in mental health treatment, 51% of patients indicated 'high' interest (a score of 8 or higher on a 0 – 10 scale) in at least one area of psychological treatment; patients most commonly reported high interest in stress management (34%), coping with heart disease (33%), and managing mood and anxiety (28%).[32] Patients were three times more likely to prefer psychotherapy over pharmacotherapy. This study also revealed the importance of peer interactions, as 35% were interested in receiving peer support and 48% were interested in providing peer support.

In order to gain a more in-depth understanding of psychological needs and treatment preferences, we conducted focus group and individual qualitative interviews with adult CHD patients.[17] Participants expressed interest in psychosocial services in three broad areas. First, they wanted opportunities for counseling, during which they could discuss previous or current challenges associated with living with CHD. Second, they identified the need to connect with other adults with CHD in order to better understand and normalize their struggles. Third, they sought psycho-education, in which they would learn about what emotions are expected across the course of treatment for most adults with CHD. Themes of coping and resilience were principal in the focus groups, as participants explained that they were seeking ways to cope and even to 'surpass challenges' associated with CHD. We used information gleaned from these interviews to develop a manualized intervention.

This developmental work indicated that group (rather than individual) therapy was identified as the preferred approach, as it also provides opportunities for peer interaction. This is consistent with other research indicating that social support (and exposure to positive role models) can promote resilience in

adolescents and young adults with CHD.[33] They also preferred briefer interventions that would accommodate the competing time demands faced by this relatively young cardiology cohort. Combined with study team members' own clinical experiences working with adults with CHD, this led to the development of an 8-session 90-minute weekly Adult CHD - Coping And REsilience (ACHD-CARE) Program. Patients were asked to provide feedback on a preliminary draft of the treatment intervention and manual through a qualitative study. Overall, they clearly stated their preference for an intervention with a focus on skills- and strengths-building.

ACHD-CARE intervention

Format and Delivery: The ACHD-CARE Program is provided during eight 90-minute weekly sessions, held in an education room at the hospital. The intervention is provided in groups of a maximum of 6 patients. All participants in the ACHD-CARE Program receive weekly handouts that comprise a treatment manual. Each week, participants are assigned one or more homework assignments to encourage practice and reinforcement of the strategies introduced during the sessions. Attendance and completion of homework assignments are monitored. A summary of the content of weekly sessions is provided in Table 1. Groups are co-led by two senior clinical psychology trainees (doctoral clinical psychology students or a pre-doctoral psychology intern) with prior cognitive-behavioural therapy (CBT) training which was complemented by training in the ACHD-CARE Program and manual. Supervision is provided by a registered psychologist.

Education: Adults with CHD often present to health care providers with knowledge and expectations that are based upon misinformation.[17] Therefore, participants of the ACHD-CARE program are provided with updated information regarding the prevalence of CHD as well as what is known about their

commonly-faced psychosocial dilemmas and challenges. Participants are directed to recommended CHD websites. The ACHD-CARE Program also provides psycho-education to help participants understand the mind-body connection as well as the interplay between stress, coping and resilience.

Cognitive-behavioural techniques: CBT is a well-supported approach for targeting the psychological challenges of cardiac patients; meta-analytic reviews support CBT for mental health[34-37] and medical populations,[38-40] including randomized trials with cardiac patients.[41-44] The ACHD-CARE program includes CBT techniques to directly address symptoms of depression and anxiety; the majority of homework assignments reinforce practice of CHD strategies. We draw on traditional cognitive therapy and mindfulness-based cognitive therapy.[45, 46] Participants are educated regarding the impact of thoughts (cognitions) on emotions and behaviours and are taught strategies to become aware of automatic modes of thinking, consider alternate explanations, and become more compassionate with themselves.[46-48] Many vignettes in the patient manual have been specifically tailored to living with CHD.

Behavioral techniques include pleasant activity scheduling, activity pacing, strategies for improved sleep, and physical activity. Behavioural activation (e.g., targeting activity scheduling and avoidance) is beneficial for both anxiety and depression.[49-51] Physical activity should be encouraged among most adults with CHD so that they may experience both physical and mental health benefits.[52, 53] Despite the fact that exercise is safe and recommended for most adults with CHD,[52, 54] many patients avoid certain physical activities.[13, 55] We encourage medically-approved physical activity primarily as a strategy to increase psychological well-being, resilience, and confidence. Participants are encouraged to speak with their cardiac team regarding specific questions (e.g., physical activity limitations).

Relaxation training is an important component of empirically-validated psychological treatments for anxiety related to medical conditions,[56, 57] including heart disease.[58-60] The ACHD-CARE Program

provides instruction in 4 specific relaxation techniques to appeal to individual preferences for relaxation methods: (i) diaphragmatic breathing, (ii) progressive muscle relaxation, (iii) autogenic training, and (iv) guided imagery. Participants are e-mailed relaxation sound files or given a CD (as per patient preference) to facilitate regular guided practice.

Social interaction and communication skills: The intervention is provided in a group to maximize social support, foster discussion, and normalize patient concerns. Social support has been demonstrated to have positive impact on psychological distress and health outcomes[61, 62] and is related to positive outcomes in cardiac patients.[63] Social adjustment is also strongly related to psychological functioning in adults with CHD[19] although deficits in social cognition are common.[64] We also provide strategies to enhance assertive communication with other people, including with health professionals. This was deemed important as our previous research showed that approximately 50% of adults with CHD have difficulty understanding or explaining symptoms or concerns to their cardiologist.[65]

PHASE TWO: FEASIBILITY STUDY PROTOCOL

Complex interventions are marked by interactions among the various components within the experimental and control conditions, multiple behaviours required of the individuals delivering and receiving the intervention, multiple outcomes, and the need for flexibility in delivery.[66] Feasibility studies help determine whether an intervention should undergo further definitive testing in a full-scale randomized controlled trial (RCT).[67] Within a feasibility study, it is not sufficient to describe the outcomes of interest in a full-scale RCT. Rather, piloting this intervention allows for the assessment of the feasibility and acceptance of the design and procedures (e.g., eligibility, recruitment and retention rates as well as the willingness of patients to be randomized to a no-treatment control group). It also allows for the assessment of the acceptability of the intervention and calculation of the standard

deviation of the outcome measure in order to facilitate future sample size calculations. Feasibility studies have proven useful when trialing psychosocial interventions in medical settings.[68-71]

Objectives and Hypotheses

Thabane et al. outlined four areas in which to assess feasibility and these guided our approach: (i) process, (ii) resources, (iii) management, and (iv) scientific outcomes.[72] We also selected a fifth domain, namely the acceptability of the study design and intervention (see Table 2). With regard to process, we hypothesized that patients would be interested in the trial and able to complete study procedures. Consistent with previous studies, we anticipated that over 60% of eligible patients who were approached and were eligible for participation would consent to take part.[73, 74] We also hypothesized that the study would be achievable without significant human or data management problems, that the intervention would be associated with improved psychosocial outcomes, and that the intervention would be accepted and valued by patients and the health care team.

Study design

We designed a 2-parallel arm non-blinded pilot RCT using individual patient randomization in blocks of 2 to: (1) the ACHD-CARE intervention or (2) Usual Care. The allocation ratio was 1:1, and was concealed through using an online randomization service (www.randomizer.org). Assessment points are pre-test, post-test (i.e., corresponding to the end of the 8 week intervention for those in the intervention group), and three-month follow-up.

This study was designed in accordance with CONSORT guidelines for randomized trials of nonpharmacologic treatment.[75] This study has the approval of the local institutional ethics review board and is registered at clinicaltrials.gov (NCT01881893). A study schema is presented in Figure 1.

Participants

Power calculations need not be undertaken in feasibility studies; sample size should instead be adequate to estimate recruitment rates.[72, 76, 77] To estimate effect sizes from pilot studies, 15-20 participants per group is recommended[78] and common among feasibility trials of psychosocial interventions.[68, 70, 79-81] To account for attrition, we aimed for the upper limit of this range, namely randomization of approximately 40 patients.

The following are study inclusion criteria: (i) documented CHD, as confirmed by echocardiogram, cardiac catheterization, or previous surgery, (ii) age $\geq$ 18 years, (iii) English-language proficiency sufficient to read and complete the consent form and questionnaires and participate in an English-language group, (iv) no planned surgery during patient's participation in the study, and (v) clinically-elevated score (i.e., $\geq$8) on the Hospital Anxiety and Depression Scale[82] depression (HADS-D) or anxiety (HADS-A) subscale. We restrict participation to patients with elevated symptoms of depression and/or anxiety because interventions have generally been shown to be most effective for patients with higher baseline distress.[83, 84] The following are study exclusion criteria: (i) current participation in psychotherapy, (ii) significant cognitive impairment, psychosis, or personality disorder as documented in their medical chart, and (iii) report of suicidal intent during screening.

Procedure

Setting

The study is conducted at the Peter Munk Cardiac Centre at the University Health Network, which is an urban tertiary care hospital located in Toronto, Canada. This hospital is home to the Toronto Congenital Cardiac Centre for Adults (TCCCA). The TCCCA was the first program established specifically to look after adult survivors of the pioneering surgery that saved the lives of children with CHD, and it remains the largest such program in the world. It has over 3,200 unique patient visits/year, with clinics held 5 days/week.

Recruitment

Four recruitment strategies were selected: in-clinic recruitment at our Adult CHD clinic (Toronto, Canada), study flyers posted throughout the hospital, referrals from clinic physicians and nurses, and a posting of the study on the website of the national CHD patient organization. With regard to the former, during routine outpatient cardiology clinic appointments, patients are approached by the study coordinator using a stepwise approach. First, patients were asked whether they are interested in learning about a research study with a focus on coping with stress. Assenting patients are then provided a brief verbal study overview along with a study information handout. For patients who choose to proceed with the study, written and verbal consent are obtained. Patients are informed that the completion of a screening survey (which include the HADS) and medical record review are necessary to determine study eligibility.

With regard to other recruitment strategies, study information flyers (with pull-tab phone numbers) are posted at strategic locations in the hospital. At the initiation of the national patient organization, the Canadian Congenital Heart Alliance (www.cchaforlife), a description of the study has been posted on their website. When interested individuals telephone, the study coordinator confirms the presence of CHD. Interested patients who are contacted by telephone are requested to provide their mailing address

and the study coordinator mails two copies of the consent form along with the screening survey and a stamped self-addressed return envelope.

Screening

Consenting patients complete a screening survey that includes the HADS as well as three additional questions pertaining to eligibility criteria: planned heart surgery, current psychotherapy, and suicidal ideation. Only patients with an elevated HADS subscale and who answered negatively to other three items are eligible for randomization. All participants who complete the screening survey are provided with a handout outlining various options to seek mental health services should they wish to do so independently from the study.

Randomization

Eligible participants complete a full battery of baseline surveys prior to randomization (described in detail below). Eligible participants are then randomly assigned to one of the two conditions. Post-randomization, the participants in the treatment arm are contacted and informed of their group allocation and their availability to attend sessions is determined. ACHD-CARE groups are not initiated until a minimum of 4 patients confirm their availability to attend.

Usual Care condition

Usual Care was chosen as the comparison group in this study. Within trials of psychosocial interventions with cardiac patients, there are examples in which interventions were not superior to Usual Care, and some non-specific interventions have even been associated with adverse effects.[73, 85, 86] There are

moderating effects (e.g., baseline distress, sex, treatment acceptance) that impact the efficacy of psychosocial interventions.[83, 84, 87] Moreover, there are no existing psychosocial interventions established as beneficial for this population to serve as a comparison. Therefore, rather than instituting a comparison condition where patients undergo time-comparable visits with a health provider which may be harmful, we contended that a Usual Care comparison was the most ethical approach. It has also been argued that results of a study that establish a superior intervention among 2 interventions cannot be extrapolated to establish that the superior intervention is better than Usual Care.[88] These factors formed the basis for selection of a Usual Care comparison.

Measures

Primary and secondary intervention outcome measures

All participants complete three sets of online surveys, beginning with the baseline surveys, which are completed prior to randomization. Survey links are e-mailed to participants. To ensure privacy, participants are provided with a unique username and password combination; no personal health information is required for survey completion. Up to two email reminders are sent as needed.

The primary outcomes are symptoms of anxiety and depression as assessed with the HADS.[82] This 14-item measure of mood and anxiety has 7 items focused on each domain; scale scores $\geq$ 8 indicate elevated symptoms. The HADS was developed and psychometrically validated for use with individuals with medical conditions.[89] It has proven to be responsive to interventions with cardiac populations.[90, 91]

Secondary measures in four domains were chosen to determine their suitability for potential inclusion in a future full-scale RCT. First, two psychometrically-validated measures of social functioning are

included: the Social Functioning subscale of the Short-Form Health Status Survey (SF-12v2)[92] and the second is the ENRICHD Social Support Inventory (ESSI).[41, 93] ESSI scores have been shown to be sensitive to change in a psychosocial intervention in cardiac patients.[41] Second, we assess resilience using the Resilience Scale (RS) which has strong psychometric properties and has been shown to improve following intervention. [94 95 22] Third we evaluate QOL in accordance with published guidelines.[96] We administer the Satisfaction with Life Scale (SWLS), which is a 5-item measure with proven reliability and validity.[97, 98] Unlike health-dependent QOL measures, the SWLS allows respondents to weight domains on an individual basis and has been used with adults with CHD.[99-102] We also administer a QOL linear analogue scale (LAS), which has been recommended as an assessment of global QOL in clinical research.[101-103] Fourth, health status is assessed with the SF-12v2.[92] The SF-12 is an efficient and reliable 12-item alternative to the Short Form-36, which is considered the most appropriate generic instrument to assess health-related QOL among cardiac patient populations.[104, 105] It produces 2 component summaries: physical component summary (PCS) and mental component summary (MCS). Higher PCS and MCS scores reflect fewer limitations and better health-related QOL. Test-retest reliability and internal consistency have been demonstrated.[92, 106] We also include the EQ-5D, which is a measure of generic health status that can be used for clinical and (possible future) economic evaluation.[107, 108]

Feasibility measures

Feasibility is assessed in five domains (Table 2). First, with regard to process, the rates of recruitment (by recruitment method) and eligibility are recorded. We also document acceptance of randomization and participant retention at both follow-up assessment points. Finally, data regarding patients' decisions not to participate in the study (if willing) are also recorded. Second, with regard to resources, we calculate the timeline of each patient's participation throughout the course of the study in addition to the

time required for study procedures. All study-related expenses are reported to allow for calculating the total budget (personnel and materials) for a future full-scale RCT. Additionally we calculate the total cost (personnel and materials) of providing the intervention which allows for calculating the budget for knowledge translation/ potential clinical implementation. Third, with regard to management, challenges experienced while conducting the trial are systematically recorded, as are suggestions to facilitate the conduct of a full-scale RCT

We are considering scientific outcomes in four areas: safety, treatment fidelity, means and standard deviations, and effect size. We monitor any adverse psychological reactions experienced by participants. We also evaluate treatment fidelity (adherence to ACHD-CARE manual/program) using both indirect and direct methods.[109] As an indirect approach, the counselor completes checklists of session procedures. As a direct approach, all sessions are audiotaped and an external auditor (not one of the counselors) listens to a random sampling of group sessions (25% in total; 2 from each treatment group) and completes a similar checklist. As per CONSORT guidelines,[75] as a quality control procedure, the counselor records notes following each session, with a particular focus on documenting how the intervention was both standardized and varied from the manual. With regard to pilot testing of the intervention, the means and standard deviations for outcome measures at each time-point (baseline, post-test, 3 months post-test) by experimental condition will be reported. The proportion, by condition, of patients who moved from above the HADS-A or HADS-D cut-off ($\geq$8) to below the cut-off score will also reported. For an estimate of the intervention effect, a repeated measures analysis of variance (ANOVA) will be computed on the primary outcome measures (HADS-A and HADS-D). An intent-to-treat analysis including all randomized participants will be used. Generalized eta squared will be computed to estimate the effect sizes for both HADS outcomes.[110, 111]

The final area is acceptability of the intervention. Engagement with the ACHD-CARE Program is assessed using two techniques utilized in a previous trial of a psychological intervention for cardiac patients.[112] We calculate the ratio of sessions attended to sessions scheduled, as well as the ratio of homework assignments completed to the total number of homework assignments. To determine the acceptability of the intervention, ACHD-CARE participants complete an additional feedback survey at the end of the group sessions. Patient acceptance regarding the specific intervention components, usefulness of specific coping strategies, content and presentation of educational materials, and the overall group experience is assessed using open- and closed-ended questions and rating scales adapted from Irvine et al.[113] Finally, once study results are available, we will invite all participants (those randomly assigned to the ACHD-CARE intervention as well as Usual Care) to participate in an additional telephone feedback session. During this session, we will provide a summary of the study findings and invite participant feedback on the study processes (e.g., recruitment, randomization) and results (i.e., any changes in HADS scores).

Analyses

Descriptive analyses are the focus of feasibility studies.[114] Both numerical feasibility outcomes (e.g., rates of recruitment and retention, financial costs) as well as those outcomes more appropriately provided as verbatim data text (e.g., challenges associated with study implementation) will be reported.

RESULTS

Preliminary feasibility outcomes

Our initial experiences offer no indication that a full-scale RCT would not be feasible. We have been able to successfully recruit and retain patients, and in-clinic recruitment appears to be the most successful strategy. The primary reasons for patient disinterest in study participation are travel distance and competing time demands. We are able to conduct the study within the allotted budget and there have been no insurmountable management challenges. Minor challenges coordinating schedules of participants randomized into the ACHD-CARE intervention; evening groups appear to be most convenient. We have had no indications that the intervention is unacceptable to patients or providers.

Global determination of study feasibility

At the conclusion of the study, we will be poised to make one of three determinations: (1) a full-scale RCT is feasible, (2) a full-scale RCT is feasible with modifications, or (3) a full-scale RCT is not feasible. Pending positive feasibility and acceptability outcomes, we could consider proceeding with a multi-site RCT including other centres managing the care of adults with CHD.

DISCUSSION

Significant improvements in diagnosis and surgical and medical treatment have contributed to a growing cohort of adults with CHD. Though one-third of North American adults with CHD have diagnosable mood or anxiety disorders, most do not receive appropriate mental health treatment. Our own quantitative and qualitative research suggests that as a group, patients themselves recognize the importance of addressing their psychosocial needs in addition to their medical needs.

The ACHD-CARE program is the first intervention designed to target psychosocial outcomes for adult CHD populations. We are unaware of any other study targeting the psychosocial needs of pediatric or

adult CHD populations and we were unable to locate any similar studies registered at clinicaltrials.gov. It would, however, be premature to being with a full-scale RCT. Instead, we implemented the Medical Research Council's methodological four-phase framework for the development of complex interventions. In this manuscript, we presented the first two phases. First, we reviewed the development of a group psychosocial intervention aimed at improving the psychosocial functioning, QOL, and resilience of adults with CHD. The development included quantitative and qualitative inquiry in to the perspectives of adults with CHD regarding their own mental health care needs. Second, we outlined out methodology necessary to undertake feasibility and pilot-testing of the intervention.

Within this feasibility study, scientific outcomes (regarding the impact of the intervention on psychosocial measures) are not the primary focus. Rather, this study underscores the importance of carefully developing and testing the methodology of evaluating psychosocial interventions in medical populations before moving to full-scale clinical trials. Although initial results appear promising, the ultimate goal of this study is to determine the feasibility of a future full-scale randomized controlled trial (RCT). As such, feasibility outcomes from this study will guide the future evaluation and provision of psychological treatment for adults with CHD.

References

1.Verheugt CL, Uiterwaal CS, van der Velde ET, et al. Mortality in adult congenital heart disease. *Eur Heart J*. 2010; 31: 1220-9.
2.Khairy P, Ionescu-Ittu R, Mackie AS, Abrahamowicz M, Pilote L and Marelli AJ. Changing mortality in congenital heart disease. *J Am Coll Cardiol*. 2010; 56: 1149-57.
3.Warnes CA. The adult with congenital heart disease: born to be bad? *J Am Coll Cardiol*. 2005; 46: 1-8.
4.Marelli AJ, Ionescu-Ittu R, Mackie AS, Guo L, Dendukuri N and Kaouache M. Lifetime prevalence of congenital heart disease in the general population from 2000 to 2010. *Circulation*. 2014; 130: 749-56.
5.Somerville J. Management of adults with congenital heart disease: an increasing problem. *Annu Rev Med*. 1997; 48: 283-93.
6.Engelfriet P, Boersma E, Oechslin E, et al. The spectrum of adult congenital heart disease in Europe: morbidity and mortality in a 5 year follow-up period. The Euro Heart Survey on adult congenital heart disease. *Eur Heart J*. 2005; 26: 2325-33.
7.Kovacs AH, Sears SF and Saidi AS. Biopsychosocial experiences of adults with congenital heart disease: review of the literature. *Am Heart J*. 2005; 150: 193-201.
8.Moons P, De Geest S and Budts W. Comprehensive care for adults with congenital heart disease: expanding roles for nurses. *Eur J Cardiovasc Nurs*. 2002; 1: 23-8.
9.Stam H, Hartman EE, Deurloo JA, Groothoff J and Grootenhuis MA. Young adult patients with a history of pediatric disease: impact on course of life and transition into adulthood. *J Adolesc Health*. 2006; 39: 4-13.
10.Popelova J, Slavik Z and Skovranek J. Are cyanosed adults with congenital cardiac malformations depressed? *Cardiol Young*. 2001; 11: 379-84.
11.Kamphuis M, Vogels T, Ottenkamp J, Van Der Wall EE, Verloove-Vanhorick SP and Vliegen HW. Employment in adults with congenital heart disease. *Arch Pediatr Adolesc Med*. 2002; 156: 1143-8.
12.Brandhagen DJ, Feldt RH and Williams DE. Long-term psychologic implications of congenital heart disease: a 25-year follow-up. *Mayo Clinic Proceedings*. 1991; 66: 474-9.
13.Horner T, Liberthson R and Jellinek MS. Psychosocial profile of adults with complex congenital heart disease. *Mayo Clin Proc*. 2000; 75: 31-6.
14.Kokkonen J and Paavilainen T. Social adaptation of young adults with congenital heart disease. *International Journal of Cardiology*. 1992; 36: 23-9.
15.McMurray R, Kendall L, Parsons JM, et al. A life less ordinary: growing up and coping with congenital heart disease. *Coronary Health Care*. 2001; 5: 51-7.
16.Ong L, Nolan RP, Irvine J and Kovacs AH. Parental overprotection and heart-focused anxiety in adults with congenital heart disease. *Int J Behav Med*. 2011; 18: 260-7.
17.Page MG, Kovacs AH and Irvine J. How do psychosocial challenges associated with living with congenital heart disease translate into treatment interests and preferences? A qualitative approach. *Psychology & health*. 2012; 27: 1260-70.
18.Bromberg JI, Beasley PJ, D'Angelo EJ, Landzberg M and DeMaso DR. Depression and anxiety in adults with congenital heart disease: a pilot study. *Heart and Lung*. 2003; 32: 105-10.
19.Kovacs AH, Saidi AS, Kuhl EA, et al. Depression and anxiety in adult congenital heart disease: predictors and prevalence. *Int J Cardiol*. 2009; 137: 158-64.
20.Bijl RV, de Graaf R, Hiripi E, et al. The prevalence of treated and untreated mental disorders in five countries. *Health Aff (Millwood)*. 2003; 22: 122-33.
21.Linden W, Phillips MJ and Leclerc J. Psychological treatment of cardiac patients: a meta-analysis. *Eur Heart J*. 2007; 28: 2972-84.
22.Cho EA and Oh HE. [Effects of laughter therapy on depression, quality of life, resilience and immune responses in breast cancer survivors]. *J Korean Acad Nurs*. 2011; 41: 285-93.

23.Lavretsky H, Siddarth P and Irwin MR. Improving depression and enhancing resilience in family dementia caregivers: a pilot randomized placebo-controlled trial of escitalopram. *Am J Geriatr Psychiatry*. 2010; 18: 154-62.
24.Fava GA and Tomba E. Increasing psychological well-being and resilience by psychotherapeutic methods. *J Pers*. 2009; 77: 1903-34.
25.Moon JR, Huh J, Kang IS, Park SW, Jun TG and Lee HJ. Factors influencing depression in adolescents with congenital heart disease. *Heart Lung*. 2009; 38: 419-26.
26.Hjemdal O, Vogel PA, Solem S, Hagen K and Stiles TC. The relationship between resilience and levels of anxiety, depression, and obsessive-compulsive symptoms in adolescents. *Clin Psychol Psychother*. 2011; 18: 314-21.
27.Runkewitz K, Kirchmann H and Strauss B. Anxiety and depression in primary care patients: predictors of symptom severity and developmental correlates. *J Psychosom Res*. 2006; 60: 445-53.
28.Connelly MS, Webb GD, Somerville J, et al. Canadian Consensus Conference on Adult Congenital Heart Disease 1996. *Can J Cardiol*. 1998; 14: 395-452.
29.Deanfield J, Thaulow E, Warnes C, et al. Management of grown up congenital heart disease. *Eur Heart J*. 2003; 24: 1035-84.
30.Warnes CA, Williams RG, Bashore TM, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Develop Guidelines on the Management of Adults With Congenital Heart Disease). Developed in Collaboration With the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2008; 52: e1-121.
31.Lane DA, Millane TA and Lip GY. Psychological interventions for depression in adolescent and adult congenital heart disease. *Cochrane Database Syst Rev*. 2013; 10: CD004372.
32.Kovacs AH, Bendell KL, Colman J, Harrison JL, Oechslin E and Silversides C. Adults with congenital heart disease: psychological needs and treatment preferences. *Congenit Heart Dis*. 2009; 4: 139-46.
33.Silva AM, Vaz C, Areias ME, et al. Quality of life of patients with congenital heart diseases. *Cardiol Young*. 2011: 1-7.
34.Haby MM, Donnelly M, Corry J and Vos T. Cognitive behavioural therapy for depression, panic disorder and generalized anxiety disorder: a meta-regression of factors that may predict outcome. *Aust N Z J Psychiatry*. 2006; 40: 9-19.
35.Hofmann SG and Smits JA. Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *J Clin Psychiatry*. 2008; 69: 621-32.
36.Stewart RE and Chambless DL. Cognitive-behavioral therapy for adult anxiety disorders in clinical practice: a meta-analysis of effectiveness studies. *J Consult Clin Psychol*. 2009; 77: 595-606.
37.Tolin DF. Is cognitive-behavioral therapy more effective than other therapies? A meta-analytic review. *Clin Psychol Rev*. 2010; 30: 710-20.
38.Crepaz N, Passin WF, Herbst JH, et al. Meta-analysis of cognitive-behavioral interventions on HIV-positive persons' mental health and immune functioning. *Health Psychol*. 2008; 27: 4-14.
39.Tatrow K and Montgomery GH. Cognitive behavioral therapy techniques for distress and pain in breast cancer patients: a meta-analysis. *J Behav Med*. 2006; 29: 17-27.
40.Malouff JM, Thorsteinsson EB, Rooke SE, Bhullar N and Schutte NS. Efficacy of cognitive behavioral therapy for chronic fatigue syndrome: a meta-analysis. *Clin Psychol Rev*. 2008; 28: 736-45.
41.Berkman LF, Blumenthal J, Burg M, et al. Effects of treating depression and low perceived social support on clinical events after myocardial infarction: the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHD) Randomized Trial. *JAMA*. 2003; 289: 3106-16.

42.Kohn CS, Petrucci RJ, Baessler C, Soto DM and Movsowitz C. The effect of psychological intervention on patients' long-term adjustment to the ICD: a prospective study. *Pacing Clin Electrophysiol*. 2000; 23: 450-6.
43.Frizelle DJ, Lewin RJ, Kaye G, et al. Cognitive-behavioural rehabilitation programme for patients with an implanted cardioverter defibrillator: a pilot study. *Br J Health Psychol*. 2004; 9: 381-92.
44.Sears SF, Sowell LD, Kuhl EA, et al. The ICD shock and stress management program: a randomized trial of psychosocial treatment to optimize quality of life in ICD patients. *Pacing Clin Electrophysiol*. 2007; 30: 858-64.
45. Beck JS. *Cognitive therapy: basics and beyond*. New York: Guilford, 1995.
46.Segal ZV, Williams JMG and Teasdale JD. *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. New York: Guilford Press, 2002.
47.Kuyken W, Watkins E, Holden E, et al. How does mindfulness-based cognitive therapy work? *Behav Res Ther*. 2010; 48: 1105-12.
48.Teasdale JD, Segal ZV, Williams JM, Ridgeway VA, Soulsby JM and Lau MA. Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *J Consult Clin Psychol*. 2000; 68: 615-23.
49.Mausbach BT, Chattillion EA, Moore RC, Roepke SK, Depp CA and Roesch S. Activity restriction and depression in medical patients and their caregivers: a meta-analysis. *Clin Psychol Rev*. 2011; 31: 900-8.
50.Trew JL. Exploring the roles of approach and avoidance in depression: An integrative model. *Clin Psychol Rev*. 2011; 31: 1156-68.
51.Kanter JW, Manos RC, Bowe WM, Baruch DE, Busch AM and Rusch LC. What is behavioral activation? A review of the empirical literature. *Clin Psychol Rev*. 2010.
52.Dua JS, Cooper AR, Fox KR and Graham Stuart A. Exercise training in adults with congenital heart disease: feasibility and benefits. *Int J Cardiol*. 2010; 138: 196-205.
53.Blair SN and Morris JN. Healthy hearts--and the universal benefits of being physically active: physical activity and health. *Ann Epidemiol*. 2009; 19: 253-6.
54.Hirth A, Reybrouck T, Bjarnason-Wehrens B, Lawrenz W and Hoffmann A. Recommendations for participation in competitive and leisure sports in patients with congenital heart disease: a consensus document. *Eur J Cardiovasc Prev Rehabil*. 2006; 13: 293-9.
55.Dua JS, Cooper AR, Fox KR and Graham Stuart A. Physical activity levels in adults with congenital heart disease. *Eur J Cardiovasc Prev Rehabil*. 2007; 14: 287-93.
56.Taylor DN. Effects of a behavioral stress-management program on anxiety, mood, self-esteem, and T-cell count in HIV positive men. *Psychol Rep*. 1995; 76: 451-7.
57.Burish TG, Carey MP, Krozely MG and Greco FA. Conditioned side effects induced by cancer chemotherapy: prevention through behavioral treatment. *J Consult Clin Psychol*. 1987; 55: 42-8.
58.Mannix LK, Chandurkar RS, Rybicki LA, Tusek DL and Solomon GD. Effect of guided imagery on quality of life for patients with chronic tension-type headache. *Headache*. 1999; 39: 326-34.
59.Carlson CR and Hoyle RH. Efficacy of abbreviated progressive muscle relaxation training: a quantitative review of behavioral medicine research. *J Consult Clin Psychol*. 1993; 61: 1059-67.
60.Dusseldorp E, van Elderen T, Maes S, Meulman J and Kraaij V. A meta-analysis of psychoeduational programs for coronary heart disease patients. *Health Psychol*. 1999; 18: 506-19.
61.Allan R and Scheidt S. Empirical basis for cardiac psychology. In: Allan R and Scheidt S, (eds.). *Heart and mind: the practice of cardiac psychology*. Washington, D.C.: American Psychological Association, 1996, p. 63-123.
62.Toobert DJ, Glasgow RE, Nettekoven LA and Brown JE. Behavioral and psychosocial effects of intensive lifestyle management for women with coronary heart disease. *Patient Educ Couns*. 1998; 35: 177-88.

63.Duits AA, Boeke S, Taams MA, Passchier J and Erdman RA. Prediction of quality of life after coronary artery bypass graft surgery: a review and evaluation of multiple, recent studies. *Psychosom Med*. 1997; 59: 257-68.
64.Bellinger DC. Are children with congenital cardiac malformations at increased risk of deficits in social cognition? *Cardiol Young*. 2008; 18: 3-9.
65.Liu S, Balint HO, Burchill L, Silversides C and Kovacs AH. Parenting factors impact communication between young adults with congenital heart disease and their cardiologists. *Canadian Cardiovascular Congress*. Montreal, Canada2010.
66.Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I and Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008; 337: a1655.
67.Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. 2009; 36: 452-7.
68.Barrera M and Schulte F. A group social skills intervention program for survivors of childhood brain tumors. *Journal of pediatric psychology*. 2009; 34: 1108-18.
69.Naumann F, Munro A, Martin E, et al. An individual-based versus group-based exercise and counselling intervention for improving quality of life in breast cancer survivors. A feasibility and efficacy study. *Psycho-oncology*. 2012; 21: 1136-9.
70.Kazak AE, Simms S, Alderfer MA, et al. Feasibility and preliminary outcomes from a pilot study of a brief psychological intervention for families of children newly diagnosed with cancer. *Journal of pediatric psychology*. 2005; 30: 644-55.
71.Altschuler A, Rosenbaum E, Gordon P, Canales S and Avins AL. Audio recordings of mindfulness-based stress reduction training to improve cancer patients' mood and quality of life--a pilot feasibility study. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*. 2012; 20: 1291-7.
72.Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010; 10: 1.
73.Frasure-Smith N, Lesperance F, Prince RH, et al. Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. *Lancet*. 1997; 350: 473-9.
74.Irvine J, Firestone J, Ong L, et al. A randomized controlled trial of cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. *Psychosom Med*. 2011; 73: 226-33.
75.Boutron I, Moher D, Altman DG, Schulz KF and Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of internal medicine*. 2008; 148: 295-309.
76.National Institute for Health Research Evaluation T, and Studies Coordinating Centre.
77.Arain M, Campbell MJ, Cooper CL and Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010; 10: 67.
78.Hertzog MA. Considerations in determining sample size for pilot studies. *Res Nurs Health*. 2008; 31: 180-91.
79.Naumann F, Munro A, Martin E, et al. An individual-based versus group-based exercise and counselling intervention for improving quality of life in breast cancer survivors. A feasibility and efficacy study. *Psycho-oncology*. 2011.
80.Altschuler A, Rosenbaum E, Gordon P, Canales S and Avins AL. Audio recordings of mindfulness-based stress reduction training to improve cancer patients' mood and quality of life-a pilot feasibility study. *Support Care Cancer*. 2011.
81.Carmack CL, Basen-Engquist K, Yuan Y, et al. Feasibility of an expressive-disclosure group intervention for post-treatment colorectal cancer patients: Results of the healthy expressions study. *Cancer*. 2011.

82.Zigmond AS and Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983; 67: 361-70.
83.Coyne JC, Lepore SJ and Palmer SC. Efficacy of psychosocial interventions in cancer care: evidence is weaker than it first looks. *Ann Behav Med*. 2006; 32: 104-10.
84.Schneider S, Moyer A, Knapp-Oliver S, Sohl S, Cannella D and Targhetta V. Pre-intervention distress moderates the efficacy of psychosocial treatment for cancer patients: a meta-analysis. *J Behav Med*. 2010; 33: 1-14.
85.Jones DA and West RR. Psychological rehabilitation after myocardial infarction: multicentre randomised controlled trial. *BMJ*. 1996; 313: 1517-21.
86.Taylor CB, Miller NH, Smith PM and DeBusk RF. The effect of a home-based, case-managed, multifactorial risk-reduction program on reducing psychological distress in patients with cardiovascular disease. *J Cardiopulm Rehabil*. 1997; 17: 157-62.
87.Crossmann A, Schulz SM, Kuhlkamp V, et al. A randomized controlled trial of secondary prevention of anxiety and distress in a German sample of patients with an implantable cardioverter defibrillator. *Psychosom Med*. 2010; 72: 434-41.
88.Thompson BT and Schoenfeld D. Usual care as the control group in clinical trials of nonpharmacologic interventions. *Proc Am Thorac Soc*. 2007; 4: 577-82.
89.Bjelland I, Dahl AA, Haug TT and Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res*. 2002; 52: 69-77.
90.Turner SC, Evans JA, Bethell HJ and Goddard J. Psychological assessments for cardiac rehabilitation patients. *Int J Cardiol*. 2003; 92: 201-7.
91.Irvine J, J. F, Ong L, et al. Cognitive behavior therapy tailored to psychological adaptation to an implantable cardioverter defibrillator. (Manuscript in preparation).
92.Ware J, Jr., Kosinski M and Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996; 34: 220-33.
93.Mitchell PH, Powell L, Blumenthal J, et al. A short social support measure for patients recovering from myocardial infarction: the ENRICHD Social Support Inventory. *J Cardiopulm Rehabil*. 2003; 23: 398-403.
94.Wagnild GM and Young HM. Development and psychometric evaluation of the Resilience Scale. *J Nurs Meas*. 1993; 1: 165-78.
95.Windle G, Bennett KM and Noyes J. A methodological review of resilience measurement scales. *Health Qual Life Outcomes*. 2011; 9: 8.
96.Moons P, Jaarsma T and Norekval TM. Requirements for quality-of-life reports. *Eur J Cardiovasc Nurs*. 2010; 9: 141-3.
97.Diener E, Emmons RA, Larsen RJ and Griffin S. The Satisfaction With Life Scale. *J Pers Assess*. 1985; 49: 71-5.
98.Pavot W, Diener E, Colvin CR and Sandvik E. Further validation of the Satisfaction with Life Scale: evidence for the cross-method convergence of well-being measures. *J Pers Assess*. 1991; 57: 149-61.
99.Moons P, Van Deyk K, Marquet K, et al. Individual quality of life in adults with congenital heart disease: a paradigm shift. *Eur Heart J*. 2005; 26: 298-307.
100.Moons P, Van Deyk K, De Bleser L, et al. Quality of life and health status in adults with congenital heart disease: a direct comparison with healthy counterparts. *Eur J Cardiovasc Prev Rehabil*. 2006; 13: 407-13.
101.Moons P, Van Deyk K, De Geest S, Gewillig M and Budts W. Is the severity of congenital heart disease associated with the quality of life and perceived health of adult patients? *Heart*. 2005; 91: 1193-8.
102.Moons P, Van Deyk K, Marquet K, De Bleser L, De Geest S and Budts W. Profile of adults with congenital heart disease having a good, moderate, or poor quality of life: a cluster analytic study. *Eur J Cardiovasc Nurs*. 2009; 8: 151-7.

103.de Boer AG, van Lanschot JJ, Stalmeier PF, et al. Is a single-item visual analogue scale as valid, reliable and responsive as multi-item scales in measuring quality of life? *Qual Life Res*. 2004; 13: 311-20.
104.Muller-Nordhorn J, Roll S and Willich SN. Comparison of the short form (SF)-12 health status instrument with the SF-36 in patients with coronary heart disease. *Heart*. 2004; 90: 523-7.
105.Dempster M and Donnelly M. Measuring the health related quality of life of people with ischaemic heart disease. *Heart*. 2000; 83: 641-4.
106.Luo X, Lynn George M, Kakouras I, et al. Reliability, validity, and responsiveness of the short form 12-item survey (SF-12) in patients with back pain. *Spine (Phila Pa 1976)*. 2003; 28: 1739-45.
107.EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy*. 1990; 16: 199-208.
108.Dyer MT, Goldsmith KA, Sharples LS and Buxton MJ. A review of health utilities using the EQ-5D in studies of cardiovascular disease. *Health Qual Life Outcomes*. 2010; 8: 13.
109.Perepletchikova F, Treat TA and Kazdin AE. Treatment integrity in psychotherapy research: analysis of the studies and examination of the associated factors. *J Consult Clin Psychol*. 2007; 75: 829-41.
110.Bakeman R. Recommended effect size statistics for repeated measures designs. *Behav Res Methods*. 2005; 37: 379-84.
111.Olejnik S and Algina J. Generalized eta and omega squared statistics: measures of effect size for some common research designs. *Psychol Methods*. 2003; 8: 434-47.
112.Cowan MJ, Freedland KE, Burg MM, et al. Predictors of treatment response for depression and inadequate social support--the ENRICHD randomized clinical trial. *Psychother Psychosom*. 2008; 77: 27-37.
113.Irvine J, Stanley J, Ong L, et al. Acceptability of a cognitive behavior therapy intervention to implantable cardioverter defibrillator recipients. *J Cognitive Psychotherapy*. (In press).
114.Hagen NA, Biondo PD, Brasher PM and Stiles CR. Formal Feasibility Studies in Palliative Care: Why They Are Important and How to Conduct Them. *J Pain Symptom Manage*. 2011.

Table 1. ACHD-CARE Program Session Overview

Session	Title	Content
1	**The Mind-Body Connection**	• Program goals/overview • CHD general education • Challenges, coping, and resilience • Mind-body connection • Introduction to relaxation training
2	**Stress and Coping**	• Sources and symptoms of stress • Managing stress, mood & anxiety • Continuation of relaxation training
3	**Awareness of your Thoughts**	• Discussion of common emotions • Introduction to A-B-C's of Thinking • Awareness of One's Thinking • Continuation of relaxation training
4	**Shifting Your Thoughts**	• Review of A-B-C's • Introduction to cognitive restructuring • Continuation of relaxation training
5	**Shifting Your Thoughts and Behaviours**	• Continuation of cognitive restructuring • Planning pleasant events
6	**Doing Things Differently**	• Physical activity • Activity pacing • Strategies to improve sleep
7	**Focus on Communication**	• Talking with new people • Communication skills • Assertion
8	**Embracing the Future**	• Talking with your doctor • Program review

Table 2. Feasibility Measures

Focus	Method of Assessment
Process	Method of recruitment Participation rate Retention rate Reason for declined participation Eligibility
Resources	Time Budget
Management	Human management Data Management Other implementation challenges
Scientific Outcomes	Safety Treatment Fidelity Means and standard deviations Effect Size
Acceptability of Intervention	Adherence Acceptability by patients Acceptability by counselor Acceptability by health care team

Figure 1. Study Schema