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Protocol for the development and validation of a measure of persistent psychological and emotional distress in cardiac patients: The Cardiac Distress Inventory

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Key words: cardiac distress, anxiety, depression, psychometrics, instrument development

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ABSTRACT

Introduction Distress is experienced by the majority of cardiac patients, yet no cardiac-specific measure of distress exists. The aim of this project is to develop and validate the Cardiac Distress Inventory (CDI). Using the CDI, health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event. Psychometric testing of a long form questionnaire will also result in the development of a short form screening version.

Methods and analysis An item pool will be generated through: identification of items by a multidisciplinary group of clinician researchers; review of generic and condition-specific distress measures; focus group testing with cardiac rehabilitation professionals; feedback from patients. The COSMIN criteria will be used to inform the development of the methodology for determining the CDI's psychometric properties. The item pool will be tested with 400 cardiac patients and responses subjected to exploratory factor analysis, Rasch analysis, test-retest reliability, construct validity testing, and latent class analysis. ROC analysis will be used to identify the optimal CDI cut off score for distinguishing whether a person experiences clinically significant distress. The study will take place over a 15 to 18-month period.

Ethics and dissemination This protocol has been approved by the Monash Health Human Research Ethics Committee (Approval number – RES-19-0000631L-55979 0). The CDI will be made available to clinicians and researchers without charge. The CDI will be translated for use with clinical populations internationally with reporting of the psychometric properties of those versions. Study findings will be shared with cardiac patient support groups; academic and medical communities via publications and presentations; in the training of cardiac secondary prevention health professionals; and in reports to funders. Authorship for all publications will be determined in line with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Strengths and limitations of this study

- This protocol describes the development and validation of the first available cardiac-specific distress measure.
- The measure is based on a multidisciplinary conceptualisation of the core construct, cardiac distress, while building on similar scale development in oncology and diabetes.
- The protocol describes a co-design process involving both cardiac patients and health professionals in item-generation and involves a range of quantitative psychometric methods in item-testing.
- We will compare a statistically-driven and a clinically-driven method to develop a short-form of the measure for use as a screening tool.

BACKGROUND

Conceptualisation of cardiac distress

As high prevalence conditions, much attention has been paid to the measurement and understanding of anxiety and depression as consequences of cardiac events. However, relatively little attention has been given to the phenomenon of 'cardiac distress' which many patients experience after acute coronary events such as myocardial infarction (AMI), unstable angina, or coronary artery bypass graft surgery (CABGS). In an earlier paper, we discussed the conceptualisation of cardiac distress and defined it as:

> "a persistent negative emotional state rather than a transient state; involving multiple psychosocial domains; that challenges a patient's capacity to cope with living with their heart condition, the treatment of the condition, and the resultant changes to daily living; and challenges the person's sense of self and future orientation"[1].

A number of previous studies have attempted to examine the relationship between post-cardiac event distress, symptom severity and mortality in relation to a range of specific heart conditions[2, 3] and procedures[4, 5], following cardiac rehabilitation[6], and in cardiovascular disease more generally[7]. A common characteristic of these studies, however, is the use of terms such as 'distress' without explicit definition. In some cases, distress is simply defined as being that which is measured by an instrument deemed to measure distress such as the Hospital Anxiety and Depression Scale[8], the General Health Questionnaire[9] or the Kessler Psychological Distress Scale[10]. Typically, these studies view psychological or emotional distress as a simple combination of anxiety and depression, as does a recent analysis of post-cardiac event psychological distress trajectories[11].

A small number of studies, however, widen this narrow view of distress by adding other psychosocial constructs to 'anxiety plus depression', including stress and stressful life events[12-14]; fear of death[13, 15]; hostility[12]; vital exhaustion and reduced quality of life[14]; vulnerabilities such as lack of pleasant events, dysfunctional attitudes, role transitions and poor dyadic adjustment[16]; feelings of helplessness, loss of control, and pain[15]; and psychological wellbeing[6].

The 'cardiac blues'

A broader approach to understanding the complexity of the psychological and emotional impacts of a cardiac event is evidenced in the concept of the 'cardiac blues' which describes a range of emotional responses to an acute cardiac event. It has been suggested that almost all patients experience at least some symptoms of the cardiac blues at the time of, or soon after, an acute cardiac event[17]. Common emotions include shock, low or fluctuating mood, sadness, worry, guilt and anger. Mood changes are displayed by tiredness, irritability, tearfulness, loss of pleasure in usual activities, withdrawal from others, early waking and other sleep disturbance, and changes in appetite and sex drive. Cognitive changes that typically co-occur include confusion and forgetfulness, inability to concentrate, nightmares, reduced self-esteem, concerns about role changes, particularly regarding paid work, physical health and independence; and pessimism about the future[17-19]. Although generally a transient condition[20, 21], if the cardiac blues does not resolve within around two months of the cardiac event, the psychological and emotional impact of the event can result in persistent cardiac distress[18, 19].

Measuring condition-specific distress

Both the oncology and diabetes fields have at least a two decade-long history of screening and psychosocial intervention for condition-specific distress. For oncology, this is reflected in the National Comprehensive Cancer Network Guidelines for Distress Management[22] where distress is considered to be a multifactorial unpleasant experience of a psychological (i.e., emotional, behavioural, cognitive), social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms or its treatment. An excellent earlier attempt to

conceptualise diabetes distress so that it could be recognised and addressed in nursing practice[23], has recently been extended by Dennick and colleagues[24]. They characterise distress as a range of negative emotional responses, such as worry, fear, frustration, guilt, sadness, anger, to aspects of living with and managing the condition, balanced against an appraisal of available coping resources[24]. Snoek and colleagues argue that diabetes-distress and depression are correlated and overlapping constructs, but are not interchangeable, and that distinguishing between them is an important factor in shaping appropriate mental health interventions[25]. In a recent systematic review of the impact of distress on health-related outcomes, Barry and colleagues agree also that distress is distinct from depression and should be assessed using condition-specific measures, as early as practicable in treatment[26].

Cardiac-specific measures of the psychosocial impact of cardiac events

The cardiac field also has a two decade-long history of attempts to measure aspects of the psychological and emotional impact of cardiac events. Examples of cardiac-specific measures include the Cardiac Depression Scale[27] , the Cardiac Event Threat Questionnaire[28], the Cardiac Anxiety Questionnaire[29], the MacNew Quality of Life measure[30] and the Screening Tool for Psychological Distress (STOP–D)[31]. These measures collectively assess a range of features associated with cardiac distress such as impaired quality of life, anxiety, depression, fear, death anxiety, illness-related dependency, feeling unable to cope, stress, worrying levels of pain, low perceived social support, and anger. However, none of the measures provides a comprehensive or detailed assessment of cardiac distress. Moreover, no currently existing measure would enable a psycho-cardiology professional to identify priority areas clearly enough to offer timely tailored psychosocial intervention for a distressed patient[32, 33]. Using the CDI, health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event.

Aims

The aims of the present study are:

1. To develop and validate the Cardiac Distress Inventory (CDI).
2. To develop a short form screening tool version of the CDI.

METHOD

Item generation

There are six steps in the item generation procedure:

i. Initial generation of items by a multidisciplinary group of researchers and clinicians including the disciplines of nursing, psychiatry, behavioural health, psychology and cardiology.
ii. Review of generic and condition-specific distress measures, to identify the elements comprising the construct of 'distress' in those measures and to identify items which could be adapted for the CDI.
iii. Review of cardiac-specific measures incorporating elements of distress as defined by the present authors[1].
iv. Review of items for appropriateness for a post-operative cardiac population by the multidisciplinary investigator group.
v. Focus group testing with two multidisciplinary groups of cardiac rehabilitation professionals: experienced practitioners undertaking intensive training in cardiac rehabilitation through the Australian Centre for Heart Health; and the National Executive of the Australian Cardiovascular Health and Rehabilitation Association (ACRA).

vi. Consultation with, and feedback from, cardiac patients (key informants) on the structure and content of the CDI.

Patient and public involvement

The need for a comprehensive measure of cardiac-related distress has been identified by the multidisciplinary clinician researcher members of the CDI development group, through their clinical practice in provision of psychosocial support to cardiac patients. This need has been endorsed by the authors' consultations with both individual patients and patient support groups such as the hospital-based or regionally-based Heart Beat programs such as Heart Beat Victoria. As evident from step vi in the item generation procedure, patients will be consulted as key informants about the structure and content of the CDI. Only after this process of consultation is complete will the CDI item pool be tested with 400 cardiac patients.

The result of the CDI development project, the psychometrically sound Cardiac Distress Inventory, will be made available to clinicians and researchers without charge, but with a request that data collected in studies using the measure will be made available for aggregation and analysis in future. The CDI will also be translated for use with clinical populations internationally with reporting of the psychometric properties of those versions. Confirmed translations will be Italian, Hebrew, Arabic, Farsi, and Spanish. Study findings will be shared with community members, particularly cardiac patient support groups such as the Heart Beat groups and their equivalents internationally; academic and medical communities via publications and presentations; in an online course in its rationale and use provided at no cost by the Australian Centre for Heart Health. The short form will be made available on the website of the Australian Centre for Heart Health for completion by patients to self-screen with suggestions for follow up psychological support where indicated.

Cardiac Distress Inventory design

Items generated through the process outlined above will be reworded where appropriate to ensure relevance to the measurement of cardiac distress, and appropriateness of fit with the following instruction and response set:

Living with a heart condition can sometimes be difficult. Listed below are some issues that people living with a heart condition may experience.

Please indicate whether or not you have experienced each issue during the past four weeks by checking 'Yes' or 'No'. For each item you have checked 'Yes', indicate how much distress this issue has caused you for the past four weeks, from 0 to 3, where "0" is no distress and "3" is severe distress.

Issue	Yes	No	If yes, indicate how much distress this causes for you			
			No distress at all	Slight distress	Moderate distress	Severe distress
Example: Having more pain than I expected to have	○	○	0	1	2	3

Trialling of the questionnaire for item reduction

Sample size required for trial

Recommendations of sample size for exploratory factor analysis in instrument development are that there should be at least 5 cases for each item in the instrument being used[34]. Rasch modelling for exploratory purposes should be based on at least N=100 and preferably N=250[35]. For the reliability and validation study, power calculations were conducted using GPower[36]. Given a probability level of 0.05, an anticipated effect size of 0.5, and a desired statistical power level of 0.8, a sample size of

N=66 is required per group. A summary of the steps and the number required for each step in the analysis is provided in Table 1.

<Table 1 about here>

Inclusion and exclusion criteria

Eligible patients will be those who have had an acute coronary event - namely acute coronary syndrome (ACS), acute myocardial infarction (AMI) or coronary artery bypass graft surgery (CABGS) in the previous 2 months and who are attending either a CR program or an outpatient clinic at a participating hospital. Patients who do not have adequate English language proficiency to read and understand the PICF and questionnaire will be excluded.

Participant recruitment

A Research Assistant (RA) will recruit patients at two months presentation directly through outpatient clinics or CR programs associated with the investigators. Clinic staff will advise the RA of potentially eligible patients and the RA will then approach these people to ascertain eligibility and willingness to participate. Specific arrangements for site visits will be made between the RA and site investigator by email and telephone. Overall and site-specific ethical approval will be in place.

In order to calculate a response rate, the RA will document the number of patients approached and the number who agree to participate and who do not. No identifying information on either participants or non-participants will be collected.

Data collection

Consenting participants will complete the PICF and the trial-version CDI, together with basic socio-demographic and event-related information. No identifying information (name, address, date of birth) will be collected as no patient follow-up is required. For reliability and validity testing, participants will also be required to complete the four Emotion Thermometers[37], the Kessler Psychological Distress Scale-6[38] (K6) and the PHQ-4[39]. In the event that the patient experiences distress while completing the questionnaire, the patient will be reminded by the RA that he/she is free to withdraw from the study (i.e., not continue with completing the questionnaire) and will be invited to contact the Australian Centre for Heart Health for a consultation with a clinical psychology specialist at no cost to the patient.

Measures

In addition to the *trial-version CDI,* the following measures will be administered:

Demographic questionnaire: Basic socio-demographic (e.g., age, sex, marital status, living arrangement) and cardiac event-related information (event type, date of event) will be collected.

Emotion Thermometers. The Emotion Thermometers are single-item measures of distress (DT), anxiety (AnxT), depression, (DepT) and anger (AngT). They consist of a "thermometer" with numerals displayed vertically from 0 to 10. Patients rate their distress "over the last week", with 0 indicating "no distress" and 10 indicating "high distress". A total score from all four mood thermometers (ETsum) indicates overall emotional problems. These thermometers, based on the NCCN cancer distress thermometer (DT)[22], have been shown to be a clinically sensitive measure of distress in patients with mixed cardiovascular conditions[37].

Patient Health Questionnaire-4[39] (PHQ-4): The PHQ is a validated brief screener (4-items) for anxiety and depression, which combines the Patient Health Questionnaire-2 (PHQ-2) and the Generalized Anxiety Disorder-2 (GAD-2)[39]. Total scores range from 0-12, with 0 indicating "no distress" and 12 indicating "severe distress".

Kessler Psychological Distress Scale-6[38] (K6): The Kessler 6 is a brief measure of psychological distress which has been validated in an Australian general population[38]. The K6 is both an effective screening measure and an indicator of distress severity. Scores range from 6-30, with lower scores indicating higher levels of distress.

Screening Tool for Psychological Distress[31](STOP-D): This is a five-item, evidence-derived self-report measure generating severity scores for depression, anxiety, stress, anger and poor social support. The screening tool has been tested with patients before and after heart transplant, patients in cardiac rehabilitation and adults with congenital heart disease[31].

Statistical analysis for the trial

Part A – Establishing dimensions of the CDI

Principal component analysis (PCA) using SPSS will be used to assess the dimensions of the CDI. PCA is commonly used in the development of new instruments to provide early indications of possible dimensions before Rasch analysis is attempted[40]. PCA is used to extract the factors followed by oblique rotation of factors using Oblimin rotation (delta = 0). Kaiser's criterion, which retains eigen values above 1, will be used to guide the identification of relevant factors. A second step in the PCA is to conduct Horn's parallel analysis[41], considered one of the most accurate approaches to estimate the number of components[42]. The size of eigen values obtained from PCA are compared with those obtained from a randomly generated data set of the same size. Only factors with eigen values exceeding the values obtained from the corresponding random data set are retained for further investigation.

Part B - Eliminating items per dimension of the CDI

Rasch analysis is a mathematical technique used to evaluate a latent variable not measurable directly from a set of categorical items. Rasch methods can be used to assess the extent to which individual items represent the underlying construct that an instrument intends to measure. The Rasch model chosen for this analysis, the Partial Credit Model[43] is applicable to polytomous rather than dichotomous data and is therefore suitable for Likert scales and response ratings.

Rasch analysis will be conducted using RUMM2030 software (RUMM Laboratory Pty Ltd., Perth, Australia). Three statistics are considered to determine the degree of fit for each CDI scale: overall fit; individual person fit; and individual item fit[44]. Adequate overall fit of the CDI to the Rasch model is indicated by a non-significant Bonferroni adjusted Chi-square probability value[45]. Satisfactory overall item and individual fit for each scale will be determined by a fit residual standard deviation (SD) value of ≤1.5. Individual item fit is indicated by two statistics: fit residual values; and Chi-square probability values. Item fit residual values −2.5 to 2.5 indicate adequate fit[46]. Above this range (underfit) suggests deviation from the model, below (overfit) suggests that some items in the scale are similar to each other[47]. A perfect model fit would be reflected by residuals with a mean of 0.00 and a SD of 1.00. Any mis-fitting item in terms of infit/outfit is discarded and the analysis re-run. This iterative process is continued until no further misfit is observed[48]. The Rasch analysis will produce the person separation index (PSI), which indicates the degree to which study participants can be differentiated into certain groups (PSI range 0–1). Values for PSI of 0.8 are acceptable[49]. A sample size of at least 100 patients is required to perform a Rasch analysis which can estimate an acceptable PSI value[35].

Statistical significance will be considered at the 5% level and Bonferroni correction for multiple testing will be applied where appropriate.

Psychometric properties of the final Cardiac Distress Inventory

The COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) criteria for evaluating the methodological quality of health-related patient-reported outcomes will

be used to inform the development of the methodology for determining the psychometric properties as far as possible[50, 51].

Reliability

Internal consistency of the CDI will be determined using Cronbach's alpha, standard test-retest methods, and evaluation of the Person Separation Index (PSI) from the Rasch analysis.

Test-retest reliability indicates agreement between repeated assessments. The CDI will be administered at two time points with at least 14 days separation, the first assessment taking place at least 30 days after the cardiac event or surgery. The intra-class correlation coefficient (ICC) will be used to examine the level of test-retest reliability. A 2-way analysis of variance (ANOVA) assuming patients' effects to be random, will be used to compute the variance needed to calculate the ICC. ICC values in the range of 0.6–0.8 represent substantial reliability and ICC values > 0.8 indicate high reliability[52]. In addition, a paired t-test will be performed to examine whether significant differences exist between test-retest assessments. A sample of at least N=66 is required for test-retesting, given an estimated effect size of 0.4, power of .90, standard deviation of 1.0 and alpha of 0.05.

Validity

Scale comparisons will be used to investigate the concurrent convergent validity of the CDI. Pearson correlation coefficients will be calculated to explore the association between CDI scores and the measure that is commonly used in clinical practice to assess distress, the six-item Kessler K6[38]. Subscale scores of the CDI will be compared with K6 scores where appropriate. We will assess the discriminant validity and predictive validity of the CDI by assessing whether it distinguishes between patients scoring high and low on the K6, using the Australian scoring cut-off of 19 to indicate probable serious mental illness[53]. Again, both CDI total and factor scores will be investigated. It is not possible to use a measure of cardiac distress for validity testing as no such measure exists.

Pearson correlation coefficients will also be calculated to explore the association between CDI scores and the Patient Health Questionnaire–4 (PHQ4)[39]. Normative data are available from a nationally representative face-to-face household survey sample of 5030 people, conducted in Germany in 2006[54]. The measure has been translated and validated in Hispanic populations, for example[55], and has been used in studies of cancer patients[56]and emergency department patients[57]. As far as the authors are aware, no validation study of the PHQ-4 has been undertaken with cardiac patients.

Comparison of CDI scores will also be conducted between the various types of cardiac patients (e.g. AMI vs CABGS). Comparison of groups will be conducted via analysis of variance (ANOVA).

Latent Class Analysis

Latent class analysis (LCA) will be used in order to describe groups of participants that differ in their response patterns to the CDI. LCA explains inter-individual differences in response patterns by means of a given number of latent classes (subgroups of participants). LCA estimates the size of the classes and a membership probability for each participant within each class[58] and will be performed using Mplus version 6.0[59]. To select the most parsimonious number of classes and maximise model fit, a series of latent class models will be applied to the data. First, the simplest 1-class model (all patients are assumed to have the same pattern of cardiac distress) will be applied to the data, followed by successive models with a unitary increase in the number of latent classes (up to eight). Model solutions are evaluated on the basis of their Bayesian information criterion (BIC) and entropy. The BIC has been shown to be a robust indicator of model fit, with lower values indicative of better model fit[60]. BIC will be used in preference to Akaike information criteria, as the latter has been shown to over-extract classes in simulation models[61]. The association of CDI latent class membership with CDI scale scores, sociodemographic characteristics, diagnosis and K6 distress scores will also be examined using Mplus[59]. Mplus generates overall chi-square values to assess significant associations between variables as well as unadjusted chi-square values for exploratory post-hoc analysis.

Development of a short form Cardiac Distress Inventory for screening purposes

A shorter version of the CDI, the CDI-S, will then be created. Importantly, item reduction based on rigorous methodological guidelines is necessary to maintain validity when shortening composite measurement scales[62]. In addition, there are a number of ways to achieve item reduction[63]. In light of these two points, we will use two methods to develop the short form screening tool – a clinically oriented method and a statistically-driven method. A concept-retention approach will create a short version of the original measure by selection of the top performing item in each domain to become part of the short, concept-retention version[64]. Rasch analysis as used in a number of health-related item reduction exercises, will also be employed[65, 66]. The Rasch analysis and psychometric evaluation of the CDI-S will follow the format described by Nishigami and colleagues[66]. Both versions of the CDI-S will then be field tested.

Thermometer testing

Receiver operating characteristic (ROC) analysis will be used to identify the optimal CDI scale cut off score for distinguishing whether a person experiences clinically significant distress as defined by the established cut-off thresholds for ETsum (the sum of all four mood thermometers). The Area Under the Curve (AUC) will be used to estimate the overall discriminative accuracy of the CDI scale cut off score relative to the established cut off scores of ETsum (a score >14 indicates moderate and >20 indicates severe emotional problems). Using qualitative guidelines for interpreting AUC values[67], namely AUC≤0.70 as acceptable discrimination, AUC≤0.80 as good discrimination and AUC≤0.90 as excellent discrimination. ROC curves will be used to show the trade-off between the sensitivity (true-positive rate) and specificity (true-negative rate) for every possible cut off score of the CDI Scale.

TIMELINE

Months 1-2: staff recruitment, CR site recruitment and liaison; Months 3-10: Administration of the full item pool draft CDI to patients attending CR or outpatient appointments. This includes test-retest of 66 cardiac patients; Months 11-12: completion of data analysis; Months 13-15: writing up the study findings will be a continuous activity with completion in months 15-18.

SUMMARY

Cardiac distress is a common problem among cardiac patients. Before cardiac distress can be treated effectively, it needs to be properly measured by a reliable, valid and sensitive instrument. The primary aim of the project is to develop a new clinical measure which health professionals can use to identify and assess cardiac distress. They can use the fine-grained assessment provided by this unique measure to structure psychological and emotional interventions to intervene in cases of persistent distress in patients, following a cardiac event. No such measure currently exists.

While physical recovery remains the highest priority in preventive cardiology, psychological recovery is now considered a primary concern for health professionals working in cardiac rehabilitation and secondary prevention. The prevalence of clinical anxiety and depression in people who have had a cardiac event is up to four times higher than in the general population, however both the prevalence and nature of the broader concept of cardiac-related distress remains unknown. Post-event psychological problems confer an increased mortality risk for patients, highlighting the importance of identifying distressed patients early in order to ensure appropriate treatment is received. The new CDI will not only enhance clinicians' ability to identify distressed patients but will also enable them to identify the specific nature of the distress, thereby optimising their ability to provide timely support targeted to the specific psychosocial needs of the patient. The new CDI has the potential to ensure that patients are provided with the specific support they require in their psychosocial recovery after a cardiac event and, in doing so, has the potential to improve their quality of life, enhance their behaviour change efforts and ultimately extend their survival.

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Table 1: Numbers required for each stage of the development and testing of the Cardiac Distress Inventory

Steps	**Purpose**	**N required with rationale**
Development		
Exploratory Factor Analysis	Establish number of dimensions	(74 items X 5=370) cardiac patients (AMI, AF, CABGS, unstable angina plus heart failure patients with New York Heart Association (NYHA) classification of mild (NYHA 11) or moderate (NYHA 111) heart failure. Allowing for 10 percent missing data, a sample size of (74 items X 5=370 + 10% = 407) would therefore be required for this phase of the study.
Rasch Analysis	Eliminate items per dimension	The Rasch Analysis will utilise the total baseline sample and will not require a sub-sample.
Testing		
Test-Retest reliability	Establish reliability	Relative reliability will be calculated using the intraclass correlation coefficient (ICC), with 95% confidence interval based on a mean-rating (k = 2), absolute-agreement, two-way mixed-effects model[68]. The ICC is interpreted according to the following criteria: values below 0.5 indicated low reliability, values between 0.5 and 0.75 indicated moderate reliability, values between 0.75 and 0.9 indicated good reliability, and values greater than 0.90 indicated excellent reliability, as suggested by Koo et al. [68]. Given an expected ICC of 0.80, a conservative 95% CI of ICC of 0.1, and alpha of 0.05, a sample size of 201 is required. Given an expected attrition rate of 20%, a total sample of N=252 from the baseline sample is required for test-retesting. This attrition rate is compatible with rates obtained in previous studies of cardiac rehabilitation (CR) participants tested at two time points [69] and is a conservative estimate given the duration between testing in this study is much shorter, at 14 days. This step uses reduced item version.
Construct validity		66 cardiac patients administered both the CDI and K6. (Using the reduced item version of the CDI).
Latent Class Analysis	Identify inter-individual differences in response patterns	The LCA analysis will utilise the total baseline sample and will not require a sub-sample.

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Protocol for the development and validation of a measure of persistent psychological and emotional distress in cardiac patients: The Cardiac Distress Inventory

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ABSTRACT

Introduction Distress is experienced by the majority of cardiac patients, yet no cardiac-specific measure of distress exists. The aim of this project is to develop and validate the *Cardiac Distress Inventory* (CDI). Using the CDI, health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event.

Methods and analysis An item pool will be generated through: identification of items by a multidisciplinary group of clinician researchers; review of generic and condition-specific distress measures; focus group testing with cardiac rehab professionals; feedback from patients. The COSMIN criteria will be used to inform the development of the methodology for determining the CDI's psychometric properties. The item pool will be tested with 400 cardiac patients and responses subjected to exploratory factor analysis, Rasch analysis, construct validity testing, and latent class analysis. ROC analysis will be used to identify the optimal CDI cut off score for distinguishing whether a person experiences clinically significant distress.

Ethics and dissemination Approved by the Monash Health Human Research Ethics Committee (Approval number – RES-19-0000631L-55979 0). The CDI will be made available to clinicians and researchers without charge. The CDI will be translated for use internationally. Study findings will be shared with cardiac patient support groups; academic and medical communities via publications and presentations; in the training of cardiac secondary prevention professionals; and in reports to funders. Authorship for publications will follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Strengths and limitations

- This will be the first available cardiac-specific distress measure based on a multidisciplinary conceptualisation of the core construct
- It builds on scale development in oncology and diabetes
- It will be developed using co-design principles.
- It will compare a clinically-driven and a statistically-driven method of developing a short-form of the measure for use as a screening tool

BACKGROUND

Conceptualisation of cardiac distress

As high prevalence conditions, much attention has been paid to the measurement and understanding of anxiety and depression as consequences of cardiac events. However, less attention has been given to the phenomenon of 'cardiac distress' which many patients experience after acute coronary events such as myocardial infarction (AMI), unstable angina, or coronary artery bypass graft surgery (CABGS). In an earlier paper, we discussed the conceptualisation of cardiac distress and defined it as:

> "a persistent negative emotional state rather than a transient state; involving multiple psychosocial domains; that challenges a patient's capacity to cope with living with their heart condition, the treatment of the condition, and the resultant changes to daily living; and challenges the person's sense of self and future orientation"[1].

A number of previous studies have attempted to examine the relationship between post-cardiac event distress, symptom severity and mortality in relation to a range of specific heart conditions[2, 3] and procedures[4, 5], following cardiac rehabilitation[6], and in cardiovascular disease more generally[7]. A common characteristic of these studies, however, is the use of terms such as 'distress' without explicit definition. In some cases, distress is simply defined as being that which is measured by an instrument deemed to measure distress such as the Hospital Anxiety and Depression Scale[8], the General Health Questionnaire[9] or the Kessler Psychological Distress Scale[10]. Typically, these studies view psychological or emotional distress as a simple combination of anxiety and depression, as does a recent analysis of post-cardiac event psychological distress trajectories[11].

A small number of studies of cardiac patients, however, widen this narrow view of distress by adding other psychosocial constructs to 'anxiety plus depression', including stress and stressful life events[12-14]; fear of death[13, 15]; hostility[12]; vital exhaustion and reduced quality of life[14]; vulnerabilities such as lack of pleasant events, dysfunctional attitudes, role transitions and poor dyadic adjustment[16]; feelings of helplessness, loss of control, and pain[15]; and psychological wellbeing[6]. In other chronic conditions such as cancer, diabetes and rheumatic conditions, fear of disease progression has also been identified as an important reason for distress[17]. This future-oriented component of distress is expressed in an extreme form in cardiac-induced post-traumatic stress disorder (CDI-PTSD) with Vilchinsky and colleagues noting that fear of death dominates the experience of patients with CDI-PTSD[18].

Traumatic components of a cardiac event are the abruptness of the event, the risk of death, and a strong sense of loss of control and helplessness during the event [18]. These reactions, coupled with the experience of surgery can lead to significant anxiety associated with death or recurrence, as well as anger, sadness and grief [19], all symptoms associated with PTSD [20, 21]. Differentiating distress from cardiac disease induced-PTSD (CDI-PTSD), however, are a range of additional psychosocial factors such as challenges to people's coping with daily living, the impact of social isolation, role transitions and challenges, and cognitive issues.

The 'cardiac blues'

A broader approach to understanding the complexity of the psychological and emotional impacts of a cardiac event is evidenced in the concept of the 'cardiac blues' which describes a range of emotional responses to an acute cardiac event. It has been suggested that almost all patients experience at least some symptoms of the cardiac blues at the time of, or soon after, an acute cardiac event[22]. Common emotions include shock, low or fluctuating mood, sadness, worry, guilt and anger. Mood changes are displayed by tiredness, irritability, tearfulness, loss of pleasure in usual activities, withdrawal from others, early waking and other sleep disturbance, and changes in appetite and sex drive. Cognitive changes that typically co-occur include confusion and forgetfulness, inability to concentrate, nightmares, reduced self-esteem, concerns about role changes, particularly

regarding paid work, physical health and independence; and pessimism about the future[22-24]. Although generally a transient condition[25, 26], if the cardiac blues does not resolve within around two months of the cardiac event, the psychological and emotional impact of the event can result in persistent cardiac distress[23, 24].

Measuring condition-specific distress

Both the oncology and diabetes fields have at least a two decade-long history of screening and psychosocial intervention for condition-specific distress. For oncology, this is reflected in the National Comprehensive Cancer Network Guidelines for Distress Management[27] where distress is considered to be a multifactorial unpleasant experience of a psychological (i.e., emotional, behavioural, cognitive), social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms or its treatment. An excellent earlier attempt to conceptualise diabetes distress so that it could be recognised and addressed in nursing practice[28], has recently been extended by Dennick and colleagues[29]. They characterise distress as a range of negative emotional responses, such as worry, fear, frustration, guilt, sadness, anger, to aspects of living with and managing the condition, balanced against an appraisal of available coping resources[29]. Snoek and colleagues argue that diabetes-distress and depression are correlated and overlapping constructs, but are not interchangeable, and that distinguishing between them is an important factor in shaping appropriate mental health interventions[30]. In a recent systematic review of the impact of distress on health-related outcomes, Barry and colleagues agree also that distress is distinct from depression and should be assessed using condition-specific measures, as early as practicable in treatment[31].

Cardiac-specific measures of the psychosocial impact of cardiac events

The cardiac field also has a two decade-long history of attempts to measure specific aspects of the psychological and emotional impact of cardiac events. Examples of cardiac-specific measures include the Cardiac Depression Scale[32] , the Cardiac Event Threat Questionnaire[33], the Cardiac Anxiety Questionnaire[34], the MacNew Quality of Life measure[35], the Screening Tool for Psychological Distress (STOP–D)[36], the Myocardial Infarction Dimensional Assessment Scale (MIDAS)[37], and the European Society of Cardiology (ESC) brief (15-item) screen of psychosocial risk factors for cardiac patients[38]. These measures collectively assess a range of features associated with cardiac distress such as impaired quality of life, anxiety, depression, fear, death anxiety, illness-related dependency, feeling unable to cope, work and family stress, worrying levels of pain, social isolation and low perceived social support , anger and Type D personality. However, there remains no single comprehensive assessment of cardiac distress as we have defined it[1]. While the Joint ESC Guidelines psychosocial screen is an excellent start in this regard[39], and provide an indicator for a health professional that psychosocial support is warranted, a measure is needed that enables a cardiac psychology professional to clearly identify priority areas in order to offer a timely tailored intervention for a distressed patient[40, 41]. Using the *Cardiac Distress Inventory* (CDI), health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event at a depth not afforded by one or two questions per construct as in the ESC core questions for the assessment of psychosocial risk factors in clinical practice[39]. For good clinical intervention, we need to know not just that people are anxious, but they are anxious about. Similarly, what is it that they fear: death, loss of function, loss of role, loss of intimacy? Achieving this degree of granularity to guide intervention is the point of the Cardiac Distress inventory.

Aims

The aims of the present study are:

1. To develop and validate the Cardiac Distress Inventory (CDI).
2. To develop a short form screening tool version of the CDI.

This protocol has been approved by the Monash Health Human Research Ethics Committee (Approval number – RES-19-0000631L-55979 0)

METHOD

The method described in this protocol for development and validation of the CDI conforms, we believe, to the 'best practices' for undertaking such a task, outlined by Boateng and colleagues[42].

Item generation

There are six steps in the item generation procedure:

i. Initial generation of items by a multidisciplinary group of researchers and clinicians including the disciplines of nursing, psychiatry, behavioural health, psychology and cardiology.
ii. Review of generic and condition-specific distress measures, to identify the elements comprising the construct of 'distress' in those measures and to identify items which could be adapted for the CDI.
iii. Review of cardiac-specific measures incorporating elements of distress as defined by the present authors[1].
iv. Review of items for appropriateness for a post-operative cardiac population by the multidisciplinary investigator group.
v. Focus group testing with two multidisciplinary groups of cardiac rehabilitation professionals: experienced practitioners undertaking intensive training in cardiac rehabilitation through the Australian Centre for Heart Health; and the National Executive of the Australian Cardiovascular Health and Rehabilitation Association (ACRA).
vi. Consultation with, and feedback from, cardiac patients (key informants) on the structure and content of the CDI.

Consistent with the approach taken to the PROMIS item bank development and testing[43], and our prior conceptualisation of the primary construct of cardiac distress as a multifactorial construct, we expect that the CDI will be a multidimensional measure incorporating emotional, belief, behavioural, cognitive and social domains[1]

Patient and public involvement

The need for a comprehensive measure of cardiac-related distress has been identified by the multidisciplinary clinician researcher members of the CDI development group, through their clinical practice in provision of psychosocial support to cardiac patients. This need has been endorsed by the authors' consultations with both individual patients and patient support groups such as the hospital-based or regionally-based Heart Beat programs such as Heart Beat Victoria. As evident from step vi in the item generation procedure, patients will be consulted as key informants about the structure and content of the CDI. Only after this process of consultation is complete will the CDI item pool be tested with 400 cardiac patients.

The result of the CDI development project, the psychometrically sound *Cardiac Distress Inventory*, will be made available to clinicians and researchers without charge, but with a request that data collected in studies using the measure will be made available for aggregation and analysis in future. The CDI will also be translated for use with clinical populations internationally with reporting of the psychometric properties of those versions. Confirmed translations will be Italian, Hebrew, Arabic, Farsi, and Spanish. Methods for translation vary[44, 45] but we will adopt the following strategy. The CDI will be translated independently by two bilingual cardiac psychologist clinician / researchers. These translations will then be back translated into English by a bilingual psychologist independent of the two original translators and not familiar with the CDI study. These back translations will be reviewed

by a subgroup of the investigators. Discrepancies will be resolved by consensus between the original translators and the review subgroup.

Study findings will be shared with community members, particularly cardiac patient support groups such as the Heart Beat groups and their equivalents internationally; academic and medical communities via publications and presentations; in an online course in its rationale and use provided at no cost by the Australian Centre for Heart Health. The short form will be made available on the website of the Australian Centre for Heart Health for completion by patients to self-screen with suggestions for follow up psychological support where indicated.

Cardiac Distress Inventory design

Items generated through the process outlined above will be reworded where appropriate to ensure relevance to the measurement of cardiac distress, and appropriateness of fit with the following instruction and response set:

> *Living with a heart condition can sometimes be difficult. Listed below are some issues that people living with a heart condition may experience.*
>
> *Please indicate whether or not you have experienced each issue during the past four weeks by checking 'Yes' or 'No'. For each item you have checked 'Yes', indicate how much distress this issue has caused you for the past four weeks, from 0 to 3, where "0" is no distress and "3" is severe distress.*

Issue	Yes	No	If yes, indicate how much distress this causes for you			
			No distress at all	Slight distress	Moderate distress	Severe distress
Example: Having more pain than I expected to have	O	O	0	1	2	3

Trialling of the questionnaire for item reduction

Sample size required for trial

Recommendations of sample size for exploratory factor analysis in instrument development are that there should be at least 5 cases for each item in the instrument being used[46]. Rasch modelling for exploratory purposes should be based on at least N=100 and preferably N=250[47]. For the reliability and validation study, power calculations were conducted using GPower[48]. Given a probability level of 0.05, an anticipated effect size of 0.5, and a desired statistical power level of 0.8, a sample size of N=66 is required per group. A summary of the steps and the number required for each step in the analysis is provided in Table 1.

<Table 1 about here>

Inclusion and exclusion criteria

Eligible patients will be those who have had an acute coronary event - namely acute coronary syndrome (ACS), acute myocardial infarction (AMI) or coronary artery bypass graft surgery (CABGS) in the previous 6 months and who are attending either a CR program or an outpatient clinic at a participating hospital. Patients who do not have adequate English language proficiency to read and understand the PICF and questionnaire will be excluded.

Participant recruitment

A Research Assistant (RA) will recruit patients at two months presentation directly through outpatient clinics or CR programs associated with the investigators. Clinic staff will advise the RA of potentially eligible patients and the RA will then approach these people to ascertain eligibility and willingness to participate. Specific arrangements for site visits will be made between the RA and site investigator by email and telephone. Overall and site-specific ethical approval will be in place.

In order to calculate a response rate, the RA will document the number of patients approached and the number who agree to participate and who do not. No identifying information on either participants or non-participants will be collected.

Data collection

Consenting participants will complete the PICF and the trial-version CDI, together with basic socio-demographic and event-related information. No identifying information (name, address, date of birth) will be collected as no patient follow-up is required. For reliability and validity testing, participants will also be required to complete the four Emotion Thermometers[49], the Kessler Psychological Distress Scale-6[50] (K6) and the PHQ-4[51]. In the event that the patient experiences distress while completing the questionnaire, the patient will be reminded by the RA that he/she is free to withdraw from the study (i.e., not continue with completing the questionnaire) and will be invited to contact the Australian Centre for Heart Health for a consultation with a clinical psychology specialist at no cost to the patient.

Measures

In addition to the *trial-version CDI,* the following measures will be administered:

Demographic questionnaire: Basic socio-demographic (e.g., age, sex, marital status, living arrangement) and cardiac event-related information (event type, date of event) will be collected.

Emotion Thermometers. The Emotion Thermometers are single-item measures of distress (DT), anxiety (AnxT), depression, (DepT) and anger (AngT). They consist of a "thermometer" with numerals displayed vertically from 0 to 10. Patients rate their distress "over the last week", with 0 indicating "no distress" and 10 indicating "high distress". A total score from all four mood thermometers (ETsum) indicates overall emotional problems. These thermometers, based on the NCCN cancer distress thermometer (DT)[27], have been shown to be a clinically sensitive measure of distress in patients with mixed cardiovascular conditions[49].

Patient Health Questionnaire-4[51] (PHQ-4): The PHQ is a validated brief screener (4-items) for anxiety and depression, which combines the Patient Health Questionnaire-2 (PHQ-2) and the Generalized Anxiety Disorder-2 (GAD-2)[51]. Total scores range from 0-12, with 0 indicating "no distress" and 12 indicating "severe distress".

Kessler Psychological Distress Scale-6[50] (K6): The Kessler 6 is a brief measure of psychological distress which has been validated in an Australian general population[50]. The K6 is both an effective screening measure and an indicator of distress severity. Scores range from 6-30, with lower scores indicating higher levels of distress.

Screening Tool for Psychological Distress[36](STOP-D): This is a five-item, evidence-derived self-report measure generating severity scores for depression, anxiety, stress, anger and poor social support. The screening tool has been tested with patients before and after heart transplant, patients in cardiac rehabilitation and adults with congenital heart disease[36].

Statistical analysis for the trial

Part A – Establishing dimensions of the CDI

Principal component analysis (PCA) using SPSS will be used to assess the dimensions of the CDI. PCA is commonly used in the development of new instruments to provide early indications of possible dimensions before Rasch analysis is attempted[52]. PCA is used to extract the factors followed by

oblique rotation of factors using Oblimin rotation (delta = 0). Kaiser's criterion, which retains eigen values above 1, will be used to guide the identification of relevant factors. A second step in the PCA is to conduct Horn's parallel analysis[53], considered one of the most accurate approaches to estimate the number of components[54]. The size of eigen values obtained from PCA are compared with those obtained from a randomly generated data set of the same size. Only factors with eigen values exceeding the values obtained from the corresponding random data set are retained for further investigation.

Part B - Eliminating items per dimension of the CDI

Rasch analysis is a mathematical technique used to evaluate a latent variable not measurable directly from a set of categorical items. Rasch methods can be used to assess the extent to which individual items represent the underlying construct that an instrument intends to measure. The Rasch model chosen for this analysis, the Partial Credit Model[55] is applicable to polytomous rather than dichotomous data and is therefore suitable for Likert scales and response ratings.

Rasch analysis will be conducted using RUMM2030 software (RUMM Laboratory Pty Ltd., Perth, Australia). Three statistics are considered to determine the degree of fit for each CDI scale: overall fit; individual person fit; and individual item fit[56]. Adequate overall fit of the CDI to the Rasch model is indicated by a non-significant Bonferroni adjusted Chi-square probability value[57]. Satisfactory overall item and individual fit for each scale will be determined by a fit residual standard deviation (SD) value of ≤1.5. Individual item fit is indicated by two statistics: fit residual values; and Chi-square probability values. Item fit residual values −2.5 to 2.5 indicate adequate fit[58]. Above this range (underfit) suggests deviation from the model, below (overfit) suggests that some items in the scale are similar to each other[59]. A perfect model fit would be reflected by residuals with a mean of 0.00 and a SD of 1.00. Any mis-fitting item in terms of infit/outfit is discarded and the analysis re-run. This iterative process is continued until no further misfit is observed[60]. The Rasch analysis will produce the person separation index (PSI), which indicates the degree to which study participants can be differentiated into certain groups (PSI range 0–1). Values for PSI of 0.8 are acceptable[61]. A sample size of at least 100 patients is required to perform a Rasch analysis which can estimate an acceptable PSI value[47].

Statistical significance will be considered at the 5% level and Bonferroni correction for multiple testing will be applied where appropriate.

Psychometric properties of the final Cardiac Distress Inventory

The COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) criteria for evaluating the methodological quality of health-related patient-reported outcomes will be used to inform the development of the methodology for determining the psychometric properties as far as possible[62, 63].

Reliability

Internal consistency of the CDI will be determined using Cronbach's alpha, and evaluation of the Person Separation Index (PSI) from the Rasch analysis.

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Validity

Scale comparisons will be used to investigate the concurrent convergent validity of the CDI. Pearson correlation coefficients will be calculated to explore the association between CDI scores and the measure that is commonly used in clinical practice to assess distress, the six-item Kessler K6[50]. Subscale scores of the CDI will be compared with K6 scores where appropriate. We will assess the discriminant validity and predictive validity of the CDI by assessing whether it distinguishes between patients scoring high and low on the K6, using the Australian scoring cut-off of 19 to indicate

probable serious mental illness[64]. Again, both CDI total and factor scores will be investigated. It is not possible to use a measure of cardiac distress for validity testing as no such measure exists.

Pearson correlation coefficients will also be calculated to explore the association between CDI scores and the Patient Health Questionnaire–4 (PHQ4)[51]. Normative data are available from a nationally representative face-to-face household survey sample of 5030 people, conducted in Germany in 2006[65]. The measure has been translated and validated in Hispanic populations, for example[66], and has been used in studies of cancer patients[67]and emergency department patients[68]. As far as the authors are aware, no validation study of the PHQ-4 has been undertaken with cardiac patients.

Comparison of CDI scores will also be conducted between the various types of cardiac patients (e.g. AMI vs CABGS). Comparison of groups will be conducted via analysis of variance (ANOVA).

Latent Class Analysis

Latent class analysis (LCA) will be used in order to describe groups of participants that differ in their response patterns to the CDI. LCA explains inter-individual differences in response patterns by means of a given number of latent classes (subgroups of participants). LCA estimates the size of the classes and a membership probability for each participant within each class[69] and will be performed using Mplus version 6.0[70]. To select the most parsimonious number of classes and maximise model fit, a series of latent class models will be applied to the data. First, the simplest 1-class model (all patients are assumed to have the same pattern of cardiac distress) will be applied to the data, followed by successive models with a unitary increase in the number of latent classes (up to eight). Model solutions are evaluated on the basis of their Bayesian information criterion (BIC) and entropy. The BIC has been shown to be a robust indicator of model fit, with lower values indicative of better model fit[71]. BIC will be used in preference to Akaike information criteria, as the latter has been shown to over-extract classes in simulation models[72]. The association of CDI latent class membership with CDI scale scores, sociodemographic characteristics, diagnosis and K6 distress scores will also be examined using Mplus[70]. Mplus generates overall chi-square values to assess significant associations between variables as well as unadjusted chi-square values for exploratory post-hoc analysis.

Development of a short form Cardiac Distress Inventory for screening purposes

A shorter version of the CDI, the CDI-S, will then be created. Importantly, item reduction based on rigorous methodological guidelines is necessary to maintain validity when shortening composite measurement scales[73]. In addition, there are a number of ways to achieve item reduction[74]. In light of these two points, we will use two methods to develop the short form screening tool – a clinically oriented method and a statistically-driven method. A concept-retention approach will create a short version of the original measure by selection of the top performing item in each domain to become part of the short, concept-retention version[75]. Rasch analysis as used in a number of health-related item reduction exercises, will also be employed[76, 77]. The Rasch analysis and psychometric evaluation of the CDI-S will follow the format described by Nishigami and colleagues[77]. Both versions of the CDI-S will then be field tested.

Thermometer testing

Receiver operating characteristic (ROC) analysis will be used to identify the optimal CDI scale cut off score for distinguishing whether a person experiences clinically significant distress as defined by the established cut-off thresholds for ETsum (the sum of all four mood thermometers). The Area Under the Curve (AUC) will be used to estimate the overall discriminative accuracy of the CDI scale cut off score relative to the established cut off scores of ETsum (a score >14 indicates moderate and >20 indicates severe emotional problems). Using qualitative guidelines for interpreting AUC values[78], namely AUC≤0.70 as acceptable discrimination, AUC≤0.80 as good discrimination and AUC≤0.90 as excellent discrimination. ROC curves will be used to show the trade-off between the sensitivity (true-positive rate) and specificity (true-negative rate) for every possible cut off score of the CDI Scale.

TIMELINE

Months 1-2: staff recruitment, CR site recruitment and liaison; Months 3-18: Administration of the full item pool draft CDI to patients attending CR or outpatient appointments. Months 19-21: completion of data analysis; Months 22-24: writing up the study findings will be a continuous activity with completion in months 22-24.

SUMMARY

Cardiac distress is complex and various aspects of cardiac distress have been shown to be common among cardiac patients. Before cardiac distress can be treated effectively, it needs to be properly measured by a reliable, valid and sensitive instrument. Stress is increasingly being recognised as a prognostic factor in those with pre-existing cardiovascular or cerebrovascular disease [79] and stress management in cardiac rehabilitation shows promise [80]. Even so, we are yet to see the totality of cardiac distress, in all of its complexity, being addressed in this way.

The primary aim of the project, therefore, is to develop a new clinical measure which health professionals can use to identify and assess cardiac distress. They can use the fine-grained assessment provided by this unique measure to structure psychological and emotional interventions to intervene in cases of persistent distress in patients, following a cardiac event. No such measure currently exists.

While physical recovery remains the highest priority in preventive cardiology, psychological recovery is now considered a primary concern for health professionals working in cardiac rehabilitation and secondary prevention. The prevalence of clinical anxiety and depression in people who have had a cardiac event is up to four times higher than in the general population, however both the prevalence and nature of the broader concept of cardiac-related distress remains unknown. Post-event psychological problems confer an increased mortality risk for patients, highlighting the importance of identifying distressed patients early in order to ensure appropriate treatment is received. The new CDI will not only enhance clinicians' ability to identify distressed patients but will also enable them to identify the specific nature of the distress, thereby optimising their ability to provide timely support targeted to the specific psychosocial needs of the patient. The new CDI has the potential to ensure that patients are provided with the specific support they require in their psychosocial recovery after a cardiac event and, in doing so, has the potential to improve their quality of life, enhance their behaviour change efforts and ultimately extend their survival.

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Table 1: Numbers required for each stage of the development and testing of the Cardiac Distress Inventory

Steps	**Purpose**	**N required with rationale**
Development		
Exploratory Factor Analysis	Establish number of dimensions	(74 items X 5=370) cardiac patients (AMI, AF, CABGS, unstable angina plus heart failure patients with New York Heart Association (NYHA) classification of mild (NYHA 11) or moderate (NYHA 111) heart failure. Allowing for 10 percent missing data, a sample size of (74 items X 5=370 + 10% = 407) would therefore be required for this phase of the study.
Rasch Analysis	Eliminate items per dimension	The Rasch Analysis will utilise the total baseline sample and will not require a sub-sample.
Testing		
Construct validity		66 cardiac patients administered both the CDI and K6. (Using the reduced item version of the CDI).
Latent Class Analysis	Identify inter-individual differences in response patterns	The LCA analysis will utilise the total baseline sample and will not require a sub-sample.

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Protocol for the development and validation of a measure of persistent psychological and emotional distress in cardiac patients: The Cardiac Distress Inventory

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Protocol for the development and validation of a measure of persistent psychological and emotional distress in cardiac patients: The Cardiac Distress Inventory

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ABSTRACT

Introduction Distress is experienced by the majority of cardiac patients, yet no cardiac-specific measure of distress exists. The aim of this project is to develop and validate the *Cardiac Distress Inventory* (CDI). Using the CDI, health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event.

Methods and analysis An item pool will be generated through: identification of items by a multidisciplinary group of clinician researchers; review of generic and condition-specific distress measures; focus group testing with cardiac rehab professionals; feedback from patients. The COSMIN criteria will be used to inform the development of the methodology for determining the CDI's psychometric properties. The item pool will be tested with 400 cardiac patients and responses subjected to exploratory factor analysis, Rasch analysis, construct validity testing, and latent class analysis. ROC analysis will be used to identify the optimal CDI cut off score for distinguishing whether a person experiences clinically significant distress.

Ethics and dissemination Approved by the Monash Health Human Research Ethics Committee (Approval number – RES-19-0000631L-55979 0). The CDI will be made available to clinicians and researchers without charge. The CDI will be translated for use internationally. Study findings will be shared with cardiac patient support groups; academic and medical communities via publications and presentations; in the training of cardiac secondary prevention professionals; and in reports to funders. Authorship for publications will follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

Strengths and limitations

- This will be the first available cardiac-specific distress measure based on a multidisciplinary conceptualisation of the core construct
- It builds on scale development in oncology and diabetes
- It will be developed using co-design principles.
- It will compare a clinically-driven and a statistically-driven method of developing a short-form of the measure for use as a screening tool

BACKGROUND

Conceptualisation of cardiac distress

As high prevalence conditions, much attention has been paid to the measurement and understanding of anxiety and depression as consequences of cardiac events. However, less attention has been given to the phenomenon of 'cardiac distress' which many patients experience after acute coronary events such as myocardial infarction (AMI), unstable angina, or coronary artery bypass graft surgery (CABGS). In an earlier paper, we discussed the conceptualisation of cardiac distress and defined it as:

> "a persistent negative emotional state rather than a transient state; involving multiple psychosocial domains; that challenges a patient's capacity to cope with living with their heart condition, the treatment of the condition, and the resultant changes to daily living; and challenges the person's sense of self and future orientation"[1].

A number of previous studies have attempted to examine the relationship between post-cardiac event distress, symptom severity and mortality in relation to a range of specific heart conditions[2, 3] and procedures[4, 5], following cardiac rehabilitation[6], and in cardiovascular disease more generally[7]. A common characteristic of these studies, however, is the use of terms such as 'distress' without explicit definition. In some cases, distress is simply defined as being that which is measured by an instrument deemed to measure distress such as the Hospital Anxiety and Depression Scale[8], the General Health Questionnaire[9] or the Kessler Psychological Distress Scale[10]. Typically, these studies view psychological or emotional distress as a simple combination of anxiety and depression, as does a recent analysis of post-cardiac event psychological distress trajectories[11].

A small number of studies of cardiac patients, however, widen this narrow view of distress by adding other psychosocial constructs to 'anxiety plus depression', including stress and stressful life events[12-14]; fear of death[13, 15]; hostility[12]; vital exhaustion and reduced quality of life[14]; vulnerabilities such as lack of pleasant events, dysfunctional attitudes, role transitions and poor dyadic adjustment[16]; feelings of helplessness, loss of control, and pain[15]; and psychological wellbeing[6]. In other chronic conditions such as cancer, diabetes and rheumatic conditions, fear of disease progression has also been identified as an important reason for distress[17]. This future-oriented component of distress is expressed in an extreme form in cardiac-induced post-traumatic stress disorder (CDI-PTSD) with Vilchinsky and colleagues noting that fear of death dominates the experience of patients with CDI-PTSD[18].

Traumatic components of a cardiac event are the abruptness of the event, the risk of death, and a strong sense of loss of control and helplessness during the event [18]. These reactions, coupled with the experience of surgery can lead to significant anxiety associated with death or recurrence, as well as anger, sadness and grief [19], all symptoms associated with PTSD [20, 21]. Differentiating distress from cardiac disease induced-PTSD (CDI-PTSD), however, are a range of additional psychosocial factors such as challenges to people's coping with daily living, the impact of social isolation, role transitions and challenges, and cognitive issues.

The 'cardiac blues'

A broader approach to understanding the complexity of the psychological and emotional impacts of a cardiac event is evidenced in the concept of the 'cardiac blues' which describes a range of emotional responses to an acute cardiac event. It has been suggested that almost all patients experience at least some symptoms of the cardiac blues at the time of, or soon after, an acute cardiac event[22]. Common emotions include shock, low or fluctuating mood, sadness, worry, guilt and anger. Mood changes are displayed by tiredness, irritability, tearfulness, loss of pleasure in usual activities, withdrawal from others, early waking and other sleep disturbance, and changes in appetite and sex drive. Cognitive changes that typically co-occur include confusion and forgetfulness, inability to concentrate, nightmares, reduced self-esteem, concerns about role changes, particularly

regarding paid work, physical health and independence; and pessimism about the future[22-24]. Although generally a transient condition[25, 26], if the cardiac blues does not resolve within around two months of the cardiac event, the psychological and emotional impact of the event can result in persistent cardiac distress[23, 24].

Measuring condition-specific distress

Both the oncology and diabetes fields have at least a two decade-long history of screening and psychosocial intervention for condition-specific distress. For oncology, this is reflected in the National Comprehensive Cancer Network Guidelines for Distress Management[27] where distress is considered to be a multifactorial unpleasant experience of a psychological (i.e., emotional, behavioural, cognitive), social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms or its treatment. An excellent earlier attempt to conceptualise diabetes distress so that it could be recognised and addressed in nursing practice[28], has recently been extended by Dennick and colleagues[29]. They characterise distress as a range of negative emotional responses, such as worry, fear, frustration, guilt, sadness, anger, to aspects of living with and managing the condition, balanced against an appraisal of available coping resources[29]. Snoek and colleagues argue that diabetes-distress and depression are correlated and overlapping constructs, but are not interchangeable, and that distinguishing between them is an important factor in shaping appropriate mental health interventions[30]. In a recent systematic review of the impact of distress on health-related outcomes, Barry and colleagues agree also that distress is distinct from depression and should be assessed using condition-specific measures, as early as practicable in treatment[31].

Cardiac-specific measures of the psychosocial impact of cardiac events

The cardiac field also has a two decade-long history of attempts to measure specific aspects of the psychological and emotional impact of cardiac events. Examples of cardiac-specific measures include the Cardiac Depression Scale[32] , the Cardiac Event Threat Questionnaire[33], the Cardiac Anxiety Questionnaire[34], the MacNew Quality of Life measure[35], the Screening Tool for Psychological Distress (STOP–D)[36], the Myocardial Infarction Dimensional Assessment Scale (MIDAS)[37], and the European Society of Cardiology (ESC) brief (15-item) screen of psychosocial risk factors for cardiac patients[38]. These measures collectively assess a range of features associated with cardiac distress such as impaired quality of life, anxiety, depression, fear, death anxiety, illness-related dependency, feeling unable to cope, work and family stress, worrying levels of pain, social isolation and low perceived social support , anger and Type D personality. However, there remains no single comprehensive assessment of cardiac distress as we have defined it[1]. While the Joint ESC Guidelines psychosocial screen is an excellent start in this regard[39], and provide an indicator for a health professional that psychosocial support is warranted, a measure is needed that enables a cardiac psychology professional to clearly identify priority areas in order to offer a timely tailored intervention for a distressed patient[40, 41]. Using the *Cardiac Distress Inventory* (CDI), health professionals will be able to identify key clusters of psychological, emotional and social concern to address with patients, post-cardiac event at a depth not afforded by one or two questions per construct as in the ESC core questions for the assessment of psychosocial risk factors in clinical practice[39]. For good clinical intervention, we need to know not just that people are anxious, but they are anxious about. Similarly, what is it that they fear: death, loss of function, loss of role, loss of intimacy? Achieving this degree of granularity to guide intervention is the point of the Cardiac Distress inventory.

Aims

The aims of the present study are:

1. To develop and validate the Cardiac Distress Inventory (CDI).
2. To develop a short form screening tool version of the CDI.

METHOD

The method described in this protocol for development and validation of the CDI conforms, we believe, to the 'best practices' for undertaking such a task, outlined by Boateng and colleagues[42].

Item generation

There are six steps in the item generation procedure:

i. Initial generation of items by a multidisciplinary group of researchers and clinicians including the disciplines of nursing, psychiatry, behavioural health, psychology and cardiology.
ii. Review of generic and condition-specific distress measures, to identify the elements comprising the construct of 'distress' in those measures and to identify items which could be adapted for the CDI.
iii. Review of cardiac-specific measures incorporating elements of distress as defined by the present authors[1].
iv. Review of items for appropriateness for a post-operative cardiac population by the multidisciplinary investigator group.
v. Focus group testing with two multidisciplinary groups of cardiac rehabilitation professionals: experienced practitioners undertaking intensive training in cardiac rehabilitation through the Australian Centre for Heart Health; and the National Executive of the Australian Cardiovascular Health and Rehabilitation Association (ACRA).
vi. Consultation with, and feedback from, cardiac patients (key informants) on the structure and content of the CDI.

Consistent with the approach taken to the PROMIS item bank development and testing[43], and our prior conceptualisation of the primary construct of cardiac distress as a multifactorial construct, we expect that the CDI will be a multidimensional measure incorporating emotional, belief, behavioural, cognitive and social domains[1]

Patient and public involvement

The need for a comprehensive measure of cardiac-related distress has been identified by the multidisciplinary clinician researcher members of the CDI development group, through their clinical practice in provision of psychosocial support to cardiac patients. This need has been endorsed by the authors' consultations with both individual patients and patient support groups such as the hospital-based or regionally-based Heart Beat programs such as Heart Beat Victoria. As evident from step vi in the item generation procedure, patients will be consulted as key informants about the structure and content of the CDI. Only after this process of consultation is complete will the CDI item pool be tested with 400 cardiac patients.

Ethics approval and dissemination of the CDI measure

This study has been approved by the Monash Health Human Research Ethics Committee (Approval number – RES-19-0000631L-55979 0) to run from May 2020 until May 2022.

The result of the CDI development project, the psychometrically sound *Cardiac Distress Inventory*, will be made available to clinicians and researchers without charge, but with a request that data collected in studies using the measure be made available for aggregation and analysis in future. The CDI will also be translated for use with clinical populations internationally with reporting of the psychometric properties of those versions. Confirmed translations will be Italian, Hebrew, Arabic, Farsi, and Spanish. Methods for translation vary[44, 45] but we will adopt the following strategy. The CDI will be translated independently by two bilingual cardiac psychologist clinician / researchers. These translations will then be back translated into English by a bilingual psychologist independent of the two original translators and not familiar with the CDI study. These back translations will be reviewed

by a subgroup of the investigators. Discrepancies will be resolved by consensus between the original translators and the review subgroup.

Study findings will be shared with community members, particularly cardiac patient support groups such as the Heart Beat peer support groups and their equivalents internationally; academic and medical communities via publications and presentations in which authorship will follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. An online course and / or webinar on the CDI rationale and use will be provided at no cost by the Australian Centre for Heart Health. The short form will be made available on the website of the Australian Centre for Heart Health for completion by patients to self-screen with suggestions for follow up psychological support where significant distress is indicated.

Cardiac Distress Inventory design

Items generated through the process outlined above will be reworded where appropriate to ensure relevance to the measurement of cardiac distress, and appropriateness of fit with the following instruction and response set:

> *Living with a heart condition can sometimes be difficult. Listed below are some issues that people living with a heart condition may experience.*
>
> *Please indicate whether or not you have experienced each issue during the past four weeks by checking 'Yes' or 'No'. For each item you have checked 'Yes', indicate how much distress this issue has caused you for the past four weeks, from 0 to 3, where "0" is no distress and "3" is severe distress.*

Issue	Yes	No	If yes, indicate how much distress this causes for you			
			No distress at all	Slight distress	Moderate distress	Severe distress
Example: Having more pain than I expected to have	O	O	0	1	2	3

Trialling of the questionnaire for item reduction

Sample size required for trial

Recommendations of sample size for exploratory factor analysis in instrument development are that there should be at least 5 cases for each item in the instrument being used[46]. Rasch modelling for exploratory purposes should be based on at least N=100 and preferably N=250[47]. For the reliability and validation study, power calculations were conducted using GPower[48]. Given a probability level of 0.05, an anticipated effect size of 0.5, and a desired statistical power level of 0.8, a sample size of N=66 is required per group. A summary of the steps and the number required for each step in the analysis is provided in Table 1.

<Table 1 about here>

Inclusion and exclusion criteria

Eligible patients will be those who have had an acute coronary event - namely acute coronary syndrome (ACS), acute myocardial infarction (AMI) or coronary artery bypass graft surgery (CABGS) in the previous 6 months and who are attending either a CR program or an outpatient clinic at a participating hospital. Patients who do not have adequate English language proficiency to read and understand the PICF and questionnaire will be excluded.

Participant recruitment

A Research Assistant (RA) will recruit patients at six months presentation directly through outpatient clinics or CR programs associated with the investigators. Clinic staff will advise the RA of potentially eligible patients and the RA will then approach these people to ascertain eligibility and willingness to participate. Specific arrangements for site visits will be made between the RA and site investigator by email and telephone. Overall and site-specific ethical approval will be in place.

In order to calculate a response rate, the RA will document the number of patients approached and the number who agree to participate and who do not. No identifying information on either participants or non-participants will be collected.

Data collection

Consenting participants will complete the PICF and the trial-version CDI, together with basic socio-demographic and event-related information. No identifying information (name, address, date of birth) will be collected as no patient follow-up is required. For reliability and validity testing, participants will also be required to complete the four Emotion Thermometers[49], the Kessler Psychological Distress Scale-6[50] (K6) and the PHQ-4[51]. In the event that the patient experiences distress while completing the questionnaire, the patient will be reminded by the RA that he/she is free to withdraw from the study (i.e., not continue with completing the questionnaire) and will be invited to contact the Australian Centre for Heart Health for a consultation with a clinical psychology specialist at no cost to the patient.

Measures

In addition to the *trial-version CDI,* the following measures will be administered:

Demographic questionnaire: Basic socio-demographic (e.g., age, sex, marital status, living arrangement) and cardiac event-related information (event type, date of event) will be collected.

Emotion Thermometers. The Emotion Thermometers are single-item measures of distress (DT), anxiety (AnxT), depression, (DepT) and anger (AngT). They consist of a "thermometer" with numerals displayed vertically from 0 to 10. Patients rate their distress "over the last week", with 0 indicating "no distress" and 10 indicating "high distress". A total score from all four mood thermometers (ETsum) indicates overall emotional problems. These thermometers, based on the NCCN cancer distress thermometer (DT)[27], have been shown to be a clinically sensitive measure of distress in patients with mixed cardiovascular conditions[49].

Patient Health Questionnaire-4[51] (PHQ-4): The PHQ is a validated brief screener (4-items) for anxiety and depression, which combines the Patient Health Questionnaire-2 (PHQ-2) and the Generalized Anxiety Disorder-2 (GAD-2)[51]. Total scores range from 0-12, with 0 indicating "no distress" and 12 indicating "severe distress".

Kessler Psychological Distress Scale-6[50] (K6): The Kessler 6 is a brief measure of psychological distress which has been validated in an Australian general population[50]. The K6 is both an effective screening measure and an indicator of distress severity. Scores range from 6-30, with lower scores indicating higher levels of distress.

Screening Tool for Psychological Distress[36](STOP-D): This is a five-item, evidence-derived self-report measure generating severity scores for depression, anxiety, stress, anger and poor social support. The screening tool has been tested with patients before and after heart transplant, patients in cardiac rehabilitation and adults with congenital heart disease[36].

Statistical analysis for the trial

Part A – Establishing dimensions of the CDI

Principal component analysis (PCA) using SPSS will be used to assess the dimensions of the CDI. PCA is commonly used in the development of new instruments to provide early indications of possible dimensions before Rasch analysis is attempted[52]. PCA is used to extract the factors followed by oblique rotation of factors using Oblimin rotation (delta = 0). Kaiser's criterion, which retains eigen values above 1, will be used to guide the identification of relevant factors. A second step in the PCA is to conduct Horn's parallel analysis[53], considered one of the most accurate approaches to estimate the number of components[54]. The size of eigen values obtained from PCA are compared with those obtained from a randomly generated data set of the same size. Only factors with eigen values exceeding the values obtained from the corresponding random data set are retained for further investigation.

Part B - Eliminating items per dimension of the CDI

Rasch analysis is a mathematical technique used to evaluate a latent variable not measurable directly from a set of categorical items. Rasch methods can be used to assess the extent to which individual items represent the underlying construct that an instrument intends to measure. The Rasch model chosen for this analysis, the Partial Credit Model[55] is applicable to polytomous rather than dichotomous data and is therefore suitable for Likert scales and response ratings.

Rasch analysis will be conducted using RUMM2030 software (RUMM Laboratory Pty Ltd., Perth, Australia). Three statistics are considered to determine the degree of fit for each CDI scale: overall fit; individual person fit; and individual item fit[56]. Adequate overall fit of the CDI to the Rasch model is indicated by a non-significant Bonferroni adjusted Chi-square probability value[57]. Satisfactory overall item and individual fit for each scale will be determined by a fit residual standard deviation (SD) value of ≤1.5. Individual item fit is indicated by two statistics: fit residual values; and Chi-square probability values. Item fit residual values −2.5 to 2.5 indicate adequate fit[58]. Above this range (underfit) suggests deviation from the model, below (overfit) suggests that some items in the scale are similar to each other[59]. A perfect model fit would be reflected by residuals with a mean of 0.00 and a SD of 1.00. Any mis-fitting item in terms of infit/outfit is discarded and the analysis re-run. This iterative process is continued until no further misfit is observed[60]. The Rasch analysis will produce the person separation index (PSI), which indicates the degree to which study participants can be differentiated into certain groups (PSI range 0–1). Values for PSI of 0.8 are acceptable[61]. A sample size of at least 100 patients is required to perform a Rasch analysis which can estimate an acceptable PSI value[47].

Statistical significance will be considered at the 5% level and Bonferroni correction for multiple testing will be applied where appropriate.

Psychometric properties of the final Cardiac Distress Inventory

The COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) criteria for evaluating the methodological quality of health-related patient-reported outcomes will be used to inform the development of the methodology for determining the psychometric properties as far as possible[62, 63].

Reliability

Internal consistency of the CDI will be determined using Cronbach's alpha, and evaluation of the Person Separation Index (PSI) from the Rasch analysis.

Validity

Scale comparisons will be used to investigate the concurrent convergent validity of the CDI. Pearson correlation coefficients will be calculated to explore the association between CDI scores and the measure that is commonly used in clinical practice to assess distress, the six-item Kessler K6[50]. Subscale scores of the CDI will be compared with K6 scores where appropriate. We will assess the discriminant validity and predictive validity of the CDI by assessing whether it distinguishes between

patients scoring high and low on the K6, using the Australian scoring cut-off of 19 to indicate probable serious mental illness[64]. Again, both CDI total and factor scores will be investigated. It is not possible to use a measure of cardiac distress for validity testing as no such measure exists.

Pearson correlation coefficients will also be calculated to explore the association between CDI scores and the Patient Health Questionnaire–4 (PHQ4)[51]. Normative data are available from a nationally representative face-to-face household survey sample of 5030 people, conducted in Germany in 2006[65]. The measure has been translated and validated in Hispanic populations, for example[66], and has been used in studies of cancer patients[67]and emergency department patients[68]. As far as the authors are aware, no validation study of the PHQ-4 has been undertaken with cardiac patients.

Comparison of CDI scores will also be conducted between the various types of cardiac patients (e.g. AMI vs CABGS). Comparison of groups will be conducted via analysis of variance (ANOVA).

Latent Class Analysis

Latent class analysis (LCA) will be used in order to describe groups of participants that differ in their response patterns to the CDI. LCA explains inter-individual differences in response patterns by means of a given number of latent classes (subgroups of participants). LCA estimates the size of the classes and a membership probability for each participant within each class[69] and will be performed using Mplus version 6.0[70]. To select the most parsimonious number of classes and maximise model fit, a series of latent class models will be applied to the data. First, the simplest 1-class model (all patients are assumed to have the same pattern of cardiac distress) will be applied to the data, followed by successive models with a unitary increase in the number of latent classes (up to eight). Model solutions are evaluated on the basis of their Bayesian information criterion (BIC) and entropy. The BIC has been shown to be a robust indicator of model fit, with lower values indicative of better model fit[71]. BIC will be used in preference to Akaike information criteria, as the latter has been shown to over-extract classes in simulation models[72]. The association of CDI latent class membership with CDI scale scores, sociodemographic characteristics, diagnosis and K6 distress scores will also be examined using Mplus[70]. Mplus generates overall chi-square values to assess significant associations between variables as well as unadjusted chi-square values for exploratory post-hoc analysis.

Development of a short form Cardiac Distress Inventory for screening purposes

A shorter version of the CDI, the CDI-S, will then be created. Importantly, item reduction based on rigorous methodological guidelines is necessary to maintain validity when shortening composite measurement scales[73]. In addition, there are a number of ways to achieve item reduction[74]. In light of these two points, we will use two methods to develop the short form screening tool – a clinically oriented method and a statistically-driven method. A concept-retention approach will create a short version of the original measure by selection of the top performing item in each domain to become part of the short, concept-retention version[75]. Rasch analysis as used in a number of health-related item reduction exercises, will also be employed[76, 77]. The Rasch analysis and psychometric evaluation of the CDI-S will follow the format described by Nishigami and colleagues[77]. Both versions of the CDI-S will then be field tested.

Thermometer testing

Receiver operating characteristic (ROC) analysis will be used to identify the optimal CDI scale cut off score for distinguishing whether a person experiences clinically significant distress as defined by the established cut-off thresholds for ETsum (the sum of all four mood thermometers). The Area Under the Curve (AUC) will be used to estimate the overall discriminative accuracy of the CDI scale cut off score relative to the established cut off scores of ETsum (a score >14 indicates moderate and >20 indicates severe emotional problems). Using qualitative guidelines for interpreting AUC values[78], namely AUC≤0.70 as acceptable discrimination, AUC≤0.80 as good discrimination and AUC≤0.90 as excellent discrimination. ROC curves will be used to show the trade-off between the sensitivity (true-positive rate) and specificity (true-negative rate) for every possible cut off score of the CDI Scale.

TIMELINE

Months 1-2: staff recruitment, CR site recruitment and liaison; Months 3-18: Administration of the full item pool draft CDI to patients attending CR or outpatient appointments. Months 19-21: completion of data analysis; Months 22-24: writing up the study findings will be a continuous activity with completion in months 22-24.

SUMMARY

Cardiac distress is complex and various aspects of cardiac distress have been shown to be common among cardiac patients. Before cardiac distress can be treated effectively, it needs to be properly measured by a reliable, valid and sensitive instrument. Stress is increasingly being recognised as a prognostic factor in those with pre-existing cardiovascular or cerebrovascular disease [79] and stress management in cardiac rehabilitation shows promise [80]. Even so, we are yet to see the totality of cardiac distress, in all of its complexity, being addressed in this way.

The primary aim of the project, therefore, is to develop a new clinical measure which health professionals can use to identify and assess cardiac distress. They can use the fine-grained assessment provided by this unique measure to structure psychological and emotional interventions to intervene in cases of persistent distress in patients, following a cardiac event. No such measure currently exists.

While physical recovery remains the highest priority in preventive cardiology, psychological recovery is now considered a primary concern for health professionals working in cardiac rehabilitation and secondary prevention. The prevalence of clinical anxiety and depression in people who have had a cardiac event is up to four times higher than in the general population, however both the prevalence and nature of the broader concept of cardiac-related distress remains unknown. Post-event psychological problems confer an increased mortality risk for patients, highlighting the importance of identifying distressed patients early in order to ensure appropriate treatment is received. The new CDI will not only enhance clinicians' ability to identify distressed patients but will also enable them to identify the specific nature of the distress, thereby optimising their ability to provide timely support targeted to the specific psychosocial needs of the patient. The new CDI has the potential to ensure that patients are provided with the specific support they require in their psychosocial recovery after a cardiac event and, in doing so, has the potential to improve their quality of life, enhance their behaviour change efforts and ultimately extend their survival.

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Table 1: Numbers required for each stage of the development and testing of the Cardiac Distress Inventory

Steps	**Purpose**	**N required with rationale**
Development		
Exploratory Factor Analysis	Establish number of dimensions	(74 items X 5=370) cardiac patients (AMI, AF, CABGS, unstable angina plus heart failure patients with New York Heart Association (NYHA) classification of mild (NYHA 11) or moderate (NYHA 111) heart failure. Allowing for 10 percent missing data, a sample size of (74 items X 5=370 + 10% = 407) would therefore be required for this phase of the study.
Rasch Analysis	Eliminate items per dimension	The Rasch Analysis will utilise the total baseline sample and will not require a sub-sample.
Testing		
Construct validity		66 cardiac patients administered both the CDI and K6. (Using the reduced item version of the CDI).
Latent Class Analysis	Identify inter-individual differences in response patterns	The LCA analysis will utilise the total baseline sample and will not require a sub-sample.