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Effects of a brief intervention based on Acceptance and Commitment Therapy versus usual care for cardiac rehabilitation patients with coronary heart disease (ACTonHEART): a randomised controlled trial

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ABSTRACT

Objectives The main objective of the study is to investigate the short-term efficacy of Acceptance and Commitment Therapy (ACT) on the simultaneous modification of biological indicators of risk and psychological well-being in patients with coronary heart disease attending cardiac rehabilitation (CR).

Design This was a two-arm randomised controlled trial comparing a brief, manualised, ACT-based intervention with usual care (UC).

Setting The study was conducted in an outpatient CR unit in Italy. Data collection took place from January 2016 to July 2017.

Participants Ninety-two patients were enrolled and randomised, following an unbalanced randomisation ratio of 2:1 to the ACT group (n=59) and the control group (n=33). Eighty-five patients completed the ACT (n=54) and the UC (n=31) interventions and were analysed.

Interventions The control group received UC, a 6 weeks multidisciplinary outpatient CR programme, encompassing exercise training, educational counselling and medical examinations. The experimental group, in addition to UC, participated in the Acceptance and Commitment Therapy on HEART disease (ACTonHEART) intervention encompassing three group sessions based on ACT.

Outcomes The primary outcomes were Low Density Lipoproteins (LDL)cholesterol, resting systolic blood pressure, body mass index (BMI) and psychological well-being measured by the Psychological General Well-Being Index (PGWBI). Outcome measures were assessed at baseline and at the end of CR.

Results Based on linear mixed models, no significant group × time interaction was observed for either the primary outcomes (β, 95% CI: PGWBI =−1.13, −6.40 to −4.14; LDL cholesterol =−2.13, −11.02 to −6.76; systolic blood pressure =−0.50, −10.76 to −9.76; diastolic blood pressure =−2.73, −10.12 to −4.65; BMI =−0.16, −1.83 to −1.51, all p values >0.05) or the secondary outcomes (all p values >0.05). A significant time effect was found for the PGWBI total (beta=4.72; p=0.03).

Conclusions Although analyses revealed null findings, the results can inform the design of future ACT-based CR interventions and can help researchers to strike a balance between the idealised implementation of an ACT intervention and the structural limitations of existing CR programmes.

Trial registration number NCT01909102.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of the study is the naturalistic setting (ie, a standard outpatient cardiac rehabilitation programme) with a relatively heterogeneous population, which increases the generalisability of the results.
⇒ Another strength is the use of an active treatment control condition.
⇒ The study intervention has been codesigned and implemented with a multidisciplinary team including psychologists, psychotherapists, physicians, dieticians and physiotherapists.
⇒ A limitation is the smaller-than-intended sample size.
⇒ Another limitation is the absence of long-term follow-up assessments.

INTRODUCTION

Cardiac rehabilitation (CR) is considered an essential component of the secondary prevention care for coronary heart disease (CHD). It is a complex intervention aimed at improving overall cardiovascular function and quality of life, while also reducing the main modifiable risk factors for cardiovascular disease.[1 2] Recent guidelines suggest

that rehabilitation programmes for patients with complex multifactorial health conditions should adopt a holistic approach and include comprehensive multidisciplinary lifestyle interventions.[3–5]

When enrolled in a CR programme, patients are tasked with implementing several lifestyle modifications, such as adopting a low-fat diet and increasing physical activity, to improve their overall cardiovascular health. While these modifiable risk factors are well known for improving cardiovascular health, adherence to such lifestyle changes is often challenging,[6–9] especially for patients with poor psychological health.[10 11] Recent meta-analyses and reviews have indicated that interventions based on Acceptance and Commitment Therapy (ACT) are associated with improvements in quality of life, health behaviours, depression and anxiety among cardiac patients.[12 13]

ACT is a third-wave cognitive–behavioural therapy. In ACT, physical and psychological pain is considered a normal and unavoidable part of human existence and efforts to stop or reduce it can lead to suffering. If individuals can increase their willingness to experience discomfort—such as bodily sensations, thoughts and emotions—without attempts to change it or suppress it, they can better focus on engaging in values-driven actions. This general ability to be open, adaptable and effective, even in the presence of difficult or uncomfortable thoughts, emotions and sensations, is called psychological flexibility.

The main goal of ACT is increasing psychological flexibility by enhancing one's ability to engage in valued behaviours such as maintaining a heart-healthy lifestyle.[13] To that end, cultivating psychological flexibility is posited to improve patients' adaptive responses to the challenges and setbacks associated with chronic medical conditions and the need to adopt healthy lifestyles.[14 15]

Experiential *acceptance* is a key factor in promoting psychological flexibility.[16] Experiential acceptance is the ability to identify and accept the presence of thoughts, physical sensations and emotions without judgement. In contrast, experiential *avoidance* is one's *un*willingness to experience thoughts, sensations and emotions. As such, individuals may avoid stressful situations to suppress those unwanted internal experiences. Among cardiac patients, experiential avoidance may manifest in maladaptive behaviours such as unhealthy eating, sedentariness or continued nicotine use,[12] and has been associated with less improvement in measures of well-being after CR among patients with moderate-to-severe psychological distress.[17]

To develop and maintain a heart-healthy lifestyle, individuals must be willing to tolerate temporary discomforts and dissatisfaction, such as the physical discomfort of exercising, dissatisfaction with low-fat and low-sodium foods, or cravings for nicotine. In addition, they have to deal with the urge to consume savoury food, alcoholic drinks or other urges that might be detrimental to their condition.

Furthermore, they must be able to adaptively cope with the uncertainties and added stressors of managing a chronic medical condition, including an increased frequency of medical appointments and adherence to medication regimens. ACT's focus on reducing experiential avoidance and increasing experiential acceptance could assist patients with CHD in responding to the discomforts and to managing the urges that might be detrimental to their condition in an adaptive and values-driven manner. This, in turn, may ultimately increase adherence to a heart-healthy lifestyle and improve overall quality of life.

Integrating ACT into standard CR could enhance coping with the challenges associated with health-behaviour change and chronic disease management. Previous studies suggest that ACT can facilitate the adoption and maintenance of a healthy lifestyle in patients with chronic health conditions.[14 18 19] A recent systematic review showed that ACT may be effective in improving self-care ability and quality of life in patients with cardiovascular disease (CVD).[12] Thus far, no study has investigated the efficacy of ACT on the simultaneous modification of biological indicators of risk and psychological well-being in CR patients.

The aim of the present study was to investigate the extent to which a brief, manualised, ACT-based intervention could improve psychological well-being, quality of life, physical activity levels and heart-related biomarkers among patients in CR. Further, mechanisms of change that are central to ACT, such as psychological flexibility, were explored.

METHODS

Study hypotheses

The primary study hypothesis was that the ACT group would demonstrate superiority, compared with the usual care (UC) group, in at least two of the following primary outcome measures: LDL-cholesterol, resting systolic blood pressure, body mass index and psychological well-being measured by the Psychological General Well-Being Index (PGWBI).

The secondary hypotheses posited that the ACT group would demonstrate significant improvement in the following outcome measures: (1) adherence to a heart-healthy lifestyle (increased physical activity; improved dietary patterns, smoking status); (2) perceived health-related quality of life; and (3) other biological indicators of cardiovascular risk (lipid profile, glycated haemoglobin level).

Lastly, it was hypothesised that the ACT intervention would increase levels of psychological flexibility, and change in this variable would mediate change in outcome variables.

Study design and procedures

All patients referred to the outpatient CR unit at S. Luca Hospital, Istituto Auxologico Italiano, Italy, were screened

according to set inclusion and exclusion criteria. Inclusion criteria for the study were (1) a definite diagnosis of CHD including recent (<8 weeks) acute myocardial infarction (MI), acute coronary syndrome, surgical revascularisation (coronary artery bypass surgery); (2) age between 18 and 75 years; (3) fluency in spoken and written Italian language; and (4) expression of written informed consent. Exclusion criteria for the study were (1) severe psychiatric disorders according to Diagnostic and Statistical Manual of mental disorders-IV Text Revision (DSM-IV TR) criteria to (2) mental incapacity to participate in the programme (eg, cognitive impairment). All study participants, across experimental and control groups, denied familiarity with mindfulness-based and acceptance-based therapies. A more detailed rationale and design of this randomised controlled trial (RCT) were previously published.[20] Four protocol revisions were made to the originally published design: (1) the duration of the ACT treatment was shortened from five sessions to three sessions to ensure participants completed the intervention prior to their last CR session; (2) due to the limited availability of patients entering the CR programme, the number of randomised participants was reduced from 168 to 92, and (3) due to unanticipated scheduling limitations with the department, 6-month and 12-month follow-up data were not collected as planned, (4) among the planned secondary outcome variables, we did not collect medication adherence data because the license pricing was not affordable within the study budget, and we did not analyse data regarding exercise capability due to the high amount of missing data.

Sample size calculation

As reported in the original protocol of this RCT, to detect a medium effect size of the ACT intervention (ie, a standardised effect of at least 0.3 SD) in the primary outcomes, with a power level of 0.80 and alpha set at 0.05, 160 participants (80 for each group) were needed. To account for a drop-out rate of 5%, it was planned to recruit 168 participants. The sample size was not reached due to the limited availability of patients entering the CR programme.

Treatment conditions and randomisation

This was a two-arm randomised controlled clinical trial with a partially nested design and a preintervention and postintervention assessment (at the end of the treatment period). Participants were randomised to one of two groups. Those randomised to the control condition received UC which includes the standard multidisciplinary individually tailored CR programme. Participants randomised to the ACT condition received UC+ the ACT-based group programme. This choice reflects the Medical Research Council guidelines[21] which consider the 'usual treatment' as a more appropriate control condition than a placebo condition in the case of trials evaluating complex interventions.

Following an unbalanced randomisation ratio of 2:1, a total of 59 participants were randomised to the ACT condition and 33 were randomised to the UC condition. An internet-based computer-generated randomisation algorithm was used (www.random.org). To allow for higher rates of participant accrual, a fixed 2:1 randomisation protocol was used.[22 23] Assessment measures were collected at baseline and at the end of the intervention.

Usual general practice care

All participants completed a standardised outpatient CR programme, according to the best EU practice.[4 24] The programme had an average duration of 6 weeks and was conducted by a multidisciplinary team. It was individually tailored and encompassed exercise training, educational counselling and periodic medical examinations by the CR team. Each exercise session lasted 90 min and included stretching and callisthenics, as well as 45 min of aerobic exercise by bicycle or treadmill. A licensed psychologist provided every participant with a single, 90-min one-on-one educational counselling session. Education on modifiable cardiovascular risk factors, as well as behavioural strategies to increase adherence to heart-healthy behaviours, was provided. Written summaries of this information were provided to participants at the end of the counselling session.

The ACT intervention

In addition to UC, participants randomly assigned to the experimental condition completed the ACT intervention. The ACT intervention consisted of 3, 2-hour sessions occurring once a week for 3 consecutive weeks. Groups had an average of seven participants per group session. Two therapists (a proficient ACT psychotherapist and a doctoral-level student trained in ACT) led the ACT intervention groups. The treatment protocol was manualised.

The therapists engaged in a debrief meeting after each ACT session monitor fidelity to the protocol and eventually improve adherence.

Each group session included psychoeducation on a heart-healthy lifestyle. Specific behavioural techniques to modify diet, increase physical activity and adherence to medications, and discontinue use of tobacco products were taught.

Participants were assisted in becoming aware of unsuccessful attempts to control their distress, including avoidance of disease cues. Cognitive defusion techniques were introduced to help participants detach from the content of unhelpful thoughts and urges that may hinder the adoption of heart-healthy behaviour changes. Next, experiential acceptance—willingness to experience thoughts, emotions and physical sensations without judgement or need to change it—was introduced as an alternative to control-based coping. Participants were instructed in experiential acceptance strategies to increase their willingness to experience unwanted urges and sensations (such as fatigue or food cravings) while engaging in healthy behaviours like exercising or consuming heart-healthy foods.

Table 1 Overview of the ACT group sessions

Session	Content
Session 1	► ACT processes: cognitive defusion and acceptance ► Presentations and introduction to the ACT group ► Group session overview ► Education on CVD and the importance of adopting a healthy lifestyle with a focus on physical exercise ► Exercises: The Pink Elephant Paradox ► Metaphor: sailing boat ► Question and answers
Session 2	► ACT processes: mindfulness and contact with the present moment ► Group set up and group session overview ► Education on CVD and the importance of adopting a healthy lifestyle with a focus on diet and smoking cessation ► Exercise—mindful breathing ► Metaphor: sailing boat (continued) ► Group discussion
Session 3	► ACT processes: connection to values and committed action ► Group set up and group session overview ► Education on adherence to medication ► Exercises: 80th birthday and Bull's Eye ► Metaphor: Tug-of-War with a monster ► Group discussion

ACT, Acceptance and Commitment Therapy; CVD, cardiovascular disease.

Mindfulness exercises and metaphors were used to enhance participant's connection with the present moment. Participants were encouraged to practice mindfulness to increase awareness of their thoughts, emotions and physical sensations in each moment. When mindfulness is practised regularly, individuals become more aware of their attempts to control thoughts (eg, 'I can't exercise if I'm not excited about it') and/or avoid negative emotions (eg, anxiety, fear) and uncomfortable physical sensations (eg, sore muscles after exercising).

Within the ACT framework, values guide behaviours rather than thoughts, emotions or physical sensations. Participants were taught to identify personal health-related values as well as how to set behavioural goals (termed committed action) that are in service of their values. Metaphors and experiential exercises were used to help participants identify personal values and goals, and to identify barriers to adopting and maintaining the same.

Table 1 displays the content, the ACT processes, the exercises and metaphors included in each session.

Measures

Participants completed study measures before randomisation and 3 weeks later (post treatment). Demographic information such as age, gender, level of education, employment and marital status were collected. A range of physiological and psychological outcome measures were used to assess biological indicators of cardiovascular risk, modifiable risk factors such as diet, exercise, nicotine use, psychological well-being and quality of life.

Biological indicators of risk

The biological cardiac risk factors were assessed at pre-treatment and post-treatment. Fasting total cholesterol (mg/dL), HDL and LDL cholesterol (mg/dl), triglycerides (mg/dL) and glycated haemoglobin (%) were analysed by a certified laboratory. Resting blood pressure was assessed via an aneroid sphygmomanometer.

Psychological well-being

Psychological well-being was assessed using the PGWBI,[25] validated in Italian.[26] The PGWBI is a self-administered questionnaire that includes six subscales (anxiety, depression, positive well-being, self-control, general health and vitality) and produces a global measure of psychological well-being, ranging from 0 to 110, with higher scores indicating better adjustment. Previous studies have shown that PGWBI has good construct validity and high internal consistency.[26 27]

Quality of life

Health-related quality of life was measured by the 36-item Short-Form Health Survey (SF-36) questionnaire.[28] It is a widely used self-report instrument validated in Italian,[29] which appears to be a valid and reliable multidimensional measure of quality of life.[29] It is composed of eight subscales: physical function, physical role, general health, social function, experience of pain, mental health, and emotional role and vitality. Physical component summary and mental component summary measures[28] were used in lieu of the eight dimensions of the SF-36 to reduce the number of statistical comparisons and type 2 error. Higher scores indicate a better quality of life.

Dietary habits

The Mediterranean diet has been associated with better cardiovascular health[30 31] and is inversely associated with serum lipids, blood pressure, inflammation and coagulation markers related to cardiovascular disease.[32]

Moreover, those with greater adherence to the Mediterranean diet are less likely to have acute coronary syndrome[30] and have a lower mortality rate among patients with prevalent CHD. Since dietary patterns are a better predictor of disease risk and mortality compared with individual food items or nutrients,[33 34] the Mediterranean Diet Score was used to assess the overall diet in this study.[32] The Mediterranean Diet Score assesses the consumption frequency of 11 main components of the Mediterranean diet (eg, all cereals, fruit, alcohol consumption) and each of the 11 items is scored on an ordinal scale from 0 to 5. Scores are summed to obtain a total score ranging from 0 to 55.

Exercise

The short version of the International Physical Activity Questionnaire (IPAQ-S)[35] was used to assess participants' physical activity levels. IPAQ is a self-report questionnaire, which comprises seven items and measures the number of days per week and the number of times per day an individual spends doing specific activities. Only activities with a minimum length of 10 consecutive minutes are taken into account. The questionnaire encompasses five categories: job-related physical activity, transportation physical activity, housework, household tasks, recreation, sport and leisure time, and time spent sitting. The five domain-specific variables were summed to obtain the total score.

IPAQ-S has been validated in an Italian sample and showed acceptable reliability properties. The short version of the questionnaire has been demonstrated to have similar performance to the long version in terms of validity.

Smoking status

Smoking status was assessed by self-report at pre-treatment and post-treatment. Participants who were active cigarette smokers were asked to report the average number of cigarettes smoked per day, over the previous week.

Psychological inflexibility

Participants' disease-specific psychological inflexibility was measured using the Cardiovascular Disease Acceptance and Action Questionnaire, a scale that measures the person's ability to accept thoughts and feelings related to cardiovascular illness and the degree to which they interfere with valued action. It comprises 7 Likert-type items and has been validated in an Italian sample of 275 cardiac patients.[36]

Exploratory factor analysis showed a structural one-factor solution with satisfactory internal consistency and test–retest reliability. The relation with other measures supported convergent and divergent validity.

Statistical analyses

Categorical variables were described using frequencies and percentages, continuous variables using means and SD. Differences between participants who received the ACT treatment and participants in the control condition regarding the sociodemographic variables at baseline were assessed using χ^2 tests or t-tests, as appropriate. The frequency and mechanisms of missing data were inspected through descriptive statistics and graphical methods. To address missing data, multiple imputation using predictive mean matching was performed, generating 20 datasets (50 iterations). The imputed datasets were then used for the subsequent analyses. The intraclass correlation coefficient (ICC) was computed to investigate whether there was a grouping structure in the ACT condition that needed to be accounted for in subsequent analyses. Since the ICC was <0.10 for each outcome, the grouping structure was not considered. For each outcome, the efficacy of the ACT treatment was assessed using random-intercept linear mixed models, which examined the interaction between time (pre vs post) and treatment (ACT vs UC). The model included time, treatment, sex and age as covariates. Before pooling the results from the multiply imputed datasets, we evaluated the homogeneity of residual variance and the normal distribution of residuals by employing graphical methods on a random sample of five models. The alpha level was set at 0.05. The analyses were conducted in R (V.4.3.0) using *ggplot2* for graphical representations, *mice* for multiple imputation and for pooling the results of the linear mixed models, and *lme4* for fitting the linear mixed models.

Patient and public involvement

None.

RESULTS

A total of 364 patients were considered for eligibility, and 255 patients did not meet the inclusion criteria: 37.3% of them were excluded because of their age higher than 75 years, 53.7% were excluded for not having CHD, while 9% were excluded because they were not fluent in spoken and written Italian. Therefore, a total of 109 CR patients were eligible to participate in the study. Among these CR patients, 92 agreed to participate and were randomised to either the ACT (n=59) or UC group (n=33). Figure 1 illustrates the flow diagram of this study, including patient recruitment and allocation to experimental arms. The drop-out rates were 8% in the ACT group and 6% in the UC group. Therefore, data from n=85 participants was analysed. The frequency of missing data for each variable is reported in the supplementary materials (online supplemental table S1).

An overview of participant demographics for each group is provided in table 2. The mean age of participants was 62.1 years. The ACT group consisted of 44 men and 10 women, and the UC group consisted of 28 men and 3 women. Most participants were high school graduates (40.7% in the ACT group and 48.4% in the control group). The majority of participants were married (77.8% and 67.7% of the patients in the ACT and UC groups, respectively). Of the 85 participants, n=48 (56%) had undergone percutaneous coronary intervention or coronary artery bypass graft (CABG) procedures, n=14 (16%) had a recent MI, n=4 (5%) had a diagnosis of chronic ischaemic cardiomyopathy, while for n=19 (22%) patients the data on diagnosis were missing.

As outlined in table 2, baseline characteristics, including sex, age, educational level and marital status, did not significantly differ between the two conditions (p >0.05).

Means and SD of outcome measures at pre-CR and post-CR for both treatment conditions are provided in table 3. The two groups responded similarly to baseline study measures. The results of the linear mixed models for the primary and secondary outcomes are provided in tables 4 and 5, respectively. A significant time effect was found for the PGWBI total (beta=4.72; p=0.03). No

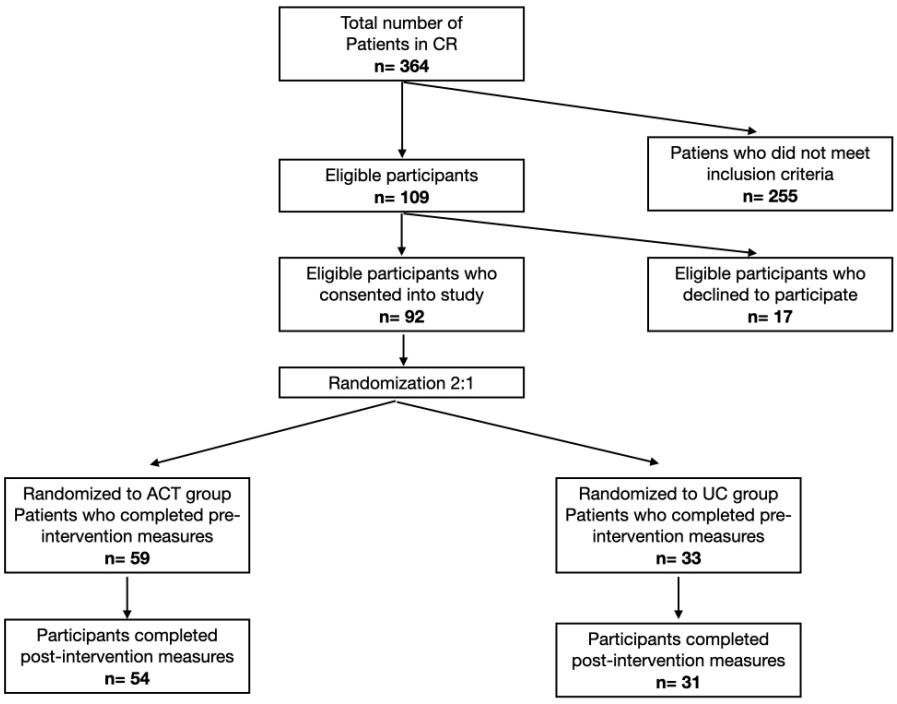

Figure 1 Study flow chart. ACT, Acceptance and Commitment Therapy; CR, cardiac rehabilitation; UC, usual care.

time × treatment effects were found, across all primary and secondary outcome variables. The results of the linear mixed models for the subscales of the PGWBI are reported in the supplementary materials (online supplemental table S2).

DISCUSSION

The primary purpose of this study was to evaluate the efficacy of adding a brief ACT-based intervention to improve cardiac risk factors and psychological well-being among CR patients. CR patients were randomly assigned to the ACT group or the UC group and no differences were found between the two groups at baseline. Drop-out rates in the ACT group were comparable to those in the UC group, suggesting that CR patients are equally willing to participate in an ACT-based CR programme. Analyses revealed no significant differences between the ACT group and the UC group across primary and secondary post-CR outcomes. These results suggest that the study hypotheses were not confirmed. A significant time effect was found on general psychological well-being, suggesting that both the ACT and the UC groups experienced relevant

Table 2 Participant demographic characteristics at baseline

		ACT (n=54)	UC (n=31)	P value
Age: mean (SD)		61.07 (8.60)	63.84 (7.41)	0.13
Sex: n (%)	Male	44 (81.5)	28 (90.3)	0.44
	Female	10 (18.5)	3 (9.7)	
Education: n (%)	Elementary school	4 (7.4)	4 (12.9)	0.65
	Middle school	18 (33.3)	8 (25.8)	
	High School	22 (40.7)	15 (48.4)	
	College or higher	10 (18.5)	4 (12.9)	
Marital status: n (%)	Unmarried	5 (9.3)	2 (6.5)	0.38
	Married	42 (77.8)	21 (67.7)	
	Widowed	2 (3.7)	4 (12.9)	
	Divorced	5 (9.3)	4 (12.9)	
Employment status: n (%)	Currently retired	19 (35.2)	17 (54.8)	0.20
	Currently unemployed	6 (11.1)	3 (9.7)	
	Currently employed	29 (53.7)	11 (38.7)	

Table 3 Comparisons of outcomes in the two groups

Outcomes	Baseline			Follow-up		
	ACT group	Control group	p_1	ACT group	Control group	p_2
BMI	27 (3.9)	26.7 (3.3)	0.76	27 (3.8)	26.9 (6.4)	0.93
Total cholesterol	126.9 (28.8)	137.2 (27.2)	0.11	123.3 (25.7)	135.9 (34.3)	0.07
HDL cholesterol	40 (11.2)	42.3 (14)	0.42	43.1 (11.3)	44.6 (14.8)	0.61
LDL cholesterol	70.7 (19.4)	79.9 (22.3)	0.05	68.2 (21.9)	79.2 (26.8)	0.04
Triglycerides	123.3 (109.5)	113.5 (48.7)	0.66	118.2 (93.1)	117.7 (48.8)	0.98
HbA1c	46 (22.3)	39 (10.2)	0.17	45.4 (20.7)	40.1 (10.8)	0.29
Systolic pressure	108.8 (18.9)	116.8 (17.3)	0.12	111.3 (22.4)	120 (18.3)	0.14
Diastolic pressure	73.3 (14.7)	71.2 (13.6)	0.61	74.4 (14.8)	76.6 (15.8)	0.61
Number of cigarettes	2 (2.2)	1.5 (1.3)	0.34	1.3 (1.4)	1 (1.2)	0.38
PGWBI tot	80 (15.6)	78.7 (16)	0.71	83.7 (13.8)	83.5 (15.7)	0.94
SF-36 PCS	61.6 (21.3)	59.6 (18.4)	0.70	64.7 (20)	65.3 (20.7)	0.90
SF-36 MCS	62.6 (26.9)	59.9 (24.3)	0.69	68.9 (21.7)	66.9 (22.1)	0.71
MDS tot	34.5 (5.5)	34.2 (4.7)	0.83	36.2 (5.3)	34.8 (4.7)	0.22
IPAQ tot	3803.8 (5895)	2777.8 (2215)	0.38	3499.0 (3440.5)	3126.9 (2768.7)	0.62
CVD-AAQ	13 (4)	14.6 (5.6)	0.13	13.5 (6.8)	14.4 (5.2)	0.55

P_1 comparisons between the two groups before the intervention; P_2 comparisons between the two groups after the intervention.
BMI, body mass index; CVD-AAQ, Cardiovascular Disease-Action and Acceptance Questionnaire; HbA1c, glycated haemoglobin; IPAQ, International Physical Activity Questionnaire; MDS, Mediterranean Diet Scale; PGWBI tot, Psychological Well-Being Index Total; SF-36 MCS, Short Form 36 Mental Component Summary; SF-36 PCS, Short Form 36 Physical Component Summary.

improvements in general psychological well-being after treatment. In the interpretation of these findings, it is important to consider that, differently from other RCTs, the present one compared the ACT treatment with an active control condition. As suggested by Gloster *et al* in their meta-analysis,[37] the effect sizes for ACT-based treatments differ depending on the comparison condition. In particular, ACT demonstrated superiority, with small-to-large effect sizes, when contrasted with passive or non-active control, while either non-significant differences or superiority when compared with other active interventions, such as treatment as usual or a combination of various active approaches.

On the other hand, the results of the present study are in contrast with those of a recent systematic review and meta-analysis, showing that ACT interventions tend to improve self-care and reduce anxiety symptoms in patients with cardiovascular disease, compared with UC care, waitlist and no-treatment control conditions.[12]

Additionally, when discussing the present results, it is important to highlight that the duration of the ACT intervention was relatively brief for this study, consisting of a total of three sessions for participants in the ACT group. While pairing down the intervention from five sessions to three sessions ensured that participants could receive the full experimental protocol prior to being discharged from CR, it is possible that more than three ACT sessions are needed to produce significant change. Indeed, ACT-based interventions for cardiac patients that led to significant improvements typically involved more than three intervention sessions. For example, Ahmadi Ghahnaviyeh *et al*'s RCT[38] on patients with MI demonstrated an increase in quality of life after an 8-session ACT programme compared with a no-treatment control condition. In another clinical trial, Nasab *et al*[39] conducted research on a sample of 45 patients who underwent a CABG. They found a decrease in health anxiety and an improvement in adherence to treatment after 12 sessions of ACT compared with a no-treatment condition. Similarly, Rahnama Zadeh *et al*[40] observed a greater improvement in depressive symptoms after an ACT programme encompassing eight 2-hour sessions, compared with the waitlist controls.

Many studies exploring ACT among cardiac patient groups use inactive control groups; a strength of the current study is the use of an active (usual CR care) group. Consistent with the best EU practices,[4 24] all study participants received an individualised educational health counselling session with a licensed clinical psychologist within the CR programme. It is important to note that there may be a meaningful difference between EU CR standards, received by both experimental and control groups, and standard non-EU CR programmes. This difference may limit the generalisability of our null findings.

The study was conducted in a naturalistic setting with broad eligibility criteria for participation. The CR patients enrolled in the study represent the general CR patient population, commonly reporting medical comorbidities and/or co-occurring general mental health conditions. Nevertheless, the naturalistic setting and minimal

Table 4 Results of the linear mixed model analyses for primary outcomes

	PGWBI total			LDL cholesterol			Systolic blood pressure			Diastolic blood pressure			BMI		
	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value
Female sex	−5.43	(−13.87 to 3.01)	0.21	3.30	(−8.51 to 15.11)	0.58	−0.38	(−12.77 to 12)	0.95	−0.12	(−9.88 to 9.64)	0.98	1.27	(−1 to 3.54)	0.27
Age	0.14	(−0.24 to 0.51)	0.48	−0.42	(−0.94 to 0.1)	0.11	0.03	(−0.54 to 0.6)	0.92	−0.23	(−0.63 to 0.17)	0.26	**−0.14**	**(−0.24 to 0.04)**	**0.01**
Group (ACT vs UC)	2.18	(−4.68 to 9.04)	0.53	−10.12	(−20.14 to to 0.1)	0.05	−3.77	(−15.08 to 7.54)	0.51	0.12	(−7.85 to 8.09)	0.98	−0.25	(−2.14 to 1.65)	0.80
Time (post vs pre)	**4.72**	**(0.58 to 8.87)**	**0.03**	−0.47	(−7.61 to 6.67)	0.9	3.86	(−4.33 to 12.06)	0.35	3.98	(−1.7 to 9.65)	0.17	0.22	(−1.1 to 1.55)	0.74
Group*time	−1.13	(−6.4 to 4.14)	0.67	−2.13	(−11.02 to 6.76)	0.64	−0.5	(−10.76 to 9.76)	0.92	−2.73	(−10.12 to 4.65)	0.46	−0.16	(−1.83 to 1.51)	0.85

Significant values are shown in bold.
BMI, body mass index; PGWBI Total, Psychological General Well-Being Index Total.

Table 5 Results of the linear mixed model analyses for secondary outcomes

	Total cholesterol			HDL cholesterol			Triglycerides			Glycated haemoglobin			SF-36 PCS		
	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value
Female sex	**14.56**	**(−1.24 to 30.37)**	**0.07**	**11.87**	**(5.07 to 18.68)**	**<0.01**	−21.4	(−71.15 to 28.34)	0.4	−2.53	(−16.05 to 10.98)	0.71	**−13.55**	**(−24.27 to 2.84)**	**0.01**
Age	−0.2	(−0.9 to 0.49)	0.56	0.11	(−0.19 to 0.41)	0.47	0.88	(−1.31 to 3.07)	0.43	0.2	(−0.40 to 0.79)	0.51	0.05	(−0.43 to 0.54)	0.83
Group (ACT vs UC)	−11.41	(−24.58 to 1.75)	0.09	−2.83	(−8.16 to 2.5)	0.3	14.32	(−24.24 to 52.88)	0.46	5.97	(−5.37 to 17.32)	0.3	3.27	(−6.07 to 12.61)	0.49
Time (Post vs pre)	0.28	(−8.62 to 9.18)	0.95	2.38	(−0.46 to 5.23)	0.1	4.44	(−10.65 to 19.52)	0.56	0.74	(−6.42 to 7.9)	0.84	6.9	(−0.21 to 14.01)	0.06
Group*Time	−2.7	(−13.74 to 8.34)	0.63	0.7	(−2.85 to 4.24)	0.7	−8.23	(−27.27 to 10.81)	0.39	−1.46	(−10.45 to 7.53)	0.75	−2.96	(−12.18 to 6.26)	0.53

	SF-36 MCS			MDS			IPAQ			CVD-AAQ		
	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value	β	95% CI	P value
Female sex	−4.98	(−17.74 to 7.78)	0.44	0.59	(−2.19 to 3.37)	0.68	−16.54	(−1889 to 1855.91)	0.99	0.73	(−1.95 to 3.41)	0.59
Age	0.07	(−0.49 to 0.64)	0.79	−0.01	(−0.14 to 0.11)	0.86	−9.33	(−93.01 to 74.35)	0.83	0.08	(−0.04 to 0.2)	0.21
Group (ACT vs UC)	3.47	(−7.66 to 14.6)	0.54	0.05	(−2.35 to 2.44)	0.97	1163.89	(−703.59 to 3031.38)	0.22	−1.81	(−4.43 to 0.8)	0.17
Time (post vs pre)	5.17	(−4.09 to 14.43)	0.27	0.35	(−1.52 to 2.23)	0.71	474.56	(−1461.18 to 2410.3)	0.63	−0.56	(−3.1 to 1.98)	0.66
Group*time	−0.16	(−11.71 to 11.39)	0.98	1.31	(−1.01 to 3.63)	0.27	−774.49	(−3214.48 to 1665.5)	0.53	1.08	(−2.04 to 4.21)	0.49

The significant models are shown in bold.
CVD-AAQ, Cardiovascular Disease-Action and Acceptance Questionnaire; IPAQ, International Physical Activity Questionnaire; MDS, Mediterranean Diet Scale; SF-36 MCS, Mental Component Summary; SF-36 PCS, Physical Component Summary.

eligibility criteria may have interfered with our ability to detect meaningful time × treatment effect. It is possible that an ACT-based intervention embedded within a CR programme leads to improvements above and beyond that of UC for a subgroup of CR patients. For instance, Farris and Kibbey[41] found that ACT-informed exposure interventions increased physical activity in a small group of low-active cardiac patients with high exercise sensitivity. Similarly, Rahnama Zadeh *et al*[40] reported that an ACT-based group intervention resulted in a significant effect on reducing depression and hypertension among a highly specific group of cardiac patients between the ages of 30 and 50 years old with a diagnosis of premature CHD and hypertension.

Strengths and limitations

One of the major strengths of this study is the novelty of embedding ACT into a CR programme and targeting multiple modifiable risk factors simultaneously. Another strength lies in the inclusion of biological indicators of risk, such as LDL and systolic blood pressure as outcome variables. Moreover, this study was conducted in a naturalistic setting (ie, a standard outpatient CR programme) with a relatively heterogeneous population, thereby increasing the generalisability of the results. Another strength is that the ACT interventions were delivered by a psychologist and a doctoral-level psychology graduate student with extensive training in ACT.

The study has several limitations. The smaller-than-intended sample size may compromise statistical power for detecting treatment effects. Moreover, a relevant imbalance in favour of men was observed, as the proportion of women in the present sample is lower than expected based on cardiovascular morbidity data. Such imbalance may limit generalisability of the present results to women; however, it is similar to that observed in other Italian CR samples.[11 42] A possible reason for this imbalance is that female patients are less likely than male ones to engage in CR programmes, as previously reported.[43] Common barriers to participation for women have been recently identified globally and include lack of awareness of CR, distance from the hospital and transportation difficulties, family responsibilities and other time conflicts, as well as a negative attitude towards physical exercise.[44] Future studies should expand CR delivery and implement women-focused CR programmes in order to overcome these barriers to women participation.

Additionally, the absence of follow-up assessments prevents the detection of possible delayed treatment effects and long-term benefits. Although the initial study design included 6-month and 12-month follow-up assessments, only baseline and post-CR data could be collected. One notable barrier to collecting follow-up data was participant travel limitations. We initially planned to collect follow-up data during the participant's 6-month and 12-month follow-up appointments, during which blood samples would be collected and self-report measures would be completed. However, many participants resided far away from the CR facility and/or relied on others for transportation, making it difficult for them to complete follow-up assessments as planned. Future researchers may consider strategies to increase adherence to CR follow-up appointments. Additionally, exploring alternative methods to collect samples, such as offsetting travel costs for participants, travelling to the participant's home for sample collection, or finding laboratories closer to the participant's residence, could be valuable. As it relates to self-report measures, researchers should consider the costs and benefits of employing internet-based self-report measures or sending/receiving measures by mail. Studies with larger sample sizes and longer follow-up periods are needed to better understand the potential intervention effects.

Our intervention consisted of three, 2-hour, group sessions totalling 6 contact hours. The limited number of sessions may have impacted the effectiveness of the treatment in improving psychological flexibility of the ACT group compared with UC. This could potentially explain the absence of differences between groups on the outcome measures, and it should be carefully considered by future researchers. In their 2023 review of ACT interventions for patients with CVD, Zhang *et al*[12] reported that most interventions had a session duration ranging from 20 min to 2 hours, with total contact hours spanning from 1 hour 40 min and 16 hours, across a range of 4–12 sessions. Because our intervention was embedded within an existing CR programme, researchers had limited control over the duration and total number of group sessions offered. It is plausible that, for example, briefer sessions across a greater number of sessions might have yielded different outcomes.[41] Moreover, in a clinical setting, the treatment duration can be adjusted to fit the patient's need, potentially improving patient outcomes. Although the inclusion of biological indicators of risk among the outcome measures may be considered a strength of this study, the short treatment duration may have prevented observing significant modification in these parameters, which usually require a wider period to change significantly and can be influenced by several other factors, such as medications. Future studies might evaluate intermediate behavioural outcomes, such as modifications in exercise and food habits, by adopting ecological momentary assessment, also by using wearable devices, which can instantly detect changes in health behaviour.

The standardised design of this RCT did not allow for patient-centred treatment plan adjustments, understandably limiting the generalisability of results to clinical settings. Future studies are needed to comprehend the effectiveness of ACT-based interventions in improving cardiovascular health and psychological well-being, as well as to identify the specific patient population and clinical setting best suited for these interventions. Moreover, as suggested in a recent review on CR delivery by Beatty *et al*,[45] the adoption of telehealth technologies may increase the feasibility of programmes with longer treatment

duration and may be more suitable for specific subpopulations of CR patients.

While having ACT-trained therapists is a relative strength, data on therapist competence and intervention protocol adherence were not collected. However, after each ACT session, the two therapists held a debrief meeting to monitor and improve fidelity to the manualised treatment protocol. Another limitation is that both researchers and participants were not blinded to group assignments. However, Moustgaard *et al*[46] found that there is no average difference in estimated treatment effect between trials with and without blinded patients, outcome assessors or healthcare providers.

CONCLUSIONS

The aim of this study was to evaluate the extent to which a brief, manualised, ACT-based intervention could improve psychological well-being, quality of life, health behaviours and heart-related biomarkers among a group of CR patients. Although analyses revealed null findings, the results can inform the design and implementation of future ACT-based CR interventions. Embedding a group-based ACT intervention into an existing CR programme posed some challenges in this study; thus, future researchers will need to strike a balance between the idealised implementation of an ACT intervention and the structural limitations of the existing CR programme. Well-designed studies are necessary to determine if integrating ACT into a CR programme results in significant improvements in heart health and overall psychological well-being above and beyond that of UC.

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