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### Mind your heart: health care, quality of life, and biological pathways in adults with congenital heart disease

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# Chapter 9

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## **Quality of life in adults with congenital heart disease: Happiness as a buffer for the negative effect of depressive symptoms**

*Submitted*

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## ABSTRACT

**Purpose** To improve patients' quality of life (QoL) we need to identify modifiable determinants. Positive affect may be an important factor for the maintenance of QoL, but is largely unstudied. Our objectives were: (1) to assess the relationship between negative (depressive symptoms and trait-anxiety) and positive affect (happiness and optimism) in patients with congenital heart disease (CHD), (2) to examine to what extent negative and positive affect are independently predictive of QoL at two year follow-up, and (3) to examine whether positive affect serves as a buffer for the detrimental consequence of negative affect on patients' QoL.

**Methods** At baseline, 845 adult CHD-patients completed questionnaires assessing depressive symptoms, trait-anxiety, happiness, and optimism. At two-year follow-up, QoL was assessed.

**Results** Many depressive symptoms and high trait-anxiety scores were related to a poor mental and physical QoL. Happiness was predictive of a better mental but poorer physical QoL. Patients with many depressive symptoms and high happiness scores reported a better mental QoL than patients with many depressive symptoms but low happiness scores. Patients with low trait-anxiety and high optimism scores reported a better physical QoL than patients with low trait-anxiety and low optimism scores. Yet, patients with high trait-anxiety scores and high optimism scores reported a poorer physical QoL than patients with high trait-anxiety but low optimism scores.

**Conclusions** Happiness functions as a buffer for the negative effect of depressive symptoms on mental QoL. Mental QoL may therefore be improved by a dual policy of decreasing negative affect and simultaneously enhancing positive affect.

## INTRODUCTION

Nowadays, over 90% of infants born with congenital heart disease (CHD) reach adulthood<sup>1</sup> thanks to the success of cardiac surgery.<sup>2</sup> CHD is defined as a malformation of the heart or the large blood vessels that develops during the fetal period.<sup>3</sup> Despite cardiac surgery, CHD-patients experience residual lesions, sometimes resulting in impairments in daily life. For this reason there has been increasing awareness for patients' quality of life (QoL). To improve their QoL, modifiable predictors need to be identified. Only few studies have examined correlates of QoL in CHD. Literature shows that patients' disease complexity, disease course, sex, age, educational status, depressive predisposition and social support are associated with QoL.<sup>4-7</sup> Most of these correlates are not amenable to intervention. Research on modifiable predictors of QoL may provide targets for interventions to improve QoL.

In general, it is well known that psychological well-being is an important component of persons' QoL.<sup>8</sup> During the last few decades the primary focus has been on negative affect (e.g. depression and anxiety) and its relation to QoL.<sup>9-14</sup> Positive affect may represent a potential target for intervention to improve CHD-patients' QoL. Recently, a growing number of studies and theories suggest that addressing psychological well-being in terms of positive affect may play a critical part in the maintenance of psychological well-being. It has been suggested that negative and positive affect are independent, in that positive affect is neither simply the opposite nor the absence of negative affect, and that individuals are capable of experiencing low or high levels of both dimensions simultaneously across time.<sup>15,16</sup> Positive affect can function as a 'buffer' for negative affect and both can co-occur.<sup>17</sup> Consequently, we hypothesize that positive affect compensates for the detrimental consequences of negative affect on mental QoL. For physical QoL we have no a priori expectations, this analysis was therefore exploratory.

The overall aim of this study was to predict patients' QoL by means of negative and positive affect. The specific objectives of this study were (1) to assess the relationship between negative (depressive symptoms and trait-anxiety) and positive affect (happiness and optimism) in patients with CHD, (2) to examine to what extent negative and positive affect are independently predictive of QoL at two year follow-up and (3) to examine whether positive affect serves as a buffer for the detrimental consequences of negative affect on patients' QoL.

## METHODS

### Study population and procedure

This longitudinal study used data from a larger research project on patient-reported outcomes of adult CHD-patients.<sup>18</sup> In March, 2009, 1670 adult CHD-patients from five tertiary referral and three regional centers, were randomly selected from the CONCOR database, a nationwide registry for CHD-patients.<sup>19</sup> Selected patients were literate in Dutch, 18 years or older and diagnosed with a CHD (patients with Marfan syndrome were excluded). Patients were invited by letter to complete a set of questionnaires. In March, 2011, first-time respondents were asked to participate again. Ethical approval is not required for questionnaire studies in the Netherlands; therefore this study

was exempted from approval by the Medical Ethics Committee of the Amsterdam Academic Medical Center.

## **Measurements**

### *Patient characteristics*

Patients' sex, age, and type of heart defect were extracted from the CONCOR database. Disease complexity was based on type of heart defect and categorized as simple, moderate or complex according to Warnes and colleagues.<sup>20</sup> New York Heart Association (NYHA) functional class was determined by one patient-based question.<sup>21</sup>

### *Negative affect*

Negative affect was defined as: "a broad range of aversive mood states that form a general distress factor which can be measured either as a transient fluctuation in mood (state) or as a stable individual difference in affective level (trait)" (p.159).<sup>22</sup> In this study depressive symptoms (state) and trait-anxiety were assessed as measures of negative affect.

Depressive symptoms were measured with the seven-item depression subscale of the Hospital Anxiety and Depression scale (HADS).<sup>23</sup> All items are answered on a 4-point (0-3) Likert scale. A sum score is calculated ranging from zero to 21 with a higher score reflecting more depressive symptoms. Studies have shown that the HADS depression subscale is reliable and valid.<sup>23,24</sup>

Trait-anxiety was measured using the 20-item Trait-subscale of the State-Trait Anxiety Inventory (STAI-trait).<sup>25</sup> A 4-point Likert scale is used to answer all items. Sum scores range from 20 to 80, with higher scores reflecting higher trait-anxiety levels. Both the reliability and validity of the STAI-trait are considered to be sufficient.<sup>26</sup>

### *Positive affect*

We used the following definition of positive affect: "the feelings that reflect a level of pleasurable engagement with the environment such as happiness, joy, excitement, enthusiasm and contentment" (p.925).<sup>27</sup> These feelings can be brief, longer lasting, or more stable trait like feelings. We measured positive affect in terms of feelings of happiness and the tendency to be optimistic.

Happiness was assessed by the four-item Subjective Happiness Scale (SHS).<sup>28</sup> All items are answered on a 7-point Likert scale. A sum score is calculated ranging from one to seven, with higher scores reflecting greater happiness. Both the validity and reliability of the SHS were found to be sufficient.<sup>28</sup>

The Life Orientation Test (LOT) was used to measure optimism.<sup>29</sup> The test consists of 12 items; which are answered on a 5-point Likert scale. The total sum score ranges from two to 24, with higher scores reflecting higher optimism levels. Studies have shown that the LOT is both reliable and valid.<sup>30</sup>

### *Quality of life*

QoL can be defined in many ways, at large there is consensus that it is a multidimensional concept including physical, psychological and social functioning.<sup>8</sup> General QoL was assessed by the Short Form Health Survey-36 (SF-36), yielding a mental (MCS) and physical component summary (PCS).<sup>31</sup> The MCS and PCS have a standardized mean of 50. The SF-36 was found to be amply validated.<sup>32</sup>

Disease-specific QoL was measured by the TNO/AZL Adult Quality Of Life-CHD (TAAQOL-CHD).<sup>33</sup> This questionnaire consists of three subscales: symptoms, worries and impact. For each subscale higher scores reflect a better QoL. There has been only one study that validated the TAAQOL-CHD.<sup>34</sup>

### **Statistical analysis**

We calculated mean scores and standard deviations for the depressive symptoms, trait-anxiety, happiness and optimism scales using descriptive statistics.

The relationship between negative (depressive symptoms and trait-anxiety) and positive affect (happiness and optimism) was calculated by a Pearson Product Moment correlation coefficient and interpreted as small ( $r < 0.10$ ), medium ( $r 0.30-0.50$ ) or large ( $r > 0.50$ ).<sup>35</sup>

In addition, we examined (1) to what extent negative (depressive symptoms and trait-anxiety) and positive affect (happiness and optimism) independently predict QoL, and (2) whether positive affect functions as a buffer for the detrimental consequences of negative affect on QoL. Therefore, multiple linear regression analyses using general linear models (GLM) were performed entering depressive symptoms, trait-anxiety, happiness, optimism, their four interaction effects (depressive symptoms x happiness, depressive symptoms x optimism, trait-anxiety x happiness, trait-anxiety x optimism) and patient characteristics simultaneously. To avoid multicollinearity between the main effects and the interaction terms, individual scores were centered before calculating interaction terms.<sup>36</sup> These analyses were performed for each QoL-scale (MCS, PCS, symptoms, worries) separately. The impact subscale was not included, because it primarily focuses on the physical load of cardiac examination. All analyses were conducted in SPSS 16.0 and results were tested at the significance level of 5%.

## **RESULTS**

### **Response, patient characteristics and mean scores for negative and positive affect**

Of the 1670 patients, 1109 responded the first time (response rate 66.4%). At follow-up 1100 patients (nine patients died during the two year follow-up period) were sent a second questionnaire. Of the 1100 eligible patients, 845 participated the second time (response rate 76.8%).

Patient characteristics of the 845 CHD-patients are shown in Table 1. More than half of the patients were female, with a mean age of 41.3 years (Table 1). Almost 60% was diagnosed with a simple congenital heart defect. Only 8.5% had a complex defect. A majority of the patients had a NYHA-I classification (71.2%). The most common diagnoses were ventricular septal defect,

atrial septal defect and aortic coarctation (together 36.3%). The distribution of diagnoses is in concordance with the distribution of diagnoses in the CONCOR database.

Table 1: *Patient characteristics and scores on negative and positive affect*

	Total (n=845)
<b>Patient characteristics</b>	
Sex (female)	457 (54.7)
Age	41.3 (14.4)
Disease complexity	
Simple	502 (59.5)
Moderate	270 (32.0)
Complex	72 (8.5)
Functional status	
NYHA-I	591 (71.2)
NYHA-II	175 (21.1)
NYHA-III	45 (5.4)
NYHA-IV	19 (2.3)
Congenital heart defect	
VSD / ASD / ASD-I / PDA	306 (36.3)
TOF / PS	162 (19.2)
BAV / AS / SubvAS	121 (14.3)
CoA	106 (12.6)
TGA / ccTGA	28 (3.3)
Other CHD-diagnoses	107 (12.7)
<b>Negative and positive affect</b>	
Depressive symptoms	2.4 (2.8)
Trait-anxiety	35.7 (10.0)
Happiness	4.8 (0.7)
Optimism	16.2 (3.5)

Note: Numbers are given in frequencies (valid percentages), and age in mean years (standard deviation). Mean scores (standard deviation) for depressive symptoms (range 0-20), trait-anxiety (range 20-80), happiness (range 1-7), and optimism (range 2-24) are provided. NYHA = New York Heart Association functional class; VSD = Ventricular Septum Defect; ASD = Atrial Septum Defect; ASD-I = Atrial Septum Defect primum; PDA = Patent Ductus Arteriosus; TOF = Tetralogy of Fallot; PS = Pulmonary Stenosis; BAV = Bicuspid Aortic Valve; AS = Aortic Stenosis; SubvAS = Subvalvar Aorta Stenosis; CoA = Coarctation of the Aorta; TGA = Transposition of the Great Arteries; ccTGA = Congenital corrected Transposition of the Great Arteries; CHD = Congenital heart defect.

Patients' mean scores for negative and positive affect are also provided in Table 1. In comparison to healthy Dutch reference populations, CHD-patients reported significantly higher levels of trait-anxiety (mean=34.0 versus mean=35.7,  $p<0.01$ ),<sup>37</sup> but significantly lower levels of depressive

symptoms (mean=3.4 versus mean=2.8,  $p<0.01$ ),<sup>38</sup> happiness (mean=5.6 versus mean=4.8,  $p<0.01$ )<sup>39</sup> and optimism (mean=25.4 versus mean=16.2,  $p<0.01$ )<sup>40</sup>. CHD-patients scored average on both the MCS and PCS (means were 50) measuring general QoL, which is comparable to the general population ( $p>0.05$ ).

### Relationship between negative and positive affect

As expected, negative affect was inversely related to positive affect (see Table 2). All correlations were large according to Cohen's guidelines.<sup>35</sup> The largest inverse correlation was between trait-anxiety and optimism ( $r=-0.69$ ,  $p<0.01$ ), that is, high levels of trait-anxiety were associated with low levels of optimism.

Table 2: Correlations between negative (depressive symptoms and trait-anxiety) and positive affect (happiness and optimism)

	Negative affect		Positive affect	
	Depressive symptoms	Trait-anxiety	Happiness	Optimism
Depressive symptoms	--	0.71*	-0.57*	-0.53*
Trait-anxiety	0.71*	--	-0.63*	-0.69*
Happiness	-0.57*	-0.63*	--	0.54*
Optimism	-0.53*	-0.69*	0.54*	--

Note: Pearson Product Moment correlation coefficients are provided; \*  $p < 0.05$ .

### Predictors of quality of life and positive affect as a buffer for negative affect

In general, older patients reported a better mental QoL (MCS:  $B=0.05$ ,  $p<0.05$ ; Worries:  $B=0.16$ ,  $p<0.01$ ), but poorer physical QoL (PCS:  $B=-0.13$ ,  $p<0.01$ ; Symptoms:  $B=-0.15$ ,  $p<0.01$ ). Males reported a better physical QoL (PCS:  $B=2.58$ ,  $p<0.01$ ; Symptoms:  $B=5.14$ ,  $p<0.01$ ). Moreover, a complex defect was independently predictive of a poorer physical QoL (PCS:  $B=-3.36$ ,  $p<0.01$ ). A poorer functional status was independently predictive of a poorer mental and physical QoL ( $p<0.05$ , see table 3 for specific contrasts).

#### Mental quality of life

In the model for the MCS scale, the only significant interaction term was depressive symptoms x happiness. Therefore we reran the analysis excluding the three non-significant interaction terms (Table 3, first column). Results showed that patients who scored high on trait-anxiety scored low on the MCS ( $B=-0.36$ ,  $p<0.01$ ). Moreover, the interaction term depressive symptoms x happiness remained significantly predictive of higher scores on the MCS scale ( $B=0.23$ ,  $p=0.02$ ). To facilitate interpretation of this interaction term, a graph is provided in Figure 1a. This graph depicts that patients with many depressive symptoms and a high happiness score reported a higher score



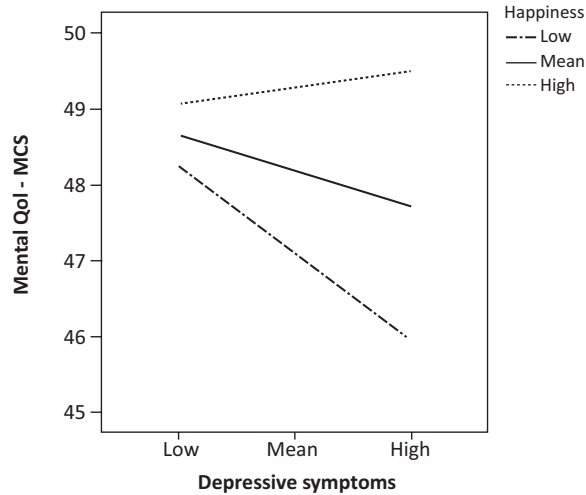
Table 3: The independent predictive value of depression, anxiety, happiness and optimism for quality of life at two-year follow-up

	MENTAL QUALITY OF LIFE				PHYSICAL QUALITY OF LIFE			
	MCS		Worries		PCS		Symptoms	
	B	p	B	p	B	p	B	p
<b>Patient characteristics</b>								
Age	0.05	<0.05*	0.16	<0.01*	-0.13	<0.01*	-0.15	<0.01*
Sex (male)	-0.31	0.61	0.02	0.98	2.58	<0.01*	5.14	<0.01*
Disease-complexity <sup>§</sup>								
Moderate	-0.57	0.38	-0.95	0.23	-0.86	0.20	-0.98	0.24
Complex	0.42	0.71	-2.54	0.07	-3.36	<0.01*	-2.77	0.06
Functional status <sup>†</sup>								
NYHA-II	0.63	0.42	-3.56	<0.01*	-8.13	<0.01*	-8.48	<0.01*
NYHA-III	1.29	0.34	-5.99	<0.01*	-16.05	<0.01*	-11.75	<0.01*
NYHA-IV	-4.49	0.03*	-11.96	<0.01*	-11.72	<0.01*	-17.56	<0.01*
<b>Negative and positive affect</b>								
Depressive symptoms	-0.15	0.38	0.17	0.40	-0.46	0.02*	-0.19	0.36
Trait-anxiety	-0.36	<0.01*	-0.35	<0.01*	-0.03	0.61	-0.23	<0.01*
Happiness	1.10	0.07	2.06	<0.01*	-1.43	0.02*	0.07	0.93
Optimism	-0.08	0.50	-0.03	0.86	0.04	0.74	-0.07	0.62
Depressive symptoms x Happiness	0.23	0.02*	--	--	--	--	--	--
Depressive symptoms x Optimism	--	--	--	--	0.04	0.29	--	--
Trait-anxiety x Happiness	--	--	0.02	0.70	--	--	--	--
Trait-anxiety x Optimism	--	--	--	--	-0.03	0.02*	--	--

Note: -- = not included in the model; MCS = Mental Component Summary of the SF-36; Worries = Worries subscale of the TAAQOL-CHD; PCS = Physical Component Summary of the SF-36; Symptoms = Symptoms subscale of the TAAQOL-CHD; NYHA = New York Heart Association functional class; § = reference category is simple; † = reference category is NYHA-I; Depressive symptoms x Happiness = the interaction term of depressive symptoms and happiness; Depressive symptoms x Optimism = the interaction term of depressive symptoms and optimism; Trait-anxiety x Happiness = the interaction term of trait-anxiety and happiness; Trait-anxiety x Optimism = the interaction term of trait-anxiety and optimism; B = B-value; p = p-value; \* p < 0.05.

on the MCS scale than patients with many depressive symptoms but a low happiness score. This effect of happiness was largest for patients reporting many depressive symptoms.

Figure 1a: *The effect that depressive symptoms have on mental quality of life is mediated by patients' score on happiness*



Note: Low = one standard deviation below the mean; High = one standard deviation above the mean.

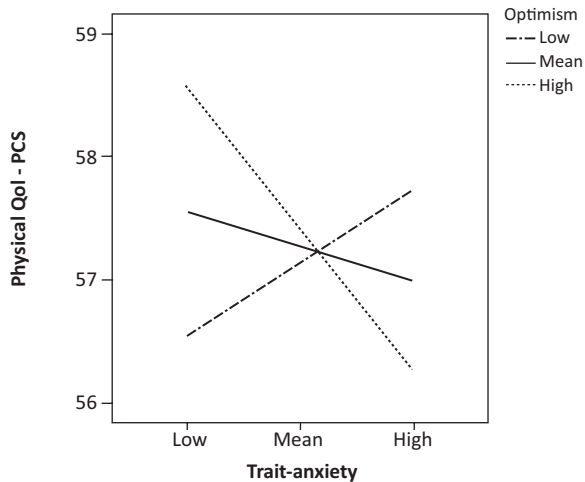
The interaction term trait-anxiety x happiness was significant in the model for the worries scale. We reran the analysis therefore excluding the three non-significant interactions (Table 3, second column). Results showed that high levels of trait-anxiety ( $B=-0.35, p<0.01$ ) but low levels of happiness ( $B=2.06, p<0.01$ ) were predictive of a lower worries score (i.e. poorer mental QoL). The interaction term trait-anxiety x happiness was no longer significant ( $B=0.02, p<0.70$ ).

### *Physical quality of life*

In the model for the PCS scale only the interaction terms depressive symptoms x optimism and trait-anxiety x optimism were significant. Therefore we reran the analysis, excluding the two non-significant interactions (Table 3, third column). Results of this analysis showed that high scores on the depressive symptoms ( $B=-0.46, p=0.02$ ) and happiness scale ( $B=-1.43, p=0.02$ ) were independently predictive of a low score on the PCS scale. The interaction term depressive symptoms x optimism was no longer significant ( $B=0.04, p=0.29$ ). There was a significant negative effect of trait-anxiety x happiness ( $B=-0.03, p=0.02$ ) (see Figure 1b). This graph shows that patients who scored low on trait-anxiety and low on optimism reported a lower score on the PCS scale, than patients who scored low on trait-anxiety, but high on optimism. For patients with an average score on trait-anxiety, the level of optimism is irrelevant with respect to their score on the PCS.

Lastly, patients with a high score on trait-anxiety and a high score on optimism reported a lower PCS score than patients with a high score on trait-anxiety but a low score on optimism.

Figure 1b: *The effect that trait-anxiety has on physical quality of life is mediated by patients' score on optimism*



Note: Low = one standard deviation below the mean; High = one standard deviation above the mean.

None of the interaction terms were significantly related in the model for the symptoms scale. The analysis was therefore repeated without the four interaction terms (Table 3, fourth column). Patients with a high score on trait-anxiety reported a lower score on the symptoms scale ( $B=-0.23$ ,  $p<0.01$ ), i.e. a poorer physical QoL.

## DISCUSSION

To our knowledge, this is the first longitudinal study in CHD-patients focusing on the predictive value of negative and positive affect for QoL and examining whether positive affect functions as a buffer. Results show that negative (depressive symptoms and trait-anxiety) as well as positive affect (happiness) are predictive of QoL two years later. Moreover, happiness seems to be protective for the negative effect of depressive symptoms on mental QoL.

Our finding that depressive symptoms, trait-anxiety, and happiness were independently predictive of QoL is in line with previous findings in various patient groups, reporting that both negative and positive affect are simultaneously predictive of QoL.<sup>41-43</sup> As one would expect, patients with few depressive symptoms, low trait-anxiety scores, and high scores on happiness reported a better mental QoL. However, unexpected was the negative relation between happiness

and physical QoL. This finding may be explained by an adaptation effect; patients with the worst physical QoL, may focus on the good things in life, therefore reporting more feelings of happiness.<sup>44</sup>

Although various studies report that optimism is related to a better mental and physical QoL,<sup>45-47</sup> we could not confirm this in our study. A possible explanation for this discrepancy is that in addition to optimism, happiness was included as a measure of positive affect. Moreover, we analyzed the predictive value of optimism for QoL independent of depressive symptoms and trait-anxiety. Indeed, in another study that controlled for measures of depression and anxiety, optimism was also found not to be related to mental or physical QoL.<sup>48</sup>

Nonetheless, a secondary role for optimism mediated by levels of trait-anxiety can be suggested for physical QoL. In patients who scored low on trait-anxiety, optimism was beneficial for their physical QoL. Unexpected was the direction of the effect for patients scoring high on trait-anxiety. Here patients who scored low on optimism reported a better physical QoL. We cannot provide a valid explanation based on the results of this study. These findings suggest that the detrimental consequence of trait-anxiety on physical QoL measured by the PCS is not buffered by optimism. A possible explanation may be found in the items of the PCS scale. These are quite literal in their assessment, for example questions assess patients' ability to climb the stairs, which makes it unlikely that the tendency to be optimistic has a buffering effect for trait-anxiety.

Our study does provide support for the notion that positive affect can function as a buffer for the detrimental consequences of negative affect on mental QoL. Results show that a high level of happiness is a buffer for the negative effect of depressive symptoms on mental QoL. This buffering effect gets larger as depressive symptoms increase. Although this buffering effect was often suggested, to our knowledge there are no studies exploring this relation. Only one previous study reported that persons with high scores on both negative and positive affect reported significantly higher scores on mental and physical QoL, compared to persons with high scores on negative but low scores on positive affect, which is in line with our results.<sup>49</sup>

Consequently, improvement of positive affect, with in particular feelings of happiness may represent a potential target for intervention, in addition to traditional therapies focusing on reducing negative affect. So called, positive psychological interventions teach individuals ways to increase their positive thinking, positive affect, and positive behaviors and can serve as a template for programs aimed at helping people who experience health-related and other types of life stress. Positive psychological interventions often consist of positive exercises such as writing letters of gratitude, counting one's blessings, practicing optimism, performing acts of kindness, meditating on positive feelings towards others and using one's signature strengths.<sup>50,51</sup> Two randomized controlled trials in patients with mild clinical depression have reported promising findings.<sup>51,52</sup> Increasing feelings of happiness may not only improve patients' QoL, yet may also have secondary beneficial effects. Several studies have reported on the beneficial effects of positive affect on ones health.<sup>53-57</sup> Noteworthy is the study by Davidson et al, who demonstrated that positive affect is protective for 10-year incident coronary heart disease independent of negative affect and cardiovascular risk-factors.<sup>56</sup> Possible mechanisms underlying this relation may be behavioral or biological. For example, patients who reported a high life satisfaction are less likely to smoke and

more likely to regularly exercise.<sup>54</sup> On the other hand positive affect (e.g. happiness) has been related to low levels of cortisol, C-reactive protein and interleukin-6, which are found to be related to various chronic diseases such as diabetes mellitus and cardiovascular conditions.<sup>54</sup>

This study has several limitations that need to be addressed. First, other predictors of QoL, such as experienced social support, personality, illness beliefs and level of education and are not measured.<sup>6,58,59</sup> Furthermore, our CHD-patients represent a group of patients who feel quite well. Consequently, further research should study patients who report more depressive symptoms, higher levels of trait-anxiety and have a poorer QoL. Therefore, results from this study cannot be automatically generalized to such patient populations.

We would also like to emphasize the strengths of this study. First, we included 845 patients from regional and tertiary centers. That is, we investigated 6.5% of all registered patients in the national database and around 2.5% of the estimated total adult CHD-population in the Netherlands. Therefore, a broad spectrum of Dutch CHD-patients represents our sample. Second, we included measures of both negative and positive affect, examining the range of emotions. Moreover, validated questionnaires to measure depressive symptoms, trait-anxiety, happiness, optimism and QoL were employed. Furthermore, we examined to what extent positive affect buffers the detrimental consequences of negative affect for QoL. In addition, both disease-specific as well as general QoL have been measured in this study. Finally, we employed a longitudinal study design.

## **Conclusions**

Positive affect is a potential target for the improvement of CHD-patients' mental QoL. This knowledge can help health care providers such as psychologists to improve therapeutic strategies. Patients' mental QoL may be more rapidly enhanced by this dual policy of decreasing negative affect and simultaneously improving positive affect. In addition to the improvement of QoL, this treatment strategy may also have beneficial secondary effects in patients' health, such as a reduced risk of coronary heart disease. Future studies examining the therapeutic value of the enhancement of positive affect (e.g. happiness) on QoL and its possible beneficial secondary effects need to be conducted.

## **ACKNOWLEDGEMENTS**

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