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The psychometric properties of the Russian version of the MacNew Heart Disease Health-related Quality of Life Scale in patients undergoing coronary artery bypass grafting surgery

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Abstract

Rationale and aims: The MacNew questionnaire is a disease-specific health-related quality of life (HRQL) measure designed for patients with heart disease. We aimed to assess the psychometric properties of the Russian MacNew heart-disease health-related quality of life (HRQL) scale in patients undergoing coronary artery bypass grafting (CABG) surgery.

Methods: The sample comprised of 226 Russian-speaking CABG patients. Patients were assessed before CABG surgery and 12 months thereafter. They completed the MacNew, the Short Form-36 Health Survey (SF-36), the Hospital Anxiety and Depression Scale and a questionnaire on demographic and lifestyle habits.

Results: Of the 226 patients who completed the questionnaires at study entry, 188 (83%) also provided data after 12 months. The internal consistency of the MacNew scales was high (alpha coefficients: 0.88-0.93). There were moderate to high correlations between similar sub-scales of the MacNew and the SF-36 domains (0.69-0.80). The MacNew scales discriminated between patients varying on 4 variables: gender, depression, anxiety and congestive heart failure. The original 3-factor structure was generally supported. Patients' scores on the MacNew scale improved over 12 months suggesting it was responsive to change.

Conclusions: The Russian version of MacNew was found to be a reliable and valid HRQL tool which is sensitive to change. This instrument offers clinicians and researchers a useful tool for understanding patient's perspective of the impact of heart disease and its treatment.

Keywords

Coronary artery disease, disease-specific HRQL, multicenter study, patient-reported outcome, psychometric properties, Russian

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Introduction

The recognition of the patient's perspective in monitoring healthcare outcomes represents an important development in healthcare in the past few decades [1]. Traditional outcomes of treatment for coronary heart disease, for example, objective physiological tests, give little information about the impact of both illness and its treatment on the patient from the patient's perspective [2].

The need to better understand the impact of disease from the patient's perspective has led to the development of instruments to quantify patients' perception of their health. A widely used patient-related outcome in healthcare has been the measure of health-related quality of life (HRQL). A few models of HRQL have been proposed in an attempt to clarify the role of the many potential variables influencing HRQL [3,4]. One influential model has been put forward by Wilson and Cleary [5]. The authors proposed a conceptual model of HRQL that integrates both biological and psychological aspects of health outcomes. Accordingly, there are 5 levels of variables including biological and physiological factors, symptoms, functioning, general health perception and overall quality of life. Furthermore, there is a causal relationships between these domains that link traditional clinical variables to measures of HRQL [5]. All of these levels of variables, apart from the biological and physiological variables, are also influenced by characteristics of the individual and the environment.

A wide range of HRQL instruments have been developed, some of which are generic, addressing multiple aspects of quality of life across a range of different patient or disease groups [6], while others are disease-specific focusing on the specific attributes of a particular disease. The advantage of disease-specific instruments is that they are more clinically sensitive and responsive to change than generic HRQL instruments [7].

One generic instrument commonly used in research and clinical evaluation in populations with coronary heart disease (CHD) is the 36-Item Short Form Health Survey (SF-36). The SF-36 [8] is a self-administered instrument comprising 36 items covering 8 domains and 2 component scores, a physical and mental component.

A modified version of the original interviewadministered Quality of Life after Myocardial Infarction instrument [9] - the MacNew Heart Disease Health-related Quality of Life questionnaire - is now available as a selfadministered instrument [10]. The MacNew is designed to evaluate how daily activities, presented as physical limitation and emotional and social functioning sub-scales and a global scale, are affected by CHD and its treatment [2].

The present study aims to assess the psychometric property of the Russian version of the MacNew scale in 226 patients undergoing coronary artery bypass grafting (CABG) surgery in Israel.

Methods

Study design

This study is ancillary to a controlled prospective study conducted between January 2004 and November 2006 in 5 cardiothoracic departments across Israel. The primary study is described in detail elsewhere [11]. In summary, it aimed to assess the effect of an educational intervention on participation rate in cardiac rehabilitation (CR) programmes of patients after coronary artery bypass grafting (CABG) surgery and to assess the effect of CR participation on clinical as well as psychological outcomes and quality of life one year after surgery. The primary study included a control and an intervention arm. The intervention was designed to improve uptake of CR programmes. In both arms, we approached consecutive patients scheduled for CABG surgery. Patients who signed informed consent were interviewed before surgery (baseline) and one-year post surgery (follow-up). The interviews were carried out by trained research interviewers.

We excluded patients from the primary study if they had severe co-morbidities for which CR was contraindicated (e.g., congestive heart failure (CHF) stage IV); institutionalized patients and patients with severe cognitive impairment (e.g., general stroke with severe disability); patients who did not understand any of the languages in which the study was conducted: Hebrew, English, Russian and Arabic and patients with poor accessibility to a CR facility, that is, residing farther than 30km from a rehabilitation centre. For standardization, we interviewed all patients during their pre-surgery hospitalization. Patients who could not be interviewed prior to surgery (e.g., due to emergency operation) were not included since their mental or cognitive state could have been affected by general anaesthesia or CABG surgery.

The study obtained approval from the Institutional Review Board (IRB) of the Sheba Medical Center and from the IRBs of all 5 participating medical centres.

Participants

A total of 1024 patients were enrolled in the primary study (Figure 1). This group is the sample frame for the present sub-study. Of these 1024 patients, 226 Russian speaking patients participated in this study. Their data from the interview before CABG surgery were used for validation of the MacNew scale. Data from follow-up interview were used for some analyses as specified below.

Measures

Participants completed a sociodemographic questionnaire, the MacNew, the Short Form-36 Health Survey (SF-36) and the Hospital Anxiety and Depression Scale (HADS) [12] at baseline; physical activity level was determined from the following question: "Do you engage in sport or physical activity regularly?" A total of 188 questionnaires were completed a second time approximately 12 months after the initial assessment. Data from the second assessment were used to examine responsiveness of these scales (see analytical strategy below).

[A] Information on demographic factors including age, gender, marital status, number of years in education, employment status, self-reported level of income (categorized in relation to the national average household income) and religiosity (conventionally divided into 4 broad categories in the Israeli population: secular Jews, religious practicing Jews, traditional Jews and others), lifestyle and behavioural parameters (e.g., tobacco use) and data on co-morbidities were collected through a face-toface interview.

Clinical data and CHF status was determined from the patient's medical chart. Patients who had a diagnosis of CHF in their letter of discharge from hospital following surgery or had an ejection fraction as recorded in an echocardiogram test of < 35% or both were classified as CHF patients. Body mass index (BMI) calculation was based on height and weight as measured during the interview before surgery.

[B] The MacNew is a self-administered heart disease HROL questionnaire consisting of 27 items which fall into 3 domains: physical limitations (13 items), emotional function (14 items) and social function (13 items) subscale making up a global scale. The time frame for the MacNew is the previous 2 weeks. Each of the items is rated on a 7-point scale, from 1 (poor HRQL) to 7 (good HRQL). For each domain, a score is calculated as the mean score of the items comprising this domain. Missing responses do not contribute to the score and item 27, 'sexual intercourse', may be excluded without altering the domain score as each domain score is calculated as the mean of the responses in that domain. For example, if only 10 of the 14 emotional items are answered, the emotional score is the mean of 10 responses. If more than 50% of the items for a domain are missing, the score for that domain is not calculated. The instrument also has a global HRQL score, which can be calculated as the mean over all scored items [2].

The MacNew scale has been validated in many languages including Farsi [13], German [14,15], Dutch [16], Chinese [17], Hebrew [18] and in patients after MI [10], pacemaker implantation [19], patients with angina [20] and heart failure [21].

The MacNew was translated into Russian using recommended forward and backward translation for linguistic equivalence [22].

[C] The SF-36 [8] is a generic self-administered HRQL questionnaire that consists of 36 items. It includes 8 sub-scales: physical functioning, role physical, bodily pain, vitality, general health, mental health, role emotional and social functioning which converge into 2 summary measures, a physical component and a mental component measure. The SF-36 is used here as the 'gold standard' instrument against which the MacNew scale is validated.

[D] The HADS [12] consists of 14 items, 7 measuring symptoms of anxiety and 7 measuring symptoms of depression. The score of each sub-scale can range from 0-21 where higher score indicates higher symptoms of depression. A score of 8 or above on the depression and anxiety sub-scales is considered to be of clinical importance and may indicate possible depressive or anxiety disorder, respectively [12].

Statistical analysis

We used frequencies, means and standard deviations (SD) to describe the clinical, sociodemographic and behavioural characteristics.

Internal consistency was assessed by Cronbach's alpha coefficient. To examine construct validity, we carried out a principal component analysis (PCA) with varimax rotation to assess how the scale fits into a 3-factor solution as observed for the original English-language version. To assess convergent validity, we examined the correlations between the MacNew Global and domain scores and the SF-36 items and component scores. Discriminant validity was assessed by comparing differences in mean score on the MacNew between patients with CHF (with and without valve replacement) undergoing CABG surgery and all other patients undergoing surgery without CHF, between men and women, between patients with clinically significant symptoms of depression *versus* all other patients and between patients with clinically significant anxiety symptoms *versus* all other patients. The comparisons between 2 groups (males and females, depressed and non-depressed, anxious and non- anxious, CHF and non-CHF) were carried out using t-test or Fisher exact test, depending on the type of a variable. In addition, we presented the effect size estimations because, in contrast with t-test or Fisher exact test, the effect size does not depend on the sample size.

To assess responsiveness that is, the instrument's ability to detect change, we assessed change in mean score over a 12 month period on the MacNew sub-scales and global scale. Only patients who completed the MacNew at study entry (baseline) and at the 12-month follow-up were included in this analysis. Statistical analyses were performed using SAS statistical software version 9.2.

Results

Figure 1 describes the sample selection process. Of the 2811 patients scheduled for CABG surgery in the 5 cardiothoracic wards that took part in the primary study, 1548 patients were eligible to participate (see methods section for inclusion criteria) of whom 1024 (66%) were recruited to the primary study, a total of 226 of whom were Russian-speaking. Their data from the interview preceding CABG surgery were used in this study. The data from 188 patients who completed the MacNew at baseline and follow-up were used in some analyses as describe above.

Patient characteristics

The sociodemographic, behavioural clinical and characteristics of the study sample according to the patient gender are displayed in Table 1. Approximately 2/3 of the sample (66.4%) were men (p<0.0001). Women were on average 6.5 years older than the men (p<0.0001). The proportion of widowers was greater in women than in men (43.4% and 11.3%, p<0.0001, respectively) and the proportion of married or cohabiting was greater in men (76.7%) than in women (43.4%) (p<0.0001). A greater proportion of women (30.7%) than men (16%) were educated to a level of 10 or less years of schooling (p=0.03). The majority of patients were not employed at the time of surgery. However, the proportion of unemployed women was greater than the proportion of unemployed men (92.1% versus 67.3%, respectively) (p<0.0001). There were no differences in level of income between men and women (p=1.0). The majority of women never smoked (84.0%) while the majority of men were past or current smokers (74.7%) (p<0.0001). Approximately

Figure 1 Study population and sample selection process



^aPrimary study: Study that assessed the effect of an intervention to increase CABG patients participation in cardiac rehabilitation programs.¹¹

^bNot eligible: Not eligible to participate in the primary study.¹¹

25% of men compared to 12% of women reported that they were engaging in physical exercise regularly (p=0.02). Overall, 57.9% of women with a BMI \geq 30 compared to 26.7% of men (p<0.0001). Diabetes was more prevalent in women (42.1%) than in men (27.7%) (p=0.03) but the proportion of CHF was similar in both (p=0.7).

MacNew internal consistency and mean scores

The internal consistency of the sub-scales and global scale was excellent as indicated by the Cronbach's alpha coefficient: (social function: α =0.92; emotional functioning: α =0.88; physical limitation: α =0.89; global scale: α =0.93). The MacNew mean score for the group was 5.46 (±1.10) on social function, 5.17 (±0.78) on the

emotional functioning, $4.77 (\pm 1.16)$ on the physical limitation sub-scales and $5.06 (\pm 0.88)$ on the global scale.

Convergent validity

We assessed the correlations of MacNew global scale and sub-scales with the SF-36 component scores. The correlations between the MacNew global scale and 3 subscales and the 2 SF-36 physical and mental component summary scores were moderate to high (all ps< 0.0001). The physical limitation sub-scale of the MacNew correlated highly with the physical (r=0.80) and the mental (r=0.81) component summary scores of the SF-36. The emotional functioning sub-scale correlated highly with the mental component score of the SF-36 (r=0.78), but moderately with physical component summary score

Table 1 Characteristics of the study sample (n=226) by gender

Characteristics	Men (n=150)	Women (n=76)	p value
	n (%)	n (%)	
Age in years (mean ±SD)	65.5 (±9.9)	72.0 (±6.7)	<0.0001
Marital status			
Single	2 (1.3)	2 (2.6)	<0.0001
Married or co-habiting	115 (76.7)	33 (43.4)	
Divorced/separated	16 (10.7)	8 (10.5)	
Widowed	17 (11.3)	33 (43.4)	
Religiosity ^a			
Secular	105 (70.0)	53 (69.7)	0.2
Traditional	37 (24.7)	20 (26.3)	
Religious	2 (1.3)	3 (4.0)	
Other	6 (4.0)	-	
Level of education			
Up to 10 years of schooling	24 (16.0)	23 (30.7)	0.03
11-12 years of schooling	16 (10.7)	9 (12.0)	
More than 12 years	110 (73.3)	43 (57.3)	
Employment	. ,	. ,	
Full-time employment	30 (20.0)	1 (1.3)	<0.0001
Part-time employment	19 (12.7)	5 (6.6)	
Not employed	101 (67.3)	70 (92.1)	
Income	· · ·		
Above average	4 (2.7)	2 (2.7)	1.0
Average	12 (8.1)	6 (8.0)	
Below average	132 (89.2)	67 (89.3)	
Behavioural and lifestyle characteristics	· · ·	. ,	
Smoking			
Never	38 (25.3)	63 (84.0)	<0.0001
Past ^b	69 (46.0)	7 (9.3)	
Current	43 (28.7)	5 (6.7)	
n (%) of physically active ^c	37 (24.7)	9 (12.0)	0.02
Body Mass Index (BMI) kg/m ²			
≥19<25	35 (23.3)	11 (14.5)	<0.0001
≥25<30	75 (50.0)	21 (27.6)	
≥30	40 (26.7)	44 (57.9)	
Clinical characteristics	· · · ·	· · /	
n (%) with the co-morbidity			
Diabetes	41 (27.7)	32 (42.1)	0.03
Congestive heart failure	23 (15.3)	10 (13.2)	0.7

^a Religiosity in the Israeli Jewish population is conventionally divided into 4 broad categories: secular Jews, religious practicing Jews, traditional Jews and others

^b Past smokers: patients who stopped smoking for at least 6 months before assessment

[°] Physically active: a positive response to the question: "Do you engage in sport or physical activity regularly?"

r=0.66). The social functioning sub-scale of the MacNew correlated highly with both the physical (r=0.80) and the mental (r=0.72) component scores of the SF-36. We also assessed the correlation between the social function sub-scale of the MacNew and the social functioning sub-scale of the SF-36 and found they were moderately correlated (r=0.69).

Discriminant validity

Table 2 presents the mean score for the MacNew scales in CABG patients varying on 4 variables: gender, depression,

anxiety and CHF. The results show that the MacNew subscales and global score discriminate between the patient groups. Men had higher HRQL mean scores than women on each MacNew scale. Patients undergoing CABG surgery with CHF had lower HRQL mean scores on the MacNew global and physical sub-scales compared to CABG patients without CHF, but not on the emotional and social functioning sub-scales. CABG patients with HADS depression or anxiety symptoms had lower score on all the MacNew scales compared to patients without symptoms.

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		Gender			Depression			Anxiety			CHF	
	Men	Women	٩	No	Yes	ď	No	Yes	٩	ON	CHF	д.
MacNew domains	n=150	n=76		n=648	n=125		n=177	n=49		n=181	n=45	
Emotional function 5.3 (±0.7) 4.9 (±0.9) 0.005	5.3 (±0.7)	4.9 (±0.9)	0.005	5.4 (±0.6) 4.3 (±0.9)	4.3 (±0.9)	<.0001	5.4 (±0.6)	4.4 (±0.9) <.0001 5.2 (±0.8) 5.0 (±0.8)	<.0001	5.2 (±0.8)	5.0 (±0.8)	0.2
Physical limitation 5.0 (±1.1) 4.4 (±1.2) 0.0006	5.0 (±1.1)	4.4 (±1.2)	0.0006	5.0 (±1.1) 3.9 (±1.1)	3.9 (±1.1)	<.0001	5.0 (±1.0)	3.8 (±1.1)	<.0001	4.9 (±1.1)	3.8 (±1.1) <.0001 4.9 (±1.1) 4.3 (±1.2)	0.003
Social function	5.6 (±1.0)	5.6 (±1.0) 5.1 (±1.2) 0.003	0.003	5.7 (±1.0)	4.6 (±1.1)	<.0001	5.7 (±0.9)	4.5 (±1.0)		5.5 (±1.1)	<.0001 5.5 (±1.1) 5.2 (±1.1)	0.07
Total	5.2 (±0.8)	4.8 (±1.0)	0.0006	5.2 (±0.8) 4.8 (±1.0) 0.0006 5.3 (±0.8)	4.3 (±0.9)	<.0001	5.3 (±0.7)		<.0001	5.1 (±0.9)	4.2 (±0.8) <.0001 5.1 (±0.9) 4.8 (±0.9)	0.03

Table 2 Discriminant validity of MacNew global score and sub-scales by gender, depression, anxiety and CHF status, Mean (±SD)

Table 3 Construct validity of the Russian version of MacNew in CABG patients (n=226) using factor analysis. Item loading on the 3 MacNew domains in the Russian MacNew and as reported for the original English MacNew [10]

	•		Th	e MACNEW su	ggested doma	ins	
	Items from MACNEW	Emotiona	I function	Physical	limitation	Social	function
		Russian	Original	Russian	Original	Russian	Original
1.	Frustrated	0.53	0.79	0.18	0.25	0.52	0.15
2.	Worthless	0.37	0.74	-0.08	0.16	0.55	0.42
3.	Confident	0.59	0.61	-0.11	0.26	0.26	0.37
4.	Down in the dumps	0.70	0.86	0.22	0.22	0.32	0.23
5.	Relaxed	0.61	0.79	0.33	0.26	-0.01	0.21
6.	Worn out	0.58	0.59	0.48	0.52	0.20	0.17
7.	Happy with personal life	0.73	0.73	0.04	0.21	0.08	0.28
8.	Restless	0.61	0.81	0.38	0.29	0.21	0.21
9.	Short of breath	0.11	0.24	0.62	0.73	0.05	0.32
10	Tearful	0.64	0.72	0.11	0.17	0.32	0.20
11	More dependent	0.22	0.39	0.42	0.20	0.65	0.62
12	Social activities	0.36	0.40	0.46	0.46	0.63	0.52
13	Others/ less confident in you	0.13	0.45	0.28	0.08	0.68	0.66
14	Chest pain	0.11	0.17	0.69	0.72	-0.08	0.17
15	Lack of self-confident	0.46	0.67	0.35	0.19	0.55	0.47
16	Aching legs	0.13	0.39	0.51	0.44	0.04	0.05
17	Sports/exercise limited	0.19	0.23	0.75	0.60	0.30	0.61
18	Frightened	0.61	0.63	0.27	0.25	0.38	0.36
19	Dizzy/ light-headed	0.11	0.39	0.52	0.61	-0.08	0.07
20	Restricted or limited	0.25	0.21	0.74	0.64	0.37	0.62
21	Unsure about exercise	0.07	0.34	0.69	0.47	0.24	0.48
22	Overprotective family	0.01	0.18	0.06	0.00	0.67	0.69
23	Burden on others	0.24	0.44	0.08	0.20	0.66	0.66
24	Excluded	0.44	0.19	0.50	0.43	0.48	0.74
25	Unable to socialize	0.35	0.23	0.57	0.46	0.42	0.68
26	Physically restricted	0.23	0.17	0.79	0.60	0.30	0.65
27	Sexual activities	-0.15	N/R	-0.03	N/R	0.64	N/R
Vari	ance explained	14.1%	28.1%	20.1%	17.2%	17.6%	21.4%

N/R=Not reported; Bold: items belonging to a respective factor as suggested by [10].

Table 4 Responsiveness - mean change score from study entry to 12-month follow-up on the MacNew sub-scales and global score (n=188)

		Mean (±SD)		Р
	Baseline	Follow-up	Mean change score	
MacNew Global	5.06 (±0.88)	5.30 (±1.01)	0.20 (±0.95)	0.005
Emotional function	5.17 (±0.78)	5.23 (±0.94)	0.20 (±0.89)	0.005
Physical limitation	4.77 (±1.16)	5.28 (±1.21)	0.46 (±1.15)	<0.0001
Social function	5.46 (±1.10)	5.65 (±1.23)	0.16 (±1.26)	0.09

Construct validity

To assess how well the MacNew scale fits into a 3-factor solution as observed for the original English-language questionnaire, we carried out a principal component analysis (PCA) with varimax rotation. Table 3 displays the factor loading of each of the 27 items of the MacNew questionnaire on each of the 3 factors as proposed by Valenti *et al.* [10]. The original 3-factor structure was generally supported with the Russian version of MacNew. Most loadings met the 0.40 threshold on the expected factor; for the emotional domain, 10 of 14 items loaded between 0.46 and 0.73 but for 4 items the loadings were lower: 'Worthless' (0.37), 'Social activities' (0.36),

'Others less confident in you' (0.13) and 'Burden on others' (0.24). For the physical domain, 12 of 13 items loaded between 0.46 and 0.79. The item 'Sexual activities' loading was -0.03. The loadings for the social domain ranged between 0.24 and 0.68. The loading of 9 of 13 items exceeded the 0.40 threshold. For 4 items, the loadings were lower: 'Sports/exercise limited' (0.30), 'Restricted or limited' (0.37), 'Unsure about exercise' (0.24) and 'Physically restricted' (0.30). Item 27, enquiring about sexual intercourse, loaded on the social factor (0.64)rather than the physical scale. In this study, the factor named physical functioning explained 20.1% of the variance whereas the social and the emotional functioning scales explained 17.6% and 14.1% of the variance, respectively. The total explained variance by the MacNew scale was 55%.

Responsiveness

Responsiveness was examined by comparing the mean change of the MacNew score over a 12-month period in CABG patients who provided both baseline and follow-up data (Table 4). Of the 226 patients who completed the baseline assessment, a total of 188 (83%) patients completed the MacNew questionnaire at both time points. Patients' mean change score from baseline to 12-month follow-up improved on the emotional function sub-scale (+0.2, p=0.005), the physical limitation sub-scale (+0.46, p<0.0001) and the global scale (+0.2, p=0.005). The change in mean score on the social function sub-scale was +0.16 (p=0.09).

Discussion

We report the psychometric properties of the Russian version of the MacNew HRQL scale in 226 patients who underwent CABG surgery. Our study is in accordance with the criteria for reviewing instruments as formulated by the Scientific Advisory Committee of the Medical Outcomes Trust [22].

The MacNew scale showed high internal consistency among Russian-speaking CABG patients. The Cronbach's alpha for items belonging to the 3 sub-scales as well as for the total scale ranged from 0.88 to 0.93, indicating a high degree of homogeneity of items within each domain and within the scale as a whole. These results are consistent with the findings from the original MacNew scale in English (Cronbach's alpha: 0.93-0.95) [10].

In the present study, patients' mean score on the emotional, physical and social MacNew subscales were 5.2, 4.8 and 5.5, respectively, fairly similar to the findings from the study reporting the psychometric properties of the original MacNew in English as assessed in patients following AMI, that is, 5.3, 5.3 and 5.6 for the emotional, physical and social MacNew scales, respectively [10].

The results showed that the MacNew sub-scale and global scores discriminate well between patient groups. Comparing the mean scores for the MacNew scales between CABG patients with CHF and those without CHF showed that the former group had lower mean score on the physical and social sub-scales and the global scores compared to the latter group as hypothesized. Furthermore, the MacNew scales discriminated well between men and women and between patients with a clinical indication of depression and anxiety showing, as anticipated, that men and patients without symptoms of anxiety or depression had significantly better HRQL scores than women and those with symptoms of anxiety or depression. These findings are in keeping with previous published data in which the MacNew scale discriminated between cardiac patients varying on gender, depression, anxiety and CHF [17,21,23,24].

Our data show that there were moderate to high correlations between similar domains on the MacNew and the SF-36. However, moderate correlations were also found between dissimilar domains of the MacNew and the SF-36, in particular, the MacNew physical limitation subscale correlated highly with the mental component of the SF-36. Nevertheless, the correlations between similar domains were, overall, stronger than correlations between less similar domains. These findings have been observed in previous studies [15,24]. Hofer *et al.* [15] suggested this may be related to the way the MacNew probes were originally developed with the focus on the patient's perceptions of the difficulties with physical activities rather than performance *per se* as in the SF-36.

Taking the same approach as Valenti and colleagues in the original factor structure [10], in which a factor loading of ≥ 0.40 was used to allocate items to a domain, most items of the Russian MacNew loaded onto the expected factor. The item loadings on the expected factors in the present study were similar though slightly lower than the item loadings reported for the original MacNew. In addition, for several items, for example, 'Social activities' the loadings on the expected factor were lower than ≥ 0.40 . Interestingly, item 27 (sexual intercourse) showed low loading on the (expected) physical factor, that is, -0.03. This item, however, loaded on the social function factor (0.64), suggesting that sexual functioning contributes to these patients' social wellbeing. This finding has been observed in other studies, for example, with the Portuguese version of MacNew [24] and in a study validating the English version of the MacNew scale in patients with angina and ischemic heart failure [20], but not in other studies [17,25]. Furthermore, in this study, the factor named physical functioning explained 20.1% of the variance, whereas the social and the emotional functioning sub-scales explained 17.6% and 14.1% of the variance, respectively. This is somewhat inconsistent with findings from the original English MacNew in which the emotional functioning scale explained most of the variance, that is, 28.1%, while the social functioning sub-scale explained 21.4% of the variance and the physical limitation sub-scale explained 17.2% of the variance.

We examined the MacNew sensitivity to change over time comparing the change in MacNew mean score of CABG patients between baseline (study entry) and oneyear follow-up. The group mean score at 12-month followup was greater on the MacNew emotional function, physical limitation sub-scales and global scale. There was weak evidence for an improvement in social functioning, however. It has been proposed that the minimal importance difference for the MacNew is 0.5 point on the 7-point scoring scale [26]. In the reported study, although patients had higher mean scores on the MacNew scales, that is, 0.2 on the emotional function and 0.2 on the social function sub-scales and 0.2 on the global scale, only the 0.5 change on the physical limitation sub-scale met the minimal importance difference criterion.

A limitation of this study relates to the primary study, which was restricted to patients who met inclusion criteria of mobility and geographical proximity to a CR facility. Of the 2811 patients who undergone CABG surgery at the study period, only 1548 (55%) were eligible for the primary study. This most likely excluded patients with more severe medical conditions and the less advantaged patients with poor access to CR facilities.

Conclusion

In conclusion, the Russian version of the MacNew questionnaire was found to be a reliable and valid HRQL tool which is sensitive to change, particularly change in physical functioning, in patients undergoing CABG surgery. This instrument offers clinicians and researchers a useful tool for understanding the impact of heart disease and its treatment from the patient's perspective.

Acknowledgements and conflicts of interest

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References

[1] Leplege, A. & Hunt, S. (1997). The problem of quality of life in medicine. *Journal of the American Medical Association* 278 (1) 47-50.

[2] Hofer, S., Lim, L., Guyatt, G. & Oldridge, N. (2004). The MacNew Heart Disease health-related quality of life instrument: a summary. *Health and Quality of Life Outcomes* 2, 3.

[3] Bergner, M. (1985). Measurement of health status. *Medical Care* 23 (5) 696-704.

[4] Johnson, R.J. & Wolinsky, F.D. (1993). The structure of health status among older adults: disease, disability, functional limitation, and perceived health. *Journal of Health and Social Behavior* 34 (2) 105-121.

[5] Wilson, I.B. & Cleary, P.D. (1995). Linking clinical variables with health-related quality of life. A conceptual

model of patient outcomes. *Journal of the American Medical Association* 273 (1) 59-65.

[6] Thompson, D.R. & Yu, C.M. (2003). Quality of life in patients with coronary heart disease-I: assessment tools. *Health and Quality of Life Outcomes* 1, 42.

[7] Wiebe, S., Guyatt, G., Weaver, B., Matijevic, S. & Sidwell, C. (2003). Comparative responsiveness of generic and specific quality-of-life instruments. *Journal of Clinical Epidemiology* 56 (1) 52-60.

[8] Ware, J.E., Jr. & Sherbourne, C.D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care* 30 (6) 473-483.

[9] Oldridge, N., Guyatt, G., Jones, N., Crowe, J., Singer, J., Feeny, D., McKelvie, R., Runions, J., Steiner, D. & Torrance, G. (1991). Effects on quality of life with comprehensive rehabilitation after acute myocardial infarction. *American Journal of Cardiology* 67 (13) 1084-1089.

[10] Valenti, L., Lim, L., Heller, R.F. & Knapp, J. (1996). An improved questionnaire for assessing quality of life after acute myocardial infarction. *Quality of Life Research* 5 (1) 151-161.

[11] Dankner, R., Geulayov, G., Ziv, A., Novikov, I., Goldbourt, U. & Drory, Y. (2011). The effect of an educational intervention on coronary artery bypass graft surgery patients' participation rate in cardiac rehabilitation programs: a controlled health care trial. *BMC Cardiovascular Disorders* 11, 60.

[12] Zigmond, A.S. & Snaith, R.P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 67 (6) 361-370.

[13] Asadi-Lari, M., Javadi, H.R., Melville, M., Oldridge, N.B. & Gray, D. (2003). Adaptation of the MacNew quality of life questionnaire after myocardial infarction in an Iranian population. *Health and Quality of Life Outcomes* 1, 23.

[14] Hofer, S., Benzer, W., Schussler, G., von, S.N. & Oldridge, N.B. (2003). Health-related quality of life in patients with coronary artery disease treated for angina: validity and reliability of German translations of two specific questionnaires. *Quality of Life Research* 12 (2) 199-212.

[15] Hofer, S., Benzer, W., Brandt, D., Laimer, H., Schmid, P. & Bernardo, A.N.O. (2004). MacNew Heart Disease questionnaire after myocardial infarction: The German version *Zeitschrift für Klinische Psychologie und Psychotherapie* 33 (4) 270-280.

[16] De Gucht, V., Van, E.T., van der Kamp, L. & Oldridge, N. (2004). Quality of life after myocardial infarction: translation and validation of the MacNew Questionnaire for a Dutch population. *Quality of Life Research* 13 (8) 1483-1488.

[17] Yu, D.S., Thompson, D.R., Yu, C.M. & Oldridge, N.B. (2008). Validation of the Chinese version of the MacNew heart disease health-related quality of life questionnaire. *Journal of Evaluation in Clinical Practice* 14 (2) 326-335.

[18] Dankner, R., Burya-Sa'adon, L., Geulayov, G., Kobalyov, A. & Drory, Y. (2011). [Health-related quality of life of Israeli heart patients according to the MacNew heart disease specific instrument]. *Harefuah* 150 (10) 760-764, 816.

[19] Hofer, S., Anelli-Monti, M., Berger, T., Hintringer, F., Oldridge, N. & Benzer, W. (2005). Psychometric properties of an established heart disease specific healthrelated quality of life questionnaire for pacemaker patients. *Quality of Life Research* 14 (8) 1937-1942.

[20] Hofer, S., Saleem, A., Stone, J., Thomas, R., Tulloch, H. & Oldridge, N. (2012). The MacNew Heart Disease Health-Related Quality of Life Questionnaire in patients with angina and patients with ischemic heart failure. *Value in Health* 15 (1) 143-150.

[21] Hofer, S., Schmid, J.P., Frick, M., Benzer, W., Laimer, H., Oldridge, N. & Saner, H. (2008). Psychometric properties of the MacNew heart disease health-related quality of life instrument in patients with heart failure. *Journal of Evaluation in Clinical Practice* 14 (4) 500-506.

[22] Scientific Advisory Committee of the Medical Outcomes. (2002). Assessing health status and quality-of-life instruments: attributes and review criteria. *Quality of Life Research* 11 (3) 193-205.

[23] Daskapan, A., Hofer, S., Oldridge, N., Alkan, N., Muderrisoglu, H. & Tuzun, E.H. (2008). The validity and reliability of the Turkish version of the MacNew Heart Disease Questionnaire in patients with angina. *Journal of Evaluation in Clinical Practice* 14 (2) 209-213.

[24] Leal, A., Paiva, C., Hofer, S., Amado, J., Gomes, L. & Oldridge, N. (2005). Evaluative and discriminative properties of the Portuguese MacNew Heart Disease Health-related Quality of Life Questionnaire. *Quality of Life Research* 14 (10) 2335-2341.

[25] Vandereyt, F., Dendale, P., Vanhees, L., Roosen, J., Hofer, S. & Oldridge, N. (2012). Psychometric properties of the Flemish version of the MacNew heart disease health-related quality of life questionnaire. *Acta Cardiologica* 67 (1) 31-39.

[26] Dixon, T., Lim, L.L. & Oldridge, N.B. (2002). The MacNew heart disease health-related quality of life instrument: reference data for users. *Quality of Life Research* 11 (2) 173-183.