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Brief Strategic Therapy and Motivational Interviewing among Cardiac Rehabilitation Patients: pre-post treatment results

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Abstract

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Objective: the MOTIV-HEART study is aimed at testing the incremental efficacy of Brief Strategic Therapy (BST) combined with Motivational Interviewing (MI) in improving selected biomedical and psychological outcomes over and beyond the stand-alone BST in Cardiac Rehabilitation (CR). *Method*: 42 heart patients referring to a single clinical center for CR and weigh loss treatment were randomly allocated into two conditions: i) 3 sessions of BST; ii) 3 sessions of BST plus MI. Data were collected at baseline and discharge (1 month later). *Results*: pre-treatment heterogeneity was found between groups, and no significant between-group difference in post-treatment medians was obtained in any variables. Within-group changes were detected for the patients' extrinsic regulation, which significantly decreased only in the BST group, and for the RAI score and the patients' willingness to change, significantly increasing only in the control group. *Discussion*: no evidence of superiority of the combined treatment (BST+MI) over stand-alone BST within CR was found. *Conclusions*: since combining BST and MI within CR for the first time, the present investigation sets out to be a pilot study, and its results can therefore guide in the implementation of stronger experimental design that would help clarifying the obtained outcomes.

Keywords: Cardiovascular Diseases; Brief Strategic Therapy; Motivational Interviewing; Cardiac Rehabilitation; Self-care.

Introduction

Cardiovascular Diseases (CVDs) are leading causes of morbidity and mortality worldwide (Beauchamp, Peeters, Tonkin, & Turrell, 2010), and obesity is an independent risk factor for the development of cardiac problems (Hubert, Feinleib, McNamara, & Castelli, 1983).

1. Problem statement

Unhealthy diet, lack of physical activity and smoking status has been identified as central barriers in contrasting chronic conditions (Beaglehole et al., 2011), such as obesity and CVDs; and psychosocial factors also considerably affect the persons' uptake of health-related behavior (Castelnuovo et al., 2015; Favoccia et al., 2014; Neylon et al., 2013). Since optimal outcomes and Quality of Life (QoL) for patients with heart failure largely depend on engagement in effective self-care activities of daily living (ADLs) (Seto et al., 2011; Wang, Lin, Lee, & Wu, 2011), to enhance individuals' motivation and confidence in their ability to modifying their health behaviours and adhere to treatment is becoming a recommended or even mandatory practice in CR (Heng-Hsin Tung et al., 2013).

2. Research questions

In this regard, a gentle form of counseling known as Motivational Interviewing has obtained varying degrees of success in addressing individuals' beliefs and concerns about their health status as well as in enhancing confidence in their abilities to overcome barriers to adherence (Pietrabissa, Ceccarini, et al., 2015; Roter et al., 1998). It is defined as *a collaborative, goal oriented style of communication with particular attention to the language of change designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion* (Miller & Rollnick, 2013). Evidence shows that MI can be used in conjunction with other forms of therapy (Dietz & Dunn, 2014) and being well-integrated into brief patient encounters (Pietrabissa, Ceccarini, et al., 2015; Rubak, Sandbaek, Lauritzen, & Christensen, 2005). It is here investigated for the first time whether MI can be effectively integrated with BST for helping CR patients improve their health-related behaviors.

3. Purpose of the study

The *MOTIV-HEART* (MOTIVational strategies for HEART patients) study aimed at testing the incremental efficacy of a brief strategic treatment (Pietrabissa, Sorgente, & Castelnuovo, 2015) including motivational components (BST + MI) in improving the selected outcomes over and beyond the stand-alone Brief Strategic Therapy (BST) within a Cardiac Rehabilitation (CR) program. The *hypotheses* are that patients assigned to the experimental condition (BST + MI), compared to those receiving the brief strategic treatment only, will show: (i) greater reductions in Kilograms (Kg), Low-Density Lipoprotein Cholesterol (LDL), Systolic Blood Pressure (SBP) and glucose level; (ii) higher improvements in identified regulation and higher decreases in introjected and external regulations; and (iii) greater improvements in anxiety, depression and impulsiveness as well as in both perceived self-efficacy and Health-Related Quality of Life (HRQoL) at discharge.

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4. Research method

4.1. Study participants

42 heart inpatients referring to a single clinical center (Saint Joseph Hospital – IRCCS, Istituto Auxologico Italiano) for CR and weigh loss treatment (duration 25 ± 3 days) were included in the trial. *Inclusion criteria were*: 1) scoring below 60 on the Psychological General Well-Being Index (PGWBI) (Grossi et al., 2006); 2) psychological assessment/support required from the treating cardiologists whatever they think is appropriate; 3) being born after 1940; 4) having Italian nationality; 5) presenting chronic cardiac diseases or having recently undergone heart surgery; and 6) signing written and informed consent to participate in the study. *Exclusion criteria* for the study were: 1) presenting cognitive or communication problems; 2) having vision impairment which makes it challenging to fill in the questionnaires; 3) having uncorrected hearing impairment which anticipates difficulty with the intervention.

4.2. Study design and procedure

The incremental efficacy of the integrated treatment (BST + MI) was assessed in a two-arm; single blind prospective randomized controlled clinical trial. Participants were randomly allocated into two conditions: *Integrated treatment* (BST+MI): 1) standard CR including 3 sessions of BST combined with MI; 2) *Control treatment* (BST): standard CR including 3 individual sessions of BST without providing MI. Sessions took place once weekly in a face-to-face setting and lasted between 30 and 45 minutes. The same psychotherapist, specialist in BST and competent in providing MI delivered both treatments. Assessment of participants took place in 3 moments: 1) *before recruitment*, as part of the CR routine psychological assessment; 2) *before randomization* and 3) at *discharge* from the hospital.

4.3. Measures

4.3.1. Psychosocial outcomes

The Italian translation and cultural adaptation of the following measures were collected before treatment and at discharge from the hospital:

The *Psychological General Well-Being Index (PGWBI)* (Grossi et al., 2006), a 22-item on a 1-6 scale questionnaire used to assess the individuals' subjective well-being or distress through six dimensions: Anxiety, Depressed Mood, Positive Well-Being, Self-Control, General Health and Vitality. Its internal consistency ranges from 0.90 to 0.94.

The *Brief Illness Perception Questionnaire (B-IPQ)* (Giardini, Majani, Pierobon, Gremigni, & Catapano, 2007), which traditionally comprises 9 items on a Likert-scale that goes from 0 to 10. The item n° 9 ("*Please list in rank-order the three most important factors that you believe caused your illness*") was not included in the present study due to the open difficulties experienced by the participants in providing the answers. Each item measures an illness perception dimension (Consequences; Timeline; Personal Control; Treatment Control; Identity; Illness Concern; Coherence;

Emotional Representation) and their sum makes up the overall patients' cognitive and emotional representations of the disease. In the present sample, the Cronbach's alpha for the B-IPQ-total score was 0.68.

The *Hospital Anxiety and Depression Scale* (HADS) (Annunziata, Muzzatti, & Altoe, 2011), a self-administered Likert scale composed of 14 items (seven relate to anxiety and depression, respectively) to which patients respond on a 4-point scale. Among the study participants, the HADS Cronbach's α coefficient was 0.88 (0.82 for anxiety and 0.80 for depression).

The *Barratt Impulsiveness Scale* (BIS-11) (Fossati, Di Ceglie, Acquarini, & Barratt, 2001), used to assess the participants' overall impulsiveness, Attentional Impulsiveness – assessing task-focus, intrusive thoughts, and racing thoughts; Motor Impulsiveness – characterizing those acting on the spur of the moment; and No-Planning Impulsiveness – lack of a sense of the future – through 30 items on a 4-point scale. Its internal consistency for the present sample was 0.71 (0.55 for attentional impulsiveness; 0.65 for motor impulsiveness; 0.73 for no-planning impulsiveness).

The *General Self-Efficacy Scale* (GSE) (Zotti et al., 2007), a 10-item on a 4-point scale questionnaire aimed at assessing the individuals' perceived self-efficacy regarding coping and adaptation abilities in a variety of life demands. The internal consistency for the GSE total score among the participants was 0.85.

The *12-Item Short Form Health Survey* (SF-12) (Jakobsson, 2007; Lim & Fisher, 1999), used for measuring the persons' HRQoL by means of two synthetic indices related to the individuals' physical and mental state, respectively: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The PCS and MCS Cronbach's α coefficients in the present sample were 0.75 and 0.80, respectively.

The *Readiness-to-Change ruler* (RR), assessing the inpatients' Willingness to modify a specific health-related behavior, evaluating how Important is for them to accomplish it and measuring their Confidence to succeed by the use of a visual analog scales ranging from 1 to 10. Low scores go from 0 to 3, scores comprised between 4 and 6 indicate uncertainty, while sufficient to high level of motivation to change are predicted by scores ranging from 7 to 10.

The *Treatment Self-Regulation Questionnaire* (TSRQ) (Levesque et al., 2007), which investigates the degree to which a person's motivation for engaging in a specific healthy behaviour is autonomous or self-determined using a 7-point Likert scale. It is based on the Self-Determination Theory (Deci, Eghrari, Patrick, & Leone, 1994; Deci & Ryan, 2012) and, for the purpose of this study, comprised 13 items clustered into four dimensions: External Regulation, Introjected Regulation, Identified Regulation and Intrinsic Regulation. Subscale scores can be used separately or a Relative Autonomous Motivation Index (RAI) can be calculated. In the present sample, the External Regulation Cronbach's α coefficient was 0.78, that of for the patients' Introjected Regulation was 0.75, while the internal consistency for Identified Regulation and Intrinsic Regulation were 0.82 and 0.74 respectively.

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Demographic information (Age, Gender, Marital Status, Employment Status, Education) were collected by self-report at baseline only.

Inpatients were tested in-group settings for convenience through a self-report procedure by a trained graduate research assistant.

4.3.2. Biomedical variables

Since part of the routine outcome assessment of CR programs, study participants' *Kilograms* (Kg), *Body Mass Index* (BMI), *Systolic Blood Pressure* (SBP), *Low-Density Lipoprotein Cholesterol* (LDL) and *Glycaemia* were collected from their medical record at inclusion and discharge from the hospital. The presence of *Diabetes* and the individuals' *Smoking Status* were also registered at inclusion to the cardiac unit.

4.4. Treatment Fidelity

MI sessions were audio recorded, transcript verbatim and some of them, randomly selected, critically supervised by an expert in the field not involved directly in the study (Martino, Ball, Nich, Frankforter, & Carroll, 2008).

4.5. Sample size calculation

Due to the novelty of the application of BST integrated with MI for cardiac patients, the current investigation is present as a pilot study, thus representing as small investigations carried out in preparation for larger studies. According to Lackey and Wingate (Lackey & Wingate, 1986), a pilot work may use at least the 10% of the sample required. Using an A-priori Sample Size Calculator for Student's t-Test (G*Power 3.1.2 software), a total sample of 428 participants (n = 214 per group) was considered adequate to detect a difference with an estimated Effect Size (Cohen's d) of 0.35, an alpha of 0.05 (two-sided) and a desired statistical power of 0.95. 42 subjects were, therefore, deemed sufficient for the aims of present trial.

5. Statistical Analysis

The Cronbach´s α coefficient of the scales was calculated. Descriptive statistics (means ± SD or medians and interquartile intervals) were used to describe the baseline characteristics of sample. Given the small number of participants enrolled, non-parametric tests (i.e. the Spearman correlation, the Mann-Whitney U test and the Wilcoxon signed rank test) were used. The statistical significance of tests was assessed by the use of the Monte Carlo method. All analyses were run by means of the Statistical Package for the Social Sciences (SPSS) software 20.0 for Windows (SPSS, version 20.0; SPSS, Inc., Chicago, IL).

6. Findings

42 patients (25 males and 17 females) were included into the trial and were assigned to the two

conditions (n = 21). The overall mean age of the sample was 60.49 (SD = 8.22) and its BMI was 42.03 on average (SD = 16.12) (Table 1).

Table 1: Socio-demographic characteristics and biomedical parameters of the sample

		BST (n = 21)		**BST + MI (n = 21)**		**Statistics**	
Observations	N						
Gender	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**P[1]**
Male		9	42,9	16	76,3	6,222	**0,028**
Female		12	57,1	5	23,7		
Employment status	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
Worker		4	19	10	47,6	3,905	0,299
Housewife		3	14,3	2	9,5		
Unemployed		2	9,6	1	4,8		
Retired		12	57,1	8	38,1		
Education	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
Junior school		4	19	1	4,8	7,914	**0,043**
Middle school		4	19	9	42,8		
High school		13	62	8	38,1		
University		-	-	3	14,3		
Marital status	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
Single		-	-	2	9,5	4,833	0,203
Married		11	52,4	13	61,9		
Separated/Divorced		5	23,8	5	23,8		
Widowed		5	23,8	1	4,8		
Obesity	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
No		2	10,5	2	9,5	0,011	1
Yes		17	89,5	19	90,5		
Smoker	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
No		7	35	6	28.6	0,93	0.671
Yes		4	20	7	33.3		
Ex		9	45	8	38.1		
Diabetes	**n%**	**N**	**%.**	**N**	**%**	**Chi²**	**p**
No		11	55	10	47,6	0,223	0.758
Yes		9	45	11	52,4		
		Median	**IQI**	**Median**	**IQI**	**U²**	**p**
Age		63.61	55.3-68.8	61.65	54.2-65.3	189	0,44

Legend: Body Mass Index (BMI); Systolic Blood Pressure (SBP); Low-Density Lipoprotein Cholesterol (LDL). IQI = interquartile intervals.
[1] Monte Carlo method
[2] Mann-Whitney U test

All the participants received the three-sessions treatment and, with the exception of two patients who filled in the baseline questionnaires only, completed both the inclusion and discharge assessments. The majority of the study participants had the specific intention to change their eating habits (n=26), 12 respondents to exercise more, while 4 subjects said they were manly motivated to stop smoking.

6.1. Pre-treatment between group comparisons

In order to check randomization, the two conditions were compared on all the baseline measures. With respect to the *demographic variables*, significant between-group differences were found for Gender and Education while, for what concern *biomedical outcomes*, the groups significantly differed

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for the SBP and Kg parameters. Regarding the *psychological variables*, significant between-group differences were found for the B-IPQ-Treatment Control dimension and for the participants' Willingness To Change (RR).

6.2. Post-treatment between group comparisons and pre-post changes

No significant between-group difference in post-treatment medians was found in any variables (table 2).

Table 2: pre-post data for the two groups

			BST n PRE = 21 n POST = 19		**BST + MI** (n = 21)		**Statistics**	
Variable	**Median and IQI**		**Median**	**IQI**	**Median**	**IQI**	**U[2]**	**P[1]**
LDL-C		**In**	99	83-127	96	75.5-149.5	194.5	0.895
		Out	76	61-108	67	60.5-95.5	167.5	0,398
Glycaemia		**In**	114	90-175	116	99-194.5	186.5	0.732
		Out	102	93-120	99	87.5-118	164.5	0.353
SBP		**In**	117	113-123	123	117.5-130	119.5	**0.036**
		Out	117	105-127	117	102.5-130	193.5	0.878
Kg		**In**	98.1	92-106.2	119.9	99.7-128.4	100.5	**0,007**
		Out	95	88.8-102.7	116.2	98.7-124.3	95.5	**0.005**
BMI		**In**	38.08	36.03-46.1	40.35	35.98-44.4	181.5	0.643
		Out	36.9	34.5-44.2	39.3	35.6-42.6	179.5	0.604
B-IPQ	**Consequences**	**In**	7	5-8	7	5-8	212	0.836
		Out	6	5-7	7	5-8	174	0.491
	Timeline	**In**	10	6.5-10	10	7.5-10	195.5	0,501
		Out	10	6-10	10	6-10	196	0.924
	Personal control	**In**	4	2-6	5	3-8.5	178	0.280
		Out	4	3-6	4	3-6.5	178	0.572
	Treatment control	**In**	2	1-3	3	1.5-4.5	137	**0.032**
		Out	2	1-3	2	1-3	193.5	0.876
	Identity	**In**	6	4-7	7	3.5-8	191	0.465
		Out	4	2-7	6	3-7	147	0.153
	Illness Concern	**In**	7	5.5-8.5	7	5-8	210.5	0.804
		Out	7	3-8	6	3.5-7.5	184	0.675
	Coherence	**In**	4	2-6	3	1.5-5	185	0.378
		Out	3	2-4	3	1-5	189	0.783
	Emotional representation	**In**	5	4.5-8	5	5-8	216.5	0.924
		Out	5	4-7	6	5-7.5	161	0.290
HADS	**Anxiety**	**In**	10	5.5-14.5	9	8.5-11	213,5	0,872
		Out	6	2-10	6	5.5-9	172.5	0.452
	Depression	**In**	7	5-12	8	5.5-11	200	0.613
		Out	7	5-9	6	3.5-9	198.5	0.985

	Total score	**In**	16	11.5-26	18	14-21.5	210	0.799
		Out	14	9-16	13	10-16.5	195	0.867
BIS-11	**Motor impulsivity**	**In**	22	19-26	22	19.5-27	201	0.638
		Out	21	17-27	22	19.5-25.5	193.5	0.881
GSE	**Total score**	**In**	2.8	2.4-3.1	2.9	2.5-3.1	206.5	0.741
		Out	2.9	2.7-3.5	2.9	2.6-3.5	183.5	0.862
SF-12	**PCS**	**In**	34.9	28.1-38	30.3	25.3-39.7	194	0.518
		Out	36.7	34.4-45.2	35.8	27-42.7	159	0.287
	MCS	**In**	36.1	27.7-45.1	40.6	35-49.7	157	0.118
		Out	50.8	40.4-56.6	53	45.6-55.1	176	0.555
RR	**Willingness**	**In**	8	6.5-9	10	7-10	134	**0.028**
		Out	8	8-10	8	7.5-10	196	0.921
	Importance	**In**	9	8-10	10	8.5-10	172	0.187
		Out	10	8-10	10	9-10	192.5	0.844
	Confidence	**In**	8	5-8.5	7	6.5-8	212.5	0.847
		Out	8	7-9	8	6-9	198.5	0.985
TSRQ	**External regulation**	**In**	3.7	2.2-5.5	3	1-5	177.5	0.276
		Out	2	1-4.7	3	1.5-4	157.5	0.258
	Introjected regulation	**In**	5.2	4.1-6.2	4.5	2.7-6.2	176	0.271
		Out	4.5	3.7-5.5	4.5	3.6-5.2	190	0.810
	Identified regulation	**In**	7	5.8-7	7	6.7-7	197.5	0.355
		Out	7	6-7	7	6.3-7	195	0.904
	Intrinsic regulation	**In**	6	5.2-7	6	4-7	192.5	0.493
		Out	6	5.3-7	6	5-6.8	183.5	0.670
	RAI	**In**	3.8	1.2-10.4	7.3	2.6-9.2	190	0.464
		Out	9.7	3.4-13.8	8.4	2.3-12.2	160.5	0.307

[1] Monte Carlo method
[2] Mann-Whitney U test

Despite the absence of significant between-group differences for the key outcome variables (as assessed by the TSRQ and RR) at the end of the treatment, changes in participants' motivation dimensions were further investigated by means of the Wilcoxon signed rank test.

6.3. Within-group changes

Contrary to expectations, *extrinsic regulation* only showed a significant decrease in the BST group. However, looking at the median values and the interquartile ranges, the subjects assigned to the BST condition reported higher scores at baseline than those in the experimental group. Similar but inverse results concern the *RAI* and the *willingness to change*, which significantly increased only in the BST group. Still, the patients assigned to this condition had lower baseline scores compared to those receiving the experimental treatment.

7. Conclusions

The incremental efficacy of combining BST with MI principles and techniques over and beyond the stand-alone BST among CR patients was here investigated for the fist time. According with the results

the integrated treatment did not contribute to the improvement of the study participants' biomedical and psychosocial outcomes.

In addition to a randomization flaw (a simple randomization plan was used), limitations of this study are also due to wrong selection criteria. For example, even if the level of motivation represents one of the study's key-outcome and patients were screened for their Readiness To Change before the enrollment, participants were neither selected nor randomized on the basis of their amount of motivation to change. Similarly, other factors (i.e., Gender, Age) were not properly controlled. This made difficult or even impossible to discern what created the observed between-group differences at baseline, making the results unreliable. In fact, while in the experimental group a majority of men was present, the control group was mainly composed by women, and this could have biased the treatment effects on both biomedical (Kg and SBP) and psychological outcomes (Treatment Control and Willingness To Change). Another limitation of the study is the low reliability of several measures. With the exception of the HADS, the MCS of the SF-12 and the TSRQ-Identified Regulation dimension, indeed, all the other measures showed an unsatisfactory internal consistency, impacting the results of the entire research design. The physical, psychological and social benefit of participating in CR activities may also have had a motivating effect on the subjects, besides influencing the methodological set-up of the study. Since the present represents a pilot study, a stronger experimental design, firstly including a higher number of participants, would help clinicians to judge how the treatment can reasonably be applied.

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