

# The ACTonHEART study: feasibility, acceptability and preliminary efficacy of a brief intervention based on Acceptance and Commitment Therapy in a cardiac rehabilitation setting.

Spatola CAM<sup>12</sup>, Cappella E<sup>12</sup>, Cattivelli R<sup>12</sup>, Rapelli G<sup>12</sup>, Castelnuovo G<sup>12</sup>, Molinari E. <sup>12</sup>



(1) Dipartimento di Psicologia, Università Cattolica del Sacro Cuore – Milano

(2) Laboratorio di Ricerche Psicologiche, Istituto Auxologico Italiano - Milano



## Background

Modifiable risk factors, including life-style habits and psychological variables, account for approximately 90% of the population risk for cardiac events. Acceptance and Commitment Therapy (ACT) has been successfully applied to promote healthy behaviors and psychological well-being in patients with a number of chronic physical conditions.

## Objective

The aim of the present study is to evaluate the feasibility and acceptability of a new acceptance-based program for the modification of cardiovascular risk factors and the improvement of psychological well-being, compared to usual secondary prevention care.

## Methods

<b>Design:</b> Randomized Clinical trial	<b>Inclusion criteria:</b> <ul style="list-style-type: none"><li>•Coronary Artery Disease</li><li>•Age ≤ 75</li></ul>
<b>Control group=</b> Usual care	<b>Randomization</b> Unbalanced randomization ratio 2:1 (intervention vs control group)
<b>ACT group=</b> Usual Care + ACTonHEART program	<b>Sample:</b> <b>83 cardiac rehabilitation patients</b> <b>53 ACT group + 30 control group</b> (Drop-out = 3.3%)
<b>ACTonHEART program:</b> 3 weekly sessions of 2 hours each 6-8 participants for group	<b>Primary outcome measures:</b> Psychological Well being Index LDL cholesterol
1- Psico-education 2- Mindfulness 3- Acceptance 4- Values and committed action	

### Analyses

- In order to evaluate acceptability rates and satisfaction about the program, 7 participants were administered a semi-structured interview, composed by 8 questions regarding the appropriateness of the program themes and the changes observed by the patient in his own life. Patients' feedbacks were analyzed through thematic analysis.
- Preliminary quantitative analyses were performed using a 2x2 repeated measure ANOVA.

## Results

### Qualitative data

The thematic analysis of interview data highlighted that participants appreciated most the experiential exercises, in particular mindfulness exercises, because of the possibility of applying them in daily life.

#### 1. Positive evaluation of experiential exercises:

*«I find that doing an exercise during every group meeting is strategic, because it triggers our curiosity. It helps you to really taste what you're learning»*

*«The most difficult thing to approach was for me the concentration, the attention on your breath; my mind wanders, and when I try to recover it I do not think about negative things; my mind continuously fluctuates...»*

#### 2. Perceived changes:

*«Before the group I was really negative minded, I was always thinking 'What if it happens again?'. Now I've come to accept it, and I live with it»*

*«I exercised at home (...) thoughts do go in the background»*

*«I pay more attention to going to physical activity and to my diet; I go to the gym, and I eat healthy: whole bread, cereals, vegetable soups»*

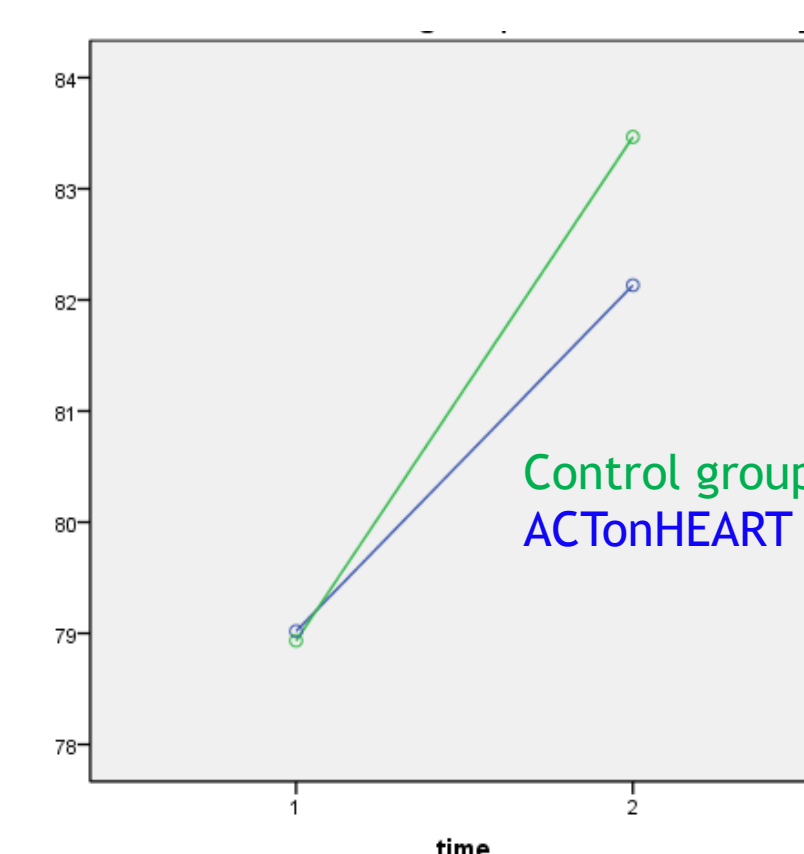
*«In the evening when I am trying to fall asleep, I think of many things. I have one thoughts, then I stop, I think of another (...). Yesterday evening I used one of our exercises, and it allowed me to fall asleep faster than usual. This way I am able to stop wandering in the labyrinth of thoughts»*

#### 3. Areas to improve:

*«I would have liked a more intensive program, with the chance of taking part in more meetings»*

*«It would have been great to have some follow-up meeting, so to keep alive our change»*

### Quantitative data



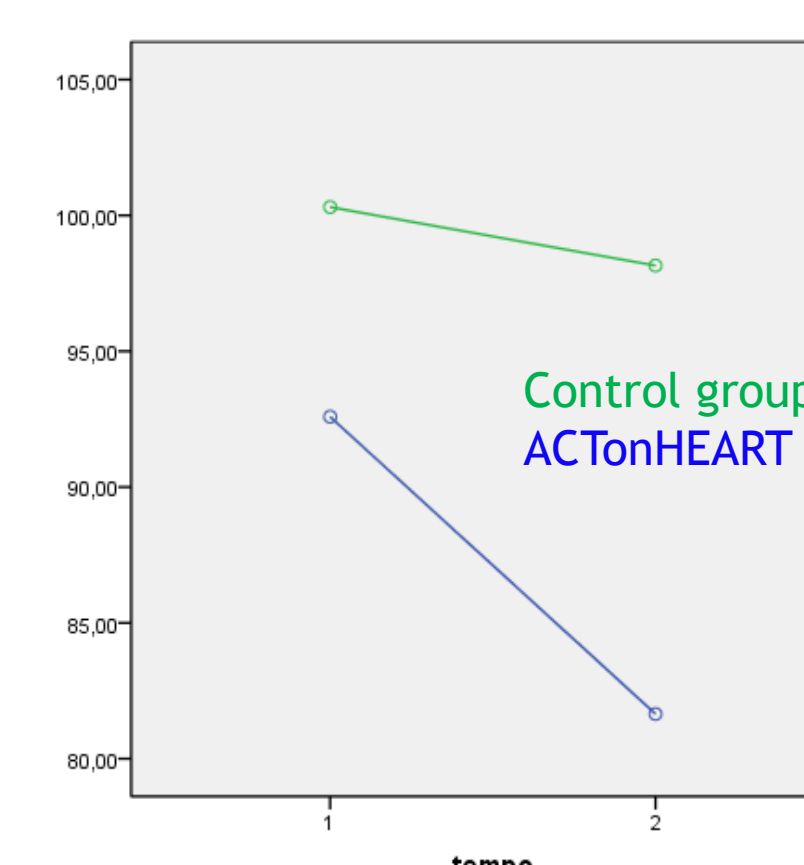
#### 1) Psychological well-being

The levels of general psychological well-being improved from baseline to post-rehabilitation ( $F_{1,81} = 10.85$ ,  $p = .001$ ) regardless of the experimental condition. There was not time  $\times$  group interaction ( $F_{1,81} = .37$ ,  $p = .54$ ), suggesting that, contrary to our expectations the two groups did not differ in terms of well-being improvement.

#### 2) LDL Cholesterol

We analyzed a sub-sample of 30 participants with LDL cholesterol levels  $>80$ . In the ACT group the mean LDL level was 92.59 (SD=13.01) at baseline and 81.65 (SD=26.55) post-CR while in the control group it changed from 100.31 (14.17) to 98.15 (27.88).

The Repeated Measures ANOVA showed no time effect ( $F_{1,28} = 1.8$ ,  $p = .19$ ), nor time  $\times$  group interaction ( $F_{1,28} = .81$ ,  $p = .38$ ).



## Conclusions

- The ACTonHEART program showed good feasibility and acceptability, as reflected both by patients' interviews and low drop-out rates. The results showed an increase of well-being levels and a decrease of LDL cholesterol levels after rehabilitation, though difference between the two groups was not statistically significant. However, the overall aim of the ACTonHEART project is to evaluate the efficacy in modifying the long term outcomes, which will be possible only after the 6- and 12-months follow-ups.
- The patients' feedbacks indicated good satisfaction with the program, though the duration was considered too short by 5 of the 7 interviewed participants. The most appreciated part of the program was the mindfulness module.
- On the basis of these preliminary analyses the study protocol will be modified by increasing from 3 to 5 the number of sessions and including a follow-up session.