SELF MANAGEMENT EDUCATION BY GROUP CARE REDUCES CARDIOVASCULAR RISK IN PATIENTS WITH TYPE 2 DIABETES: ANALYSIS OF THE ROMEO CLINICAL TRIAL

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SELF MANAGEMENT EDUCATION BY GROUP CARE REDUCES CARDIOVASCULAR RISK IN PATIENTS WITH TYPE 2 DIABETES. ANALYSIS OF THE ROMEO CLINICAL TRIAL

Short title: Cardiovascular risk in ROMEO

Jacopo Sicuro M Econ [a], Lorena Charrier MD [b], Paola Berchialla MD [b], Franco Cavallo MD [b], Stefano Merlo M Psychol [a], Aurora Mazzeo BSc [a], Massimo Porta MD PhD[a], Marina Trento MedSci, BPsychol, MBA[a], for the ROMEO investigators.

[a]Laboratory of Clinical Pedagogy, Department of Medical Sciences,University of Turin;
[b]Department of Public Health and Paediatrics,University of Turin.

Corresponding author and reprint requests:
Dr. Marina Trento
Laboratory of Clinical Pedagogy
Department of Medical Sciences, University of Turin
Corso AM Dogliotti 14, I-10126 Torino, Italy
Tel +39 011 6632354
Fax +39 011 6708477
e-mail: marina.trento@unito.it

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Treatment of type 2 diabetes includes lifestyle and pharmacologic interventions. Drugs are marginally effective in achieving glycemic targets and reducing cardiovascular (CV) events, whereas intervention on lipids, blood pressure and lifestyle is more effective. Rethink Oraganization to iMprove Education And Outcomes (ROMEO) (ISRCTN19509463), a 4-year multicentre randomized trial, showed that patients with type 2 diabetes on Group Care (GC), a previously described systemic self-management education model, improved body weight, HbA1c, HDL and LDL cholesterol, blood pressure, quality of life and health behaviours, compared with patients on usual care and similar pharmacological treatment (1). The ROMEO dataset was fed into three risk engines: Framingham (2), UKPDS (3) and CUORE (4) to verify if GC modifies CV risk scores.

A total 815 non insulin-treated patients aged <80 were allocated to either GC or traditional care (Controls). Risk calculations were performed at baseline and throughout the 4 years of the trial in 466 patients (257 on GC and 209 Controls) who completed ROMEO. Reasons for dropping out were reported (5), and dropouts (105 GC and 128 controls) did not differ from other patients for any variables at baseline.

A generalized least - square regression model was used to ascertain interactions between groups and time. A correlation structure was specified to account for repeated measures. A compound symmetry structure corresponding to a constant correlation resulted in the best fit model, based on Akaike Information Criterion (AIC). Model fitting was considered as significantly improved on the basis of the AIC applied backwards starting from a model with all relevant variables. The non-linear effect of covariates was modelled using a restrictive cubic-spline function. Interaction among variables was checked. To ensure normality assumptions, risk scores were modeled on a logarithmic scale. Data were analyzed with R. $p<0.05$ was considered significant.

Four year trends are shown in Figure 1 for each risk model. Interactions between time and group showed that, using Framingham and CUORE, the risk for GC patients was 7.2% lower than in controls over 1 year (model coefficient: -0.006/month, $p<0.0001$). Using UKPDS, GC patients achieved a risk reduction of 3.6% over 1 year ($p<0.0001$).

All three models showed lower CV risk among patients on GC compared to controls, despite similar pharmacological prescriptions. The Framingham and CUORE models are based upon North-American and Italian cohorts and include diabetes as a dichotomous variable. The UKPDS score, developed in British patients with newly diagnosed type 2 diabetes, incorporates HbA1c and time

since diagnosis in a diabetes-specific model and was recently shown to accurately predict CV events also in Italian populations (3). Look AHEAD (Action for Health in Diabetes), an independent clinical trial, reported that lifestyle intervention does not reduce CV events in type 2 diabetes (5). However, since it compared an intensive lifestyle intervention with a less intensive group education approach, it could be argued that Look AHEAD did not disprove the effectiveness of lifestyle modification, but rather proved the non inferiority of a highly intensive intervention over a more sustainable pragmatic approach, similar in part to our GC model at least in timing if not education philosophy and methodology.

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Duality of Interest.

No potential conflict of interest relevant to this article were reported.

Author Contributions.

JS collected and analyzed the data and revised the manuscript, LC, PB, and FC, did the statistical analysis and revised the manuscript. SM and AM collected the data and revised the manuscript, MP planned the study, and drafted the manuscript, MT planned the study, collected and researched the data, revised the manuscript and is guarantor of this article.

Guarantor statement.

Dr. Marina Trento is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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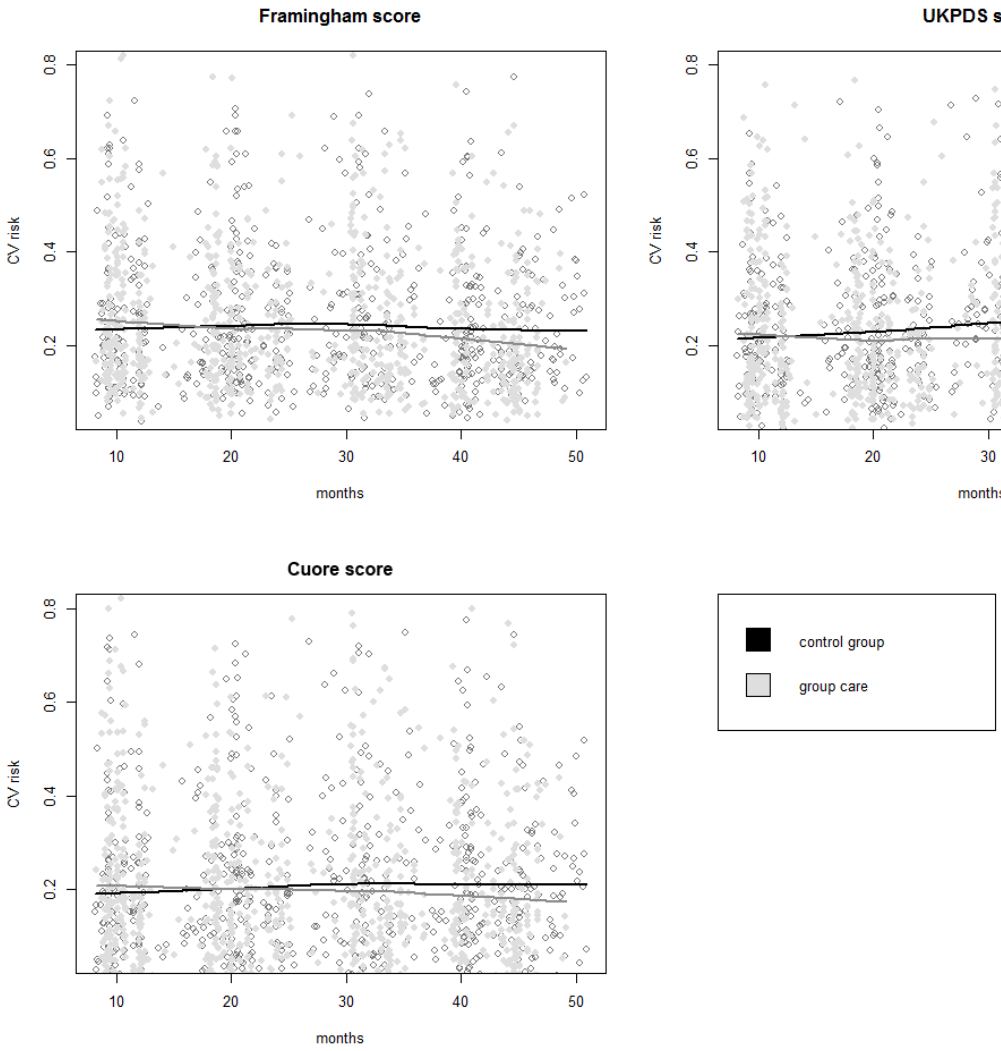
Figure 1. Temporal trends of cardiovascular risk measured by Framingham, UKPDS and CUORE Risk Scores, estimated using locally weighted regression.



List of ROMEO investigators:

E. Ansaldi, F. Malvicino, M. Battezzati, P. Maresca, C. Cappa, C. Palenzona, G. Rosti, *Alessandria*

L. Gentile, G. De Corrado, M Fernicola, R. Gambaudo, E Molina, T. Miroglio, S. Poggio, E. Repetti, F. Rosso, P Viglione, *Asti*

G. Morone, F. Travaglino, *Biella*

A. Chiambretti, M Albertone, A. Birocco, MP Maritano, E. Mularoni, R. Fornengo, D. Rolfo, *Chivasso*

S. Gamba, *Ospedale Maria Vittoria, Torino*

A. Mormile, P. De Murtas, AM. Ingaramo, A. Marchesini, *Ospedale Mauriziano,Torino*

E. Orsi, F. Albani, L Giarratana, *Milano*

G. Corigliano, I.Vaccarella, *Napoli*

M. Patella, M Masin, G Sartore, R. Toniatto, R. Valentini, A. Barison, D. Fedele, *Padova*

V.Miselli, P. Accorsi, U.Pagliani, *Scandiano-Reggio Emilia*

L. Tonutti, C. Boscariol, M. Armellini, R. Lesa, C Sartori, C. Noacco, C.Taboga, *Udine*

L. Richiardi, S. Borla, *Ospedale Valdese, Torino*