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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Treatment of type 2 diabetes includes lifestyle and pharmacological 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 Organisation to iMprove Education and Outcomes (ROMEO) (ISRCTN19509463), a 4-year multicenter randomized trial, showed that patients with type 2 diabetes on group care (GC), a previously described systemic self-management education model, improved body weight, HbA_{1c}, HDL and LDL cholesterol, blood pressure, quality of life, and health behaviors, compared with patients on usual care and similar pharmacological treatment (1). The ROMEO data set was fed into three risk engines, Framingham (2), UK Prospective Diabetes Study (UKPDS) (3), and CUORE (4), to verify if GC modifies CV risk scores.

A total of 815 non-insulin–treated patients aged <80 years 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 backward starting from a model with all relevant variables. The nonlinear effect of covariates was modeled 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 Project for Statistical Computing. $P < 0.05$ was considered significant.

Four-year trends are shown in Fig. 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 with 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 HbA_{1c} and time since diagnosis in a diabetes-specific model and was recently shown to accurately also predict CV events 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, as 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 noninferiority 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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**A complete list of the ROMEO Investigators can be found in APPENDIX.*

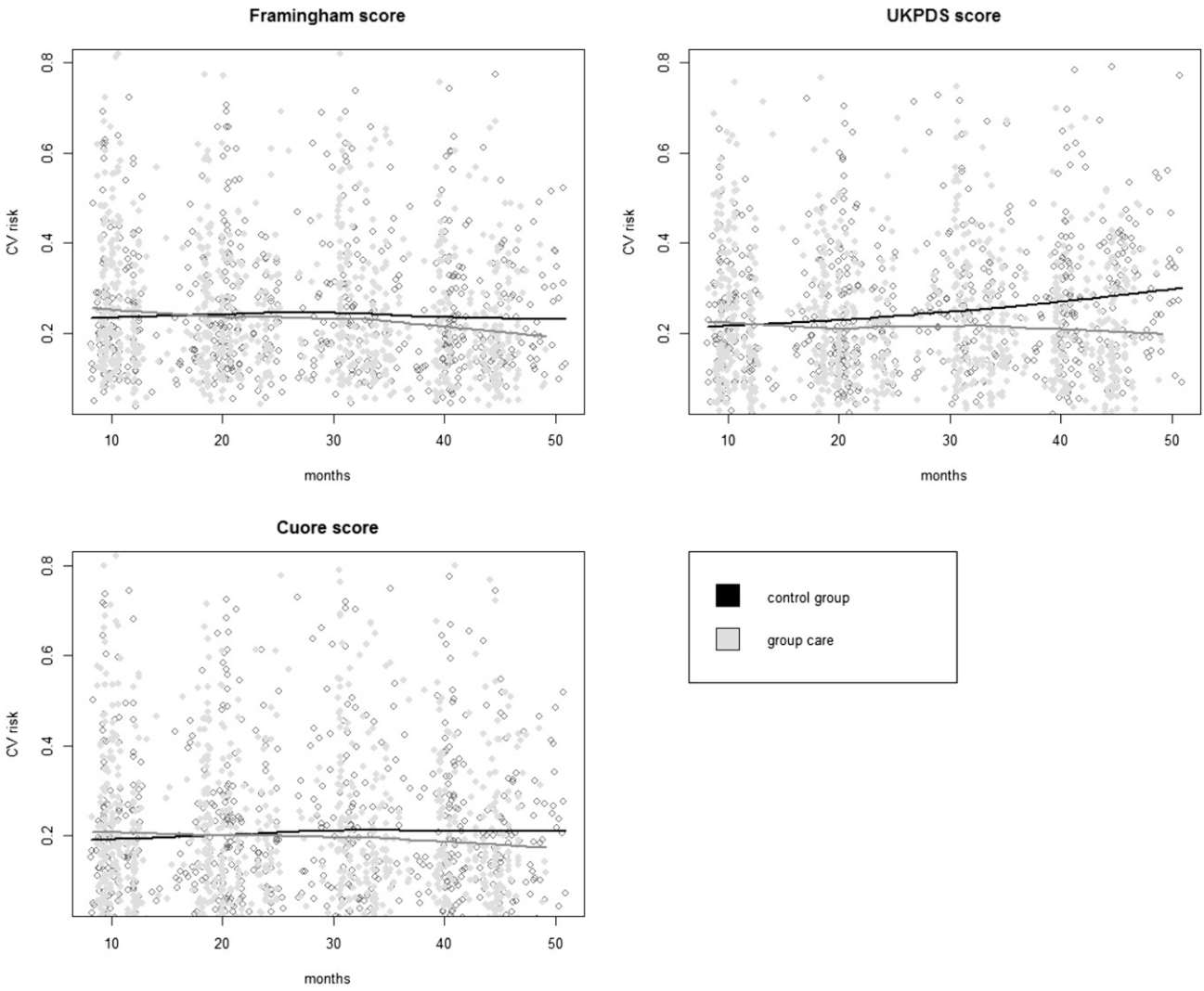

Figure 1—Temporal trends of CV risk measured by Framingham, UKPDS, and CUORE risk scores, estimated using locally weighted regression.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.
Author Contributions. J.S. collected and analyzed the data and revised the manuscript. L.C., P.B., and F.C. did the statistical analysis and revised the manuscript. S.M. and A.M. collected the data and revised the manuscript. M.P. planned the study and drafted the manuscript. M.T. planned the study, collected and researched the data, and revised the manuscript. M.T. 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.

Appendix

List of ROMEO investigators: E. Ansaldi, F. Malvicino, M. Battezzati, P. Maresca, C. Cappa, C. Palenzona, and G. Rosti (Alessandria); L. Gentile, G. De Corrado, M. Fernicola, R. Gambaudo, E. Molina, T. Miroglio, S. Poggio, E. Repetti, F. Rosso, and P. Viglione (Asti); G. Morone and F. Travaglino (Biella); A. Chiambretti, M. Albertone, A. Birocco, M.P. Maritano, E. Mularoni, R. Fornengo, and D. Rolfo (Chivasso); S. Gamba (Ospedale Maria Vittoria, Torino); A. Mormile, P. De Murtas, A.M. Ingaramo, and A. Marchesini (Ospedale Mauriziano, Torino); E. Orsi, F. Albani and L. Giarratana (Milano); G. Corigliano and I. Vaccarella (Napoli); M. Patella, M. Masin, G. Sartore, R. Toniatto, R. Valentini, A. Barison, and D. Fedele (Padova); V. Miselli, P. Accorsi, and U. Pagliani (Scandiano-Reggio Emilia); L. Tonutti, C. Boscariol, M. Armellini, R. Lesa, C. Sartori, C. Noacco, and C. Taboga (Udine); and L. Richiardi and S. Borla (Ospedale Valdese, Torino).

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