Rethink Organization to iMprove Education and Outcomes (ROMEO)

A multicenter randomized trial of lifestyle intervention by group care to manage type 2 diabetes

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OBJECTIVE — A trial was performed to establish whether our group care model for lifestyle intervention in type 2 diabetes can be exported to other clinics.

RESEARCH DESIGN AND METHODS — This study was a 4-year, two-armed, multicenter controlled trial in 13 hospital-based diabetes clinics in Italy (current controlled trials no. ISRCTN19509463). A total of 815 non–insulin-treated patients aged <80 years with ≥1 year known diabetes duration were randomized to either group or individual care.

RESULTS — After 4 years, patients in group care had lower A1C, total cholesterol, LDL cholesterol, triglycerides, systolic and diastolic blood pressure, BMI, and serum creatinine and higher HDL cholesterol ($P < 0.001$, for all) than control subjects receiving individual care, despite similar pharmacological prescriptions. Health behaviors, quality of life, and knowledge of diabetes had become better in group care patients than in control subjects ($P < 0.001$, for all).

CONCLUSIONS — The favorable clinical, cognitive, and psychological outcomes of group care can be reproduced in different clinical settings.

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Lifestyle intervention reduces incidence of (1,2) and helps improve metabolic control in (3,4) type 2 diabetes. However, lifestyle advice given during individual consultations remains secondary to pharmacological intervention (5). We developed a model to deliver diabetes care as group education sessions, which improves clinical outcomes, patients' quality of life (QoL), and clinicians' satisfaction while optimizing use of the typically limited resources of busy clinics (6–8).

The Rethink Organization to iMprove Education and Outcomes (ROMEO) trial was a multicenter trial (9) aimed at evaluating if setting and results of group care can be reproduced in other clinics.

RESEARCH DESIGN AND METHODS

— A total of 815 patients with non–insulin-treated type 2 diabetes of ≥1 year known duration, aged <80 years, were randomized to either group (case subjects) or traditional one-to-one (control subjects) care (online appendix Fig. 1 [available at http://care.diabetesjournals.org/cgi/content/full/dc09-2024/DC1]). Patients from 13 hospital-based clinics gave their informed consent (online appendix Table 1). ROMEO was approved by the ethics committee of the coordinating center in Turin. Power calculations indicated that 550 patients would allow to detect a decrease in A1C from 8.0 to 7.5%, with an $\alpha = 0.05$ and $\beta = 0.05$. Randomization was done locally by random table numbers.

Body weight, fasting glycemia, blood pressure, and A1C were measured every 3 months. Creatinine, total and HDL cholesterol, and triglycerides were measured yearly. LDL cholesterol was calculated by Friedewald's formula (10). Health behaviors (Condotte di Riferimento = CdR) (8) and QoL (11) were measured by previously described specific questionnaires at baseline and years 2 and 4. Knowledge of diabetes (12) was measured at baseline and year 4 by the Italian Study Group for Diabetes Education (Gruppo Italiano di Studio Educazione e Diabete [GISED]).

Group care sessions and individual visits were every 3 months by the same operators. The approach and curriculum were described previously (6–8). In brief, seven 1-h sessions were held over 2 years and repeated. Education involved mainly group work, hands-on activities, problem solving, real-life simulations, and role playing (online appendix 2). All patients received individual consultations at least yearly, whenever deemed necessary by operators, or upon request.

Trial investigators were trained in our laboratory on principles of adult education and analysis of the intervention program and were supported in transferring group care to their clinics. Operating manual (available in an online appendix), teaching materials, logistical support, and supervision were provided throughout the study. Individual visits remained based upon local clinical practice.

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Analysis was by intention to treat. Descriptive data are shown as absolute frequencies if categorical and means ± SD if continuous variables. Differences between groups at baseline were checked by χ^2 or *t* test for independent data, as applicable. Differences between baseline and year 4 were tested by *t* test for dependent data.

Results are expressed as differences and 95% CI between treatment groups. Differences between case and control subjects were adjusted for center, sex, family history for diabetes, schooling, occupation, years of attendance in clinic, and baseline values of the dependent variable. The different frequencies of patients reaching clinical targets at baseline and year 4 were tested by the McNemar test for paired samples. Odds ratios of being at target at year 4 being a case rather than a control subject were estimated by a multivariate logistic model adjusted for age, sex, duration of diabetes, family history, and baseline value for the considered variable. Differences were considered significant for $P < 0.05$.

RESULTS — Two clinics did not complete the trial. Case ($n = 106$) and control ($n = 128$) dropouts had similar baseline variables. In the case subjects, BMI, fasting glycemia, A1C, total cholesterol, triglycerides, LDL cholesterol, and systolic and diastolic blood pressure decreased from baseline to year 4, while HDL cholesterol increased ($P < 0.001$, for all) and creatinine did not change (online appendix Table 2). BMI, A1C, triglycerides, and creatinine increased in control subjects, whereas total, HDL, and LDL cholesterol and systolic blood pressure did not change and diastolic blood pressure decreased. At study end, case subjects had higher HDL cholesterol (1.42 ± 0.29 vs. 1.29 ± 0.33 mmol/l) and lower A1C (7.3 ± 0.9 vs. 8.8 ± 1.2%), fasting glycemia (8.78 ± 2.27 vs. 9.44 ± 2.89 mg/dl), total cholesterol (4.88 ± 0.96 vs. 5.47 ± 0,94 mmol/l), LDL cholesterol (2.79 ± 0.94 vs. 3.31 ± 0,97 mmol/l), triglycerides (1.46 ± 0.59 vs. 1.94 ± 1.17 mmol/l), systolic blood pressure (138.0 ± 16.1 vs. 143.6 ± 18.5 mmHg), diastolic blood pressure (79.1 ± 9.4 vs. 80.6 ± 8.4 mmHg), body weight (80.4 ± 14.6 vs. 82.1 kg), BMI (30.1 ± 5.0 vs. 30.4 ± 5.8 kg/m^2), and creatinine (76.0 ± 23.0 vs. 85.7 ± 26.5 mmol/l) than control subjects ($P < 0.001$, for all).

Health behaviors, QoL, and knowledge improved in case subjects ($P < 0.001$, for all). Health behaviors did not

Table 1—*Patients at target*

	Group care			Control subjects			All patients*	
	Baseline	4 years	*P*† (baseline vs. 4 years)	Ba90 baseline	4 years	*P*† (baseline vs. 4 years)	Odds ratio (95% CI) of being at target for case versus control subjects	*P*
A1C ≤7.0% (percent of available data)	150/420 (35.7%)	135/315 (42.9)	$P < 0.001$	116/375 (30.9)	10/270 (3.7)	$P < 0.001$	29.4 (14.2–60.8)	$P < 0.001$
A1C ≤6.5% (percent of available data)	99/420 (23.6)	58/315 (18.4)	NS	69/375 (18.4)	0/270 (0)	$P < 0.001$	82.08 (11.1–616.5)	$P < 0.001$
Systolic blood pressure	111/411 (27)	113/295 (38.3)	$P < 0.002$	117/394 (29.7)	84/266 (31.6)	NS	1.4 (0.9–1.9)	NS
Diastolic blood pressure 80 mmHg	236/411 (57.4)	212/295 (71.9)	$P < 0.001$	255/394 (64.7)	185/266 (69.5)	NS	1.2 (0.8–1.82)	NS
Systolic blood pressure ≤130 and diastolic blood pressure ≤80 mmHg	93/411 (22.6)	105/295 (35.6)	$P < 0.001$	101/394 (25.6)	74/266 (27.8)	NS	1.5 (1.02–2.1)	$P < 0.05$
Total cholesterol ≤4.0 mmol/l (175 mg/dl)	74/421 (17.6)	107/308 (34.7)	$P < 0.001$	77/394 (19.5)	37/264 (14.0)	NS	4.0 (2.5–6.4)	$P < 0.001$
Triglyceride ≤1.7 mmol/l (150 mg/dl)	251/421 (59.6)	226/309 (73.1)	$P < 0.001$	212/394 (53.8)	145/264 (54.9)	NS	2.3 (1.5–3.4)	$P < 0.001$
LDL cholesterol ≤2.58 mmol/l (100 mg/dl)‡	81/414 (19.6)	115/305 (37.7)	$P < 0.001$	92/385 (23.9)	53/262 (20.2)	NS	2.9 (1.9–4.4)	$P < 0.001$
Patients at target for all variables§	10/418 (2.4)	15/308 (4.9)	$P < 0.05$	10/393 (2.5)	1/270 (0.4)	NS	14.5	$P < 0.01$

Data are *n* (%), unless otherwise indicated. *Odds ratios have been estimated by a logistic model, where being at target at 4 years was considered as the dependent variable and belonging to the group of case or control subjects, age, sex, duration of diabetes, familiarity, and situation at baseline were the independent variables. †McNemar test for paired samples. ‡Friedwald formula: LDL cholesterol = total cholesterol − HDL cholesterol − triglycerides/5 (only patients with triglycerides <4.5 mmol/l included). §A1C ≤7.0% + systolic blood pressure ≤130 mmHg + diastolic blood pressure ≤80 mmHg + LDL cholesterol ≤2.58 mmol/l (100 mg/dl).

change in control subjects, whereas QoL and knowledge worsened. At study end, health behaviors (15.24 ± 2.62 vs. 11.07 ± 3.00), QoL (63.22 ± 10.27 vs. 77.88 ± 13.14), and knowledge (48.37 ± 13.42 vs. 38.69 ± 14.07) were better in the case subjects ($P < 0.001$, all).

The proportion of cases with A1C ≤7.0%, systolic pressure ≤130 mmHg, diastolic pressure ≤80 mmHg, and LDL cholesterol ≤2.58 mmol/l (100 mg/dl) at year 4 increased from baseline, and those who met all targets doubled (Table 1). Control subjects remained stable or worsened. Prescriptions of hypoglycemic, antihypertensive, and lipid-lowering medications were similar for case and control subjects. A total of 50 of 315 case subjects (15.87%) and 56 of 266 control subjects (21.05%) were on insulin at study end.

CONCLUSIONS — Lifestyle intervention requires delivery of continuing patient education and care without increasing clinical workload and with measurable outcomes. In our experience, reorganizing working practice as routinely delivered group care is a feasible and cost-effective approach to improve metabolic control and QoL in type 2 diabetes (6–8).

ROMEO, a multicenter controlled trial, showed that group care is transferable and confirmed its efficacy. A1C and lipids improved and, at study end, the share of case subjects achieving currently recommended clinical targets (5) increased from baseline, the opposite being true for control subjects. That improvement occurred without additional medication strongly suggests that healthier behaviors were induced by group care.

As the acronym ROMEO suggests, group care requires reallocation of tasks, roles, and resources and a change in providers' attitudes from the traditional prescriptive approach to a more empathic role of facilitator. This may limit its transferability, as one clinic did not start the trial and another withdrew after 2 years.

Previous studies of education in diabetes management varied in approach, were shorter, and measured less outcomes (13,14). The Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND), the only other multicenter trial of education in type 2 diabetes, did not register improvements in A1C or QoL over a 1-year follow-up in newly diagnosed patients (15). Continuing interactive patient-centered education by group care is reproducible and improves diabetes management and outcomes.

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