Pro-Active Call Center Treatment Support (PACCTS) to Improve Glucose Control in Type 2 Diabetes

A randomized controlled trial

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OBJECTIVE — To determine whether Pro-Active Call Center Treatment Support (PACCTS), using trained nonmedical telephonists supported by specially designed software and a diabetes nurse, can effectively improve glycemic control in type 2 diabetes.

RESEARCH DESIGN AND METHODS — A randomized controlled implementation trial of 1-year duration was conducted in Salford, U.K. The trial comprised 591 randomly selected individuals with type 2 diabetes. By random allocation, 197 individuals were assigned to the usual care (control) group and 394 to the PACCTS (intervention) group. Lifestyle advice and drug treatment in both groups followed local guidelines. PACCTS patients were telephoned according to a protocol with the frequency of calls proportional to the last HbA_{1c} level. The primary outcome was absolute reduction in HbA_{1c}, and the secondary outcome was the proportion of patients reducing HbA_{1c} by at least 1%.

RESULTS — A total of 332 patients (84%) in the PACCTS group and 176 patients (89%) in the control group completed the study. Final HbA_{1c} values were available in 374 patients (95%) in the PACCTS group and 180 patients (92%) in the usual care group. Compared with usual care, HbA_{1c} improved by 0.31% (95% CI 0.11–0.52, $P = 0.003$) overall in the PACCTS patients. For patients with baseline HbA_{1c} >7%, the improvement increased to 0.49% (0.21–0.77, $P < 0.001$), whereas in patients with baseline HbA_{1c} <7% there was no change. The difference in the proportions of patients achieving a ≥1% reduction in HbA_{1c} significantly favored the PACCTS intervention: 10% (4–16, $P < 0.001$) overall and 15% (7–24, $P < 0.001$) for patients with baseline HbA_{1c} >7%.

CONCLUSIONS — In an urban Caucasian trial population with blood glucose HbA_{1c} >7%, PACCTS facilitated significant improvement in glycemic control. Further research should extend the validity of findings to rural communities and other ethnic groups, as well as to smoking and lipid and blood pressure control.

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Abbreviations: OHA, oral hypoglycemic agent; PACCTS, Pro-Active Call Center Treatment Support.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

A worldwide epidemic of type 2 diabetes is threatening to overwhelm the capacity of health care service providers. There is good evidence that tight blood glucose, blood pressure, and lipid control can markedly reduce the adverse impact of type 2 diabetes and deliver substantial health benefits (1–4). Reviews of implementation strategies to achieve these treatment targets indicate that a multifaceted approach is most successful (5). Although a stepped-care program based on guidelines, education of primary care professionals, and support from secondary and intermediate care specialists has achieved appreciable improvements in blood pressure and lipid control in the Salford area, it has failed, thus far, to improve blood glucose control (6).

Chronic disease management programs seem to be most successful when they support treatment adherence and self-efficacy (7–10). Attaining type 2 diabetes treatment targets requires appreciable pharmacologic intervention (1,3,4). However, good blood glucose control may be particularly difficult because of the stringent complementary lifestyle demands and the progressive increase in the need for hypoglycemic therapy. Diabetes educator–led, Pro-Active Call Center Treatment Support (PACCTS) for diabetes care is well established as a health care delivery vehicle in the U.S. It seems to offer service delivery characteristics that might enhance effectiveness, such as continuity, convenience, and risk-stratified intervention. However, it has not been subject to rigorous or large-scale clinical trial assessment of its effectiveness or efficiency (11).

Therefore, we decided to examine the clinical effectiveness, acceptability, and cost-effectiveness of PACCTS in a publicly funded primary health care setting. The aim was to provide a convenient, risk-stratified intervention to improve glucose control by promoting lifestyle

Table 1—*Patient baseline characteristics*

	Missing (test/control)	PACCTS	Usual care
n		394	197
Age (years)	0/0	67 (29–91)	67 (22–88)
Sex (male)	0/0	227 (58)	114 (58)
BMI (kg/m^2)	94/48	30.2 (18.3–57.5)	30.3 (22.4–57.7)
Duration of diabetes (years)	13/3	6 (1–39)	6 (1–35)
Carstairs Deprivation 4 & 5*	0/0	335 (85)	167 (85)
Baseline treatment			
Lifestyle	0/0	95 (24)	45 (23)
One OHA†	0/0	115 (29)	58 (30)
Two OHAs	0/0	92 (23)	58 (30)
Insulin with or without OHA	0/0	92 (23)	35 (18)
HbA_{1c} (%)	0/0	7.9 (5.2–15.1)	8.0 (4.8–14.9)

Data are means (range) or *n* (%). *Carstairs V: Deprivation indices: their interpretation and use in relation to health. *J Epidemiol Community Health* 49 (Suppl 2):S3–S8, 1995. †OHAs: metformin, sulphonylurea, or thiazolidinedione.

management, treatment adherence, and self-efficacy. The study was a randomized control trial within an unselected sample of the Salford population of individuals with type 2 diabetes. Considering the shortage of trained personnel in the U.K., we modified the U.S approach by designing the program to be delivered predominantly by previously untrained "telecarers" backed up by a diabetes specialist nurse when treatment changes or problem solving were necessary. A comprehensive qualitative study, assessing the acceptability of the PACCTS intervention, and an economic analysis of trial findings were conducted and will be reported separately.

RESEARCH DESIGN AND METHODS

The usual care (control) group continued with conventional treatment based on local guidelines, which had been in place for >10 years, supported by a continuing education program among all primary care practices. The guidelines advocate a standard stepped-care protocol for management of type 2 diabetes, including a comprehensive annual review. In addition to usual care, the PACCTS group received call center support (see below).

The target mean difference between the intervention and control groups was specified as 1% HbA_{1c}. The within-group HbA_{1c} SD was estimated as 2% from the Salford District Diabetes Information System. For a significance level of 5% (two sided) and a desired power of 90%, a total sample size of 190 was required. A secondary end point was specified as the proportion of patients with a reduction in HbA_{1c} of >1%. Assuming proportions of 10 and 20% in the control and intervention groups, respectively, implies a total sample size of 608 (significance level 5%, power 90%). To power the study for both targets and for reasons of clinical validity (the PACCTS group would be large enough to simulate a real treatment delivery program), it was agreed to randomize intervention to control in a ratio of 2:1. The target, therefore, was to recruit 600 randomly selected individuals with type 2 diabetes from participating practices. Recruitment was carried out by the call center staff (diabetes specialist nurse and telecarers) between October 2001 and February 2002. In all recruits, baseline HbA_{1c} was measured when consent for participation was given. Postrecruitment block randomization, stratified by baseline HbA_{1c} (<7, 7–9 or >9%), was performed by the statisticians (S.H. and T.F.) using SAS software (block length 9, 6 intervention to 3 control; SAS Institute, Cary, NC). Those allocated to the intervention group received their first call between April and June 2002 and their final call during April and June 2003. Both usual care and PACCTS patients provided final HbA_{1c} values during April through June 2003.

Recruitment

Salford is an inner-city location within Greater Manchester, U.K. The population is 95% white European. More than 80% of the population is in the lowest two socioeconomic categories. All 67 Salford general practices were invited to participate; among 23 group practices, 22 agreed and 1 declined. Of the 44 single-handed practices, 25 participated, 2 declined, and 15 did not respond. Patients were excluded because of diagnosis of diabetes <1 year previously, inability to use the phone, or terminal illness. In consequence, 2,894 patients (80% of the total registered population of people with type 2 diabetes) were available for recruitment. Random selections of these people were informed about the study by letter; from 1,970 letters, there were 1,047 responses, 689 of which indicated agreement to attend a formal group recruitment session. A total of 599 respondents actually attended, 596 of whom agreed to take part in the study. Because five respondents died before receiving the first call, 591 individuals actually entered the study. Patients enrolled were representative of the diagnosed diabetes population in Salford with respect to age, sex, duration of diagnosed diabetes, socioeconomic status, and type of treatment. By random allocation, 197 patients were assigned to the usual care group and 394 patients were assigned to the PACCTS group. The baseline characteristics were similar for the two groups and are shown in Table 1. A total of 7.6% of control subjects and 7.5% of the PACCTS patients were lost due to death, serious illness, or moving away. An additional 8.2% of intervention patients left the study because they could not cope with the calls (2.3%), were unhappy with the advice (1%), changed their mind (0.8%), were traveling (0.8%), were too busy (0.8%), were bereaved (0.8%), or had other reasons (0.8%)

Call center technology

A research call center incorporating Cisco Systems intranet protocol equipment (Cisco Systems, San Jose, CA) was established within the local research facility. A type 2 diabetes script application based on J2EE (Java; Sun Microsystems, Santa Clara, CA) was written in partnership between the Diabetes Project Team and British Telecom. The application supported patient education (lifestyle and medication adherence), metabolic management, and referrals between telecarers and the diabetes specialist nurse. The personnel comprised two part-time telecarers (1.4 whole time equivalents) and one diabetes specialist nurse (0.4 whole time equivalent nursing, 0.6 whole time equivalent project management). The staff had ac-

cess to the local electronic diabetes record, which contains test results, clinical observations, notes of routine contacts, medications, and clinical correspondence.

Call center staff

We sought to recruit call center operatives (telecarers) who had a calm, reassuring, and professional telephone manner, had an excellent speaking voice, could follow health care protocols, and could work partially unsupervised. Essential requirements were previous experience of working with the general public, keyboard and data input skills, and flexibility in working patterns (to allow for early and late calls).

The telecarers were managed by a diabetes specialist nurse, who supervised a 3-month training program that comprised the following: principles of managing type 2 diabetes; impact of living with chronic disease; communication skills, especially focused listening; building a telephone relationship; change management and motivational interviewing; use of the PACCTS application; and data collection and basic database methodology.

PACCTS intervention

The core interventions were the outbound interval calls by the telecarers. These calls were performed once every 3 months if HbA_{1c} was ≤7%, every 7 weeks if HbA_{1c} was in the range 7.1–9%, and monthly if HbA_{1c} was >9%. After registration, the call center application selected the week during which the patient should be called and the patient was offered the opportunity to book the day and the time at which they would receive the call. Each call lasted 20 min. The application enabled the telecarers to resume incomplete interval calls and to schedule follow-up calls tailored to address specific needs. Most calls were scheduled outbound, but the application also enabled unscheduled inbound calls to be processed and recorded systematically. The telecarers operated according to the mission statement "the intention of the call is to support and guide the patient as an individual toward achieving the best possible management of their diabetes." They followed the script within the call center application but were trained to customize the pace and detail of the call to the social context of the individual patient. They were also trained to identify health beliefs and to use motivational interviewing techniques when lifestyle barriers were jeopardizing agreed treatment plans.

The call center application covered four main domains. First, there were questions that explored gaps in knowledge about diabetes and provided educational advice about lifestyle improvements, including weight management, healthy eating, physical activity, stress management, and smoking. The second domain was "readiness to change;" this area helped the telecarer and patient identify whether the patient was motivated to make a change, to keep communication open until they (ideally) reached that point, and to support and encourage ongoing change. The third domain was medication adherence; the telecarers reviewed whether patients were taking their medications, taking them at the correct time, and, if applicable, whether their injection technique was appropriate. The fourth domain was blood glucose control: patients were questioned about recent urine glucose, blood glucose, or HbA_{1c} results. Additionally, they were advised about how to carry out self-testing and were reminded, if necessary, to have laboratory testing performed.

Results that were above target became the subject of review, and if lifestyle or medication adherence seemed to be the explanation for an above-target result, education and motivation in the relevant areas were consolidated. If supplementary lifestyle counseling or medication adjustments seemed to be required, the telecarer booked a call with the diabetes specialist nurse. The recommended algorithmic (stepped-care) treatment adjustments embedded within the application were designed using the long-established local guidelines for the management of people with type 2 diabetes. These local guidelines were modeled on the English National Guidelines for managing glucose control in type 2 diabetes (available at www.NICE.org.uk) and were not influenced by any other outside agencies. The same guidelines were used by all the primary care teams treating the patients in the control group. Therefore, PACCTS was not introducing new guidelines but simply endeavoring to implement the existing clinical policies more effectively. The diabetes specialist nurse received referrals (booked telephone consultations) from the telecarers. She/he answered urgent queries about hypoglycemia or intercurrent illness and queries about aspects of diabetes (e.g., complications) out with the scope of the telecarers, negotiated adjustments in treatment (implemented through patient group directives), and/or made recommendations to primary care providers about supplementary treatment. These recommendations were recorded on the PACCTS application communicated by phone and confirmed by mail.

The primary biomedical outcome variable was HbA_{1c}. Study blood samples were taken at recruitment and after 12 months of the call center intervention.

Analysis

Statistical analysis was carried out on an intention-to-treat basis. All patients with baseline HbA_{1c} were considered for the analysis, and the last observation carried forward was used when values at 1 year were missing. For the continuous primary outcome HbA_{1c}, key tests with Satterthwaite approximation allowing for unequal variances were used to test hypotheses of equal means for all strata: 95% CIs are given for the differences between the PACCTS and control groups. For the binary secondary outcome, the percentage of responders for the PACCTS and control groups for all three strata were computed. Proportions were compared using the χ^2 test. Approximate 95% CIs are given for the differences of the proportions for the intervention group. A pooled estimate for the treatment effect was calculated for both continuous and binary outcomes as the weighted mean of the stratum treatment effects weighted by stratum size: 95% CIs and *P* values based on normal approximations are given. For medication changes, a Wilcoxon's rank-sum test was performed to compare the intervention control group. When the medication was higher (lower) by at least one step, the change was classified as "up (down)." For each group, the Wilcoxon's signed-rank test was computed to determine whether patients moved to higher or lower medication. Two-sided tests were used in all cases, and only *P* values <5% were considered significant. No adjustments for multiple testing were performed. Analyses were performed using SAS version 8.2 (SAS Institute, Cary, NC).

The following subcategories were defined prospectively: initial glycemic control: HbA_{1c} ≤7% (good), HbA_{1c} 7.1–9% (moderate), and HbA_{1c} >9% (poor); medication: none (lifestyle management

Table 2—*Mean difference in HbA_{1c}*

Baseline HbA_{1c} (%)	Percent of patients		HbA_{1c} change from baseline				
	Usual care	PACCTS	Usual care	PACCTS	Difference	95% CI	*P*
<7	29.4	29.9	0.2 ± 0.6	0.2 ± 0.8	0.04	(−0.17 to 0.25)	0.74
7–9	51.7	52.2	0.0 ± 1.3	−0.5 ± 0.9	−0.49	(−0.21 to −0.77)	<0.001
>9	18.8	17.8	1.5 ± 2.0	−1.9 ± 1.6	−0.37	(−1.13 to 0.11)	0.33
All					−0.31	(−0.11 to 0.52)	0.003

Data are means ± SD unless otherwise indicated.

only); lifestyle and one oral hypoglycemic agent (OHA); lifestyle and two or more OHAs; lifestyle and insulin with or without oral hypoglycemic drugs.

RESULTS — During the 12 months of the trial, there were >4,000 telephone consultations (90% outbound, 10% inbound). Withdrawal from the study occurred in 10.7% of usual care subjects and 15.7% of PACCTS patients. Approximately one-third of the intervention group dropouts were linked to the PACCTS intervention (see above). Patients withdrawing from the study were not different in age, sex, or socioeconomic status from those who continued.

Overall, medication increased in the control group. There was no change in 91% and a step up in 9% of patients (six patients increased medication by one OHA, one increased by two OHAs, and eight started insulin therapy; $P < 0.001$). In the PACCTS group, medication decreased in 3%, did not change in 75%, and stepped up in 22% of patients (11 patients stopped or reduced OHAs, 57 increased by one OHA, six increased by two OHAs, and 24 started insulin therapy; $P < 0.001$). Medication increased more in the PACCTS group than the usual care group ($P = 0.002$).

Mean differences in HbA_{1c} were analyzed on an intention-to-treat basis overall and by baseline HbA_{1c} strata (Table 2). Overall, HbA_{1c} improved by 0.3% in the PACCTS group when compared with the usual care group ($P < 0.003$). For patients with baseline HbA_{1c} ≥7% (moderate or poor control at baseline), the improvement increased to 0.49% ($P < 0.001$), whereas in patients with baseline HbA_{1c} <7%, there was no change. Defining response as an absolute improvement in HbA_{1c} of 1% (Table 3), significantly more patients responded overall (10%, $P < 0.001$) and more patients with baseline HbA_{1c} >7% (15%, $P < 0.001$).

Further investigation of these results showed that there was no age, sex, or practice (group versus single-handed) effect. Results of the acceptability and cost-effectiveness studies are the subjects of companion articles.

CONCLUSIONS — In this randomized controlled trial, PACCTS for patients with type 2 diabetes did not achieve the prespecified target mean HbA_{1c} reduction of 1%. However, over 1 year, it did achieve an average reduction of 0.49% HbA_{1c} in patients who were moderately or poorly controlled at baseline (HbA_{1c} >7%), a clinically worthwhile effect. The effect of PACCTS was achieved with only a modest influence on net prescribing, and companion articles show that the PACCTS approach was very popular with patients and borderline cost-effective (12). The three reports together build on previous research, provide an information-rich health technology assessment, and explore long-term implications, consistent with Medical Research Council guidance on evaluating complex interventions (13).

The largest, longest, and most influential study of glucose control in type 2 diabetes, U.K. Prospective Diabetes Study (UKPDS) (1) illustrated the effort required to obtain and maintain improved glucose control. Our study suggest that, with PACCTS, it is possible to obtain an improvement about half as large as that achieved in UKPDS among people whose glucose control is above target. Furthermore, because there was little difference in prescribed medication, this improvement seems to be substantially due to lifestyle changes and treatment adherence. There is emerging evidence that telephone-based diabetes education may be effective (14–18). In previous studies, the telephone education has usually been delivered by nurses and dietitians, whereas PACCTS used trained call operatives (telecarers) supported by a specifically designed call center application, with a specialist nurse being deployed only for training, supervision, and alteration of medication. In one study in which automated calls were combined with nurse follow-up self-efficacy, depression and satisfaction were improved (19).

The demand for chronic disease management support is burgeoning, and demographic forces imply that this trend will continue into the foreseeable future. The demand for ongoing, convenient education and supported self-efficacy, the cornerstones of effective chronic disease management, is likely to be met only by novel systems of health care delivery that can be shown to be effective, affordable,

Table 3—*Proportion of patients achieving at least 1% absolute reduction in HbA_{1c}*

Baseline HbA_{1c} (%)	*n*	Percent with ≥1% reduction in HbA_{1c}				
		Usual care	PACCTS	Difference	(95% CI)	*P*
<7	176	2	1	−1	(−5 to 3)	0.61
7–9	308	16	29	13	(4–22)	0.01
>9	107	51	73	22	(2–41)	0.03
All	591			10	(4–16)	<0.001

and acceptable. The evidence from this study suggests that, among the population studied, PACCTS lead by trained telecarers and supported by diabetes nurses may be such a system. However, further evidence will be needed from studies in populations with different characteristics (e.g., rural communities and ethnic minorities) over a longer period of time and encompassing other aspects of diabetes care (e.g., smoking, lipids, and blood pressure) to determine whether PACCTS provides a transferable, sustainable, and cost-effective intervention.

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