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RESEARCH

Effectiveness of general practice based, practice nurse led telephone coaching on glycaemic control of type 2 diabetes: the Patient Engagement And Coaching for Health (PEACH) pragmatic cluster randomised controlled trial

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Abstract

Objective To evaluate the effectiveness of goal focused telephone coaching by practice nurses in improving glycaemic control in patients with type 2 diabetes in Australia.

Design Prospective, cluster randomised controlled trial, with general practices as the unit of randomisation.

Setting General practices in Victoria, Australia.

Participants 59 of 69 general practices that agreed to participate recruited sufficient patients and were randomised. Of 829 patients with type 2 diabetes (glycated haemoglobin (HbA_{1c}) >7.5% in the past 12 months) who were assessed for eligibility, 473 (236 from 30 intervention practices and 237 from 29 control practices) agreed to participate.

Intervention Practice nurses from intervention practices received two days of training in a telephone coaching programme, which aimed to deliver eight telephone and one face to face coaching episodes per patient.

Main outcome measures The primary end point was mean absolute change in HbA_{1c} between baseline and 18 months in the intervention group compared with the control group.

Results The intervention and control patients were similar at baseline. None of the practices dropped out over the study period; however, patient attrition rates were 5% in each group (11/236 and 11/237 in the intervention and control group, respectively). The median number of coaching sessions received by the 236 intervention patients was 3 (interquartile range 1-5), of which 25% (58/236) did not receive any coaching sessions. At 18 months' follow-up the effect on glycaemic control did not differ significantly (mean difference 0.02, 95% confidence interval −0.20 to 0.24, P=0.84) between the intervention and control groups, adjusted for HbA_{1c} measured at baseline and the clustering. Other biochemical and clinical outcomes were similar in both groups.

Conclusions A practice nurse led telephone coaching intervention implemented in the real world primary care setting produced comparable outcomes to usual primary care in Australia. The addition of a goal focused coaching role onto the ongoing generalist role of a practice nurse without prescribing rights was found to be ineffective.

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Telephone coaching intervention

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Introduction

Addressing the global epidemic of type 2 diabetes is a pressing problem, affecting developed and newly emerging economies.[1] The condition imposes a health and economic burden on people and communities, while increasing the costs of healthcare.[1] There is no doubt that improving disease control improves long term health outcomes in patients with type 2 diabetes, slowing development and progression of vascular complications and reducing use of healthcare resources.[2] Yet many studies identify a consistent failure to achieve targets for glucose and other cardiovascular risk factors in most patients.[3 4] Clinical care is integral to supporting patients to achieve such control. In the context of frequent comorbidity and where self management plays such an important role,[5] clinical care for diabetes needs to balance medication interventions with a focus on lifestyle change and psychosocial support. To achieve these, most evidence based guidelines focus on surrogate targets and stepwise medication treatment pathways.[6] Again, there is good evidence that clinical practice consistently fails to adhere to such guidelines or to achieve adequate control of risk factors.[7] The difference between such treatment recommendations and the treatment that actually occurs has been referred to as "the treatment gap."[8] Reasons for this gap include reluctance to initiate additional treatment or to titrate to therapeutic levels to achieve targets, and non-adherence or discontinuation of treatment.[9]

Evidence shows that telephone based support of self management or coaching interventions delivered by a range of health professionals and lay people is effective in reducing the treatment gap and improving glycaemic, blood pressure, lipid, and psychosocial outcomes in patients with type 2 diabetes.[10-21] Elements of telephone coaching interventions include goal setting, motivational interviewing technique, and support for patients' self management. However, evidence on the effectiveness of this type of intervention in a pragmatic real world setting is not available.[22] In Australia, the majority of management for type 2 diabetes occurs in general practice. To tackle the increasing burden of chronic diseases, an aging population, and clinician shortage, the Australian government has provided incentives for primary care practices to employ practice nurses—registered or enrolled nurses who are employed by, or whose services are otherwise retained by, a general practice.[23 24] The contribution of Australian practice nurses to patient care is evolving. In the past practice nurses predominantly dealt with vaccinations, cervical smears, and wound dressings, whereas their involvement in chronic disease care is increasing.

Our coaching intervention was adapted from a programme of telephone coaching developed and shown to be effective in the hospital setting using trained, task dedicated coaches for patients after an acute cardiac event.[25 26] We adapted this model because the lifestyle and medication treatments relevant to cardiovascular disease are comparable to those for diabetes. The programme had not been tested in primary care, or with practice nurses acting as coaches. Our treatment goals were adapted from the Steno-2 Study, which showed reduced end stage kidney failure, cardiovascular events, death from cardiovascular disease, and death from all causes with intensive treatment of type 2 diabetes.[27] The Steno-2 Study operated in a specialist hospital context and sought to discover whether comparable improvements could be achieved in general practice.

We tested the effectiveness of telephone coaching delivered by practice nurses in the real world of general practice for improving control of glycaemia and other cardiovascular disease risk factors over 18 months among patients with type 2 diabetes whose levels of glycaemia were above the treatment targets.[28] We chose this methodology and its mode of delivery because we wanted an approach that would be generalisable and sustainable and would utilise existing staff in the Australian healthcare system.

Methods

The Patient Engagement And Coaching for Health (PEACH) study was an 18 month stratified cluster randomised controlled trial of practice nurse led telephone coaching compared with usual general practice care among patients with poorly controlled type 2 diabetes. Details of the study protocol have been published elsewhere.[28] We used the CONSORT guidelines for the reporting of pragmatic and cluster randomised trials to report this study.[29 30]

Recruitment of general practices and patients

General practices and patients were recruited between October 2006 and January 2009. Details and costs of practice recruitment have been published.[31] In brief, the PEACH study was promoted to members of all Divisions of General Practice (geographical organisations of general practices) in the State of Victoria, Australia.[31 32] In 2007 there were around 1700 practices, 6000 general practitioners, and 1850 practice nurses in Victoria, with 60% of practices employing at least one practice nurse.[33 34] Practices that employed practice nurses were eligible to participate. The research team visited practices who expressed an interest, to explain the study in detail. Written consent was obtained from general practitioners and practice nurses who agreed to take part in the study.

Each participating general practice generated a list of all eligible patients from their local laboratories and the practice electronic database. Patients were eligible if they had a diagnosis of type 2 diabetes, their most recent glycated haemoglobin (HbA_{1c}) level within the past 12 months was above 7.5%, they were aged more than 18 years, they received healthcare from the participating practice, and they were contactable by telephone. We excluded patients if they had a complex debilitating coexisting medical condition (for example, severe mental illness or end stage cancer) or were unable to provide signed consent. Eligible patients were sent an invitation to join the study on practice letter headed paper signed by their general practitioners, together with an expression of interest form, a study brochure, a brief demographic survey, and a reply prepaid envelope to the study team. Patients were asked to return the expression of interest form and to complete the brief demographic survey even if they declined to take part in the study. The study team informed practice nurses of patients who had expressed an interest in participating. The study was explained by the practice nurse and written informed consent was obtained from each patient before baseline assessment.

Patients completed baseline assessment with their practice nurse during a face to face interview at the practice. This assessment comprised patients' knowledge of appropriate testing and goals for risk factors; smoking status; current exercise levels; dietary intake, using a validated food frequency questionnaire[35]; physical measures (height, weight, waist and hip circumferences); data from the patients' clinical files on treatment, diabetes related complications, clinical visits, and most recent pathology results; and self report data on diabetes self efficacy,[36] diabetes support,[37] quality of life,[38] and depression.[39] Patients then attended their local pathology service to have baseline tests of HbA_{1c}; total,

high density lipoprotein, low density lipoprotein cholesterols, and triglycerides; and renal function. All the pathology laboratories used HbA_{1c} assay methods aligned with the standard set by the Diabetes Control and Complications Trial[40] and undertook quality assurance for HbA_{1c} assays.

Data collected at 18 months after randomisation used the same questionnaires as for baseline assessment. During a face to face appointment at the practice, the practice nurse recorded data from the patients' clinical files and performed physical measures. Patients were instructed to have follow-up tests as for baseline at their local laboratories. Every effort was made to minimise missing data for the primary outcome. When the HbA_{1c} test was not completed by the participant within 15 to 21 months after coaching began, we used the closest HbA_{1c} result available from the patient medical records or pathology provider. The 18 month self reported questionnaires were mailed to patients. The remaining data were collected by independent research assistants blinded to the study allocation of the patient, using a computer assisted telephone interview method. Follow-up data collection was completed in November 2011.

Practices were reimbursed for their nurses' time spent on the PEACH study, including for patient recruitment, data collection, and delivery of the intervention. We reimbursed patients who completed 18 months follow-up for their travel. These strategies were designed to ensure practice nurses had dedicated time to undertake the study requirements and to maximise study retention.

Intervention

The intervention involved practice nurses being taught to deliver structured telephone coaching to prime patients with the aim of self managing their diabetes. The practice nurses were trained to engage their patients through a series of scheduled and structured telephone sessions dealing with lifestyle issues, medication adherence and dosing, self monitoring of their disease, and how to take greater initiative in the therapeutic alliance with the treating doctor, facilitating appropriate intensification of medications to achieve treatment goals. We adapted the coaching programme used for patients after an acute cardiac event[25 26] to enhance self management of type 2 diabetes[28] based on consultation with patients with type 2 diabetes.[41] The supplementary file describes the empowerment based[42] pragmatic educational telephone coaching intervention used in the PEACH study.

Each practice nurse from practices assigned to the intervention group completed a two day training programme in telephone coaching. The training covered evidence for and methods to achieve intensification of drug treatment and lifestyle risk factor modification, focusing particularly on achieving an HbA_{1c} level <6.5%. This revised target was consistent with the Steno-2 Study.[27] The PEACH study treatment algorithm also used targets of total cholesterol <4.0 mmol/L, low density lipoprotein cholesterol <2.0 mmol/L, and blood pressure <130/80 mm Hg (without microalbuminuria) or <125/75 mm Hg (with microalbuminuria). Medication goals were for patients with microalbuminuria to receive angiotensin converting enzyme inhibitors or angiotensin II receptor blockers unless contraindicated, and all patients to be receiving an antiplatelet agent unless contraindicated.

The practice nurses were trained to deliver five telephone coaching sessions at intervals of six weeks in the first six months, telephone coaching sessions at months 8 and 10, a face to face coaching session at 12 months, and a final telephone coaching session at 15 months. The intervals allowed sufficient time for patients to implement action plans, including review by general practitioners after the coaching session; for general practitioners to intensify and prescribe medications; for changes in the medications to take effect; and to measure biochemical outcomes. Data from each coaching session were to be recorded using a standardised form, then entered into secure web based software to generate reports summarising what was discussed. The report included a one page chart of the patients' risk factors, risk factor targets, and whether the targets were currently met. Each report of a coaching session was sent to the patient, with a copy to the general practitioner.

The continuous improvement framework was a key feature of design for the coaching programme, with each coaching session the basis for the subsequent one. At each coaching session, practice nurses were meant to discuss progress, empower patients to visit their general practitioners to obtain further measurement of their risk factors, educate patients about risk factor targets, and negotiate a plan of action to reach target levels by means of lifestyle modifications and intensification of treatment with medications. Medication intensification, including dose adjustment and changes in type of medications, was an integral component of the coaching programme. Patients were asked to discuss their plan of action and to seek intensification of their treatment with their general practitioners, as practice nurses did not have prescribing rights to adjust medications. As coaching was tailored to suit patients' risk factors, the length of each session was not prescribed and patients were also able to contact their practice nurses between coaching sessions. Patients also received usual care from their general practitioners throughout the duration of the trial.

The research team provided support to practice nurses during the intervention period, including one visit to the practice, monthly telephone calls, and a group meeting, where all intervention practice nurses could share their experience and learning from conducting telephone coaching. As part of process evaluation, we recorded and analysed a sample of telephone coaching sessions.[43]

Control

Usual general practice care was provided between baseline and 18 months' follow-up, which may have included referral to diabetes educators, dietitians, and diabetes specialists as part of the standard diabetes care provided by that practice.

Outcomes

The primary outcome was HbA_{1c} level at 18 months post-baseline. Secondary outcomes were lipid profile (total, high density lipoprotein cholesterol, low density lipoprotein cholesterol, and triglycerides), renal function (estimated glomerular filtration rate[44] and urinary albumin to creatinine ratio), blood pressure, body mass index, waist circumference, smoking status, quality of life,[38] diabetes self efficacy,[36] diabetes support,[37] depression status,[39] and intensification of treatment (diabetes, antihypertensive, statin, and aspirin). Other secondary outcomes, including health services utilisation, physical activity, nutrition, and economic evaluation will be reported separately. As per protocol,[28] follow-up was planned for 12 and 18 months after randomisation. However, the response rate at 12 and 18 months of the first 282 participants was around 50%, lower than anticipated. Feedback from the patients and practice nurses indicated that more time was required to organise and complete data collection in this group of patients. To increase the response rates and minimise missing data we stopped the data collection at 12 months and only analysed data collected at 18 months.

Sample size

The original sample size was revised because fewer patients meeting the eligibility criteria were available for recruitment within practices than had been anticipated.[28 31] For 80% power at 5% significance level (two sided test), 464 eligible patients (average of eight per practice) from 58 general practices were required to detect an absolute 0.5% reduction in mean HbA_{1c} between the intervention and control groups at 18 months. Sample size was based on a two sample *t* test, a standard deviation of 1.44.[45] This value was then inflated by 1.3 to allow for the correlation of outcomes of patients within the same practice, assuming an intracluster correlation of 0.05[45] and variation in sample cluster size, and a further 20% for attrition over 18 months.

Randomisation

The unit of randomisation was the general practice. Randomisation was stratified by the organisational and financial arrangements of the practice (fee for service private practice or state government funded community health centre) and participation in the Australian Primary Care Collaboratives (APCC) programme.[46] To ensure that the number of practices was fairly balanced between the study groups, the allocation sequence was generated using random permuted block sizes of two and four with an allocation ratio of 1:1 within each of the four strata. A statistician blinded to the identity of the practices and not involved in the recruitment of practices or patients or in data collection, computer generated the randomisation schedule. Patient baseline assessments in the practice were completed before random practice allocation was revealed. Blinding of practices and patients was not possible owing to the nature of the intervention.

Statistical analysis

We used Stata version 12 for data analyses. Using descriptive statistics we compared characteristics of general practices, general practitioners, practice nurses, and patients between the two study groups. We estimated the intracluster correlations for key baseline variables using one way analysis of variance. Participants were analysed in the study group to which they were assigned. Continuous outcomes followed a broadly normal distribution, except for estimated glomerular filtration rate and urinary albumin to creatinine ratio, which were dichotomised. We compared the two study groups using linear regression adjusted for baseline measure of the outcome and stratification (practice type and APCC programme) for continuous outcomes and logistic regression adjusted for stratification for binary outcomes. To allow for the correlation of outcomes within practices we used generalised estimating equations with information sandwich (robust) standard errors provided the estimated intracluster correlation for the fitted model was non-negative. Estimates of the intervention effect were reported as the difference in the mean change in outcome before and after intervention for continuous outcomes and odds ratio for binary outcomes, with respective 95% confidence intervals and P values. We also analysed the urinary albumin to creatinine ratio on the $\log_{10}$ scale and back transformed the estimate and reported it as a geometric mean ratio with a 95% confidence interval. Missing data were not computed because the overall proportion of missing responses for the HbA_{1c} at 18 months was small (7%, 33/473) and the proportion was similar in the two study groups; 6.4% (15/236) in the intervention group and 7.6% (18/237) in the control group. We carried out a sensitivity analysis to explore the effect of including HbA_{1c} measures that were not completed within a few months of the 18 month follow-up after coaching started. Intervention participants were divided into three groups based on the number of coaching sessions received: 0, 1-4 (half of the nominated eight sessions), or 5 or more (more than half the nominated sessions). Exploratory analysis investigated whether there was an association between the number of telephone coaching sessions received by intervention patients and demographic characteristics, biochemical outcomes, and clinical outcomes using linear regression, adjusting for baseline outcome measure and clustering. To examine the association between two categorical variables we used Pearson's χ^2 statistic, adjusted for clustering using the survey command in Stata.

Results

Of the 829 eligible patients sent a study invitation from 69 practices that had consented to participate, 473 patients from 59 participating general practices (average of eight per practice) consented to participate in the study (figure⇓). Ten practices with 61 patients (mean cluster size of six patients per practice) failed to recruit sufficient patients, and a further 267 patients from the 57 participating practices dropped out before randomisation.

Baseline personal characteristics of the participants (n=473) were similar to patients who were invited to participate in the study but declined and returned a demographic survey (n=267) (data not shown). The duration of diabetes, management, and complications did not differ significantly between participants and non-participants. The proportion of participants not receiving diabetes drugs, oral hypoglycaemic agents, and insulin (with or without oral agents) was 4% (n=20), 69% (n=311), and 27% (n=121), respectively. The proportion was similar among non-participants: 7% (n=18), 67% (n=165), and 25% (n=62), respectively (P=0.27).

The baseline characteristics of the practices and participants were balanced between the study groups (table 1⇓). All 59 practices randomised continued to participate during the trial period. The mean number of general practitioners taking part from each practice was 2.8 (range 1-5) in the intervention group and 3.2 (range 1-8) in the control group. There were 34 practice nurses in the intervention group and 36 in the control group, and all were women. Most of the practices (49/59, 83%) had one nurse involved in the study, nine had two nurses, and one control practice had three nurses. Seven nurses in the intervention group and four in the control group had received training in diabetes. Four nurses in the intervention group and six in the control group worked a minimum of 35 hours weekly.

None of the practices dropped out over the study period and the number of participants lost to follow-up and their reasons were similar in both study groups (figure).3Most participants (71%, 312/440) had an HbA_{1c} test recorded within 15 to 21 months from the first coaching date for the practice. Ten per cent (45/440) had less than 15 months of follow-up from the start of the coaching intervention when HbA_{1c} was measured, and 19% (83/440) had HbA_{1c} testing after 21 months. The distribution in the timing of the HbA_{1c} test did not differ between the study groups (P=0.82, Wilcoxon rank sum test) and there was no association between the HbA_{1c} result at follow-up and timing of the test (Spearman's rank correlation coefficient 0.0002, 95% confidence interval −0.093 to 0.094, based on Fisher's transformation). Table 2⇓ shows the number of tests available for other biochemical measures by study group, which were fewer than for HbA_{1c}. At follow-up, 89% (419/473) of

participants had clinical measures and 82% (388/473) returned the self reported survey for the psychosocial measures (figure).

Biochemical, clinical, and psychosocial outcomes

Baseline measures of the biochemical, clinical, and psychosocial outcomes were balanced between the two study groups, except for high density lipoprotein cholesterol (table 2). The mean HbA_{1c} level did not differ between the intervention and control groups at 18 months' follow-up (table 2). A sensitivity analysis of HbA_{1c} showed that the difference in mean HbA_{1c} between the two study groups was relatively unchanged but with wider confidence intervals after exclusion of HbA_{1c} tests not measured between 15 and 21 months after intervention (results not shown). There was no statistical difference observed on other biochemical measures at 18 months between the study groups. Evidence suggested that a higher proportion reached a healthy weight (body mass index <25 kg/m^2) in the intervention group compared with the control group, but there was no evidence that overall weight changed more favourably in the intervention group. There were trends for improvements in systolic blood pressure and diabetes social support scale in favour of the intervention group and in high density lipoprotein cholesterol level in favour of the control group. None of the other clinical or psychosocial outcomes differed by study group (table 2).

Telephone coaching number and content analysis

Overall, 730 coaching sessions were recorded from 178 of 236 (75%) intervention patients. The median number of total coaching sessions received by intervention participants was 3 (interquartile range 1-5). Of those who received at least one coaching session, the median was 4 (2-6), and 6% (10/178) of patients received more than eight coaching sessions. The time spent by practice nurses in delivering coaching and tailoring action plans ranged between 10 and 120 minutes per session, with a median of 30 minutes.

Distribution of age and sex was similar for participants who received none, 1-4, or ≥5 coaching sessions (results not shown). A higher proportion of healthcare card holders (concession cards for low income or welfare recipients, entitling holders to reduced healthcare and prescription costs) received 1-4 coaching sessions (73/104, 70%) compared with patients who did not receive coaching (28/56, 50%) or ≥5 sessions (37/65, 57%, P=0.007). Mean HbA_{1c} at baseline (8.15 (SD 1.24)) was higher in the group that received at least one coaching session compared with the group that received no coaching sessions (7.44 (SD 1.0)) and the difference in means was 0.69 (95% confidence interval 0.41 to 0.97, P<0.001). When the outcomes were analysed in relation to the number of telephone coaching sessions actually delivered (table 3⇓), the only outcome measures that showed improvement that trended in line with the intensity of the intervention were total cholesterol and diastolic blood pressure. Content analysis of the written coaching records found that out of 730 coaching sessions, only 70% (514/730) documented the current medications used by the patients. Only 18% (130/730) of coaching telephone calls recorded advice about intensification of hypoglycaemic agents.

As part of process evaluation we analysed a sample of recorded coaching sessions. We identified two predominant styles of coaching—namely, "treat to target" and "personalised care," corresponding to directive and non-directive approaches.[47] Treat to target coaching concentrated solely on the protocol to improve glycaemia and other risk factors and had a more directive relationship with patients, whereas personalised care coaching tended to focus on psychosocial issues and had a more supportive relationship with patients.

Glycaemic treatment

At baseline, 97% (228/234) and 94% (217/232) of intervention and control participants were receiving hypoglycaemic agents. Of the 234 intervention patients, 74% were taking oral medications only, 7% insulin only, and 16% both. The percentages taking the oral medications and insulin were similar for the 232 control participants (70%, 5%, and 19%, respectively). At 18 months follow-up of the 220 intervention patients, 2% (n=5) were not taking any hypoglycaemic agents, 58% (n=127) were taking oral medications only, 9% (n=19) were taking insulin only, and 31% (n=69) were taking both compared with the 222 control patients: 4% (n=8), 61% (n=136), 9% (n=19), and 27% (n=59) (P=0.55). A higher proportion of patients in the intervention (40%) and control (35%) groups were taking insulin at 18 months follow-up compared with baseline (23% and 24%, respectively), with a slightly greater increase observed in the intervention group post-intervention (difference in proportions 4.9%, 95% confidence interval −4.4% to 14.2%, P=0.30).

Discussion

This pragmatic cluster randomised controlled trial in primary care patients with poorly controlled type 2 diabetes found no evidence that telephone coaching by existing generalist practice nurses without prescribing rights was more effective than usual primary care, either in reaching treatment targets or achieving more intensive treatment. Our study adapted an evidence based intervention without right to prescribe, developed in a hospital environment for improvement of cardiovascular risk factors, to the management of type 2 diabetes in general practice[25 26] and embedded this within real world routine care using existing resources.[28] A key focus of our intervention was on intensification of drug treatment, with the practice nurses advising patients to visit their general practitioners and to discuss intensification of their drugs to achieve treatment targets.[25] We found that our practice nurse led telephone coaching intervention had no impact on glycated haemoglobin (HbA_{1c}), intensification of insulin therapy, or other measures at 18 months. Non-significant results favouring the intervention were found in systolic blood pressure and diabetes social support, and an unfavourable outcome for high density lipoprotein cholesterol. The only benefit observed was that a higher proportion of patients attained a healthy weight, although there was no impact on overall weight.

Strengths and limitations of this study

The key strength of this study was that it was a pragmatic trial, rigorously designed to be conducted in a real world general practice setting using existing resources. The cluster randomised design minimised the risk of contamination of the control group. Randomisation of practices occurred after participants were recruited and baseline measures were collected, minimising selection bias. Furthermore, characteristics of participants and non-participants were similar, meaning greater generalisability to a population of patients with poorly controlled diabetes in Australia.

An important limitation of our study is that the intensity and fidelity of the intervention was compromised so that the intended dose of the intervention was not delivered to a high proportion of patients and in many cases the key element of a focus on

medication intensification through negotiation with the treating general practitioners was not achieved. This may, however, be best seen as an outcome rather than a limitation, given the pragmatic nature of the study. Another limitation is that baseline and follow-up data on medications were collected through general practice medical records, the quality of which may vary between practices. While intake of medications, including prescribed, over the counter, and complementary medicines, was confirmed by practice nurses with patients during data collection, it was beyond the scope of our study to measure medication adherence.

Comparison with other studies

Our study finding is consistent with recent trials which showed that a nurse led telephone coaching intervention was not effective in reducing HbA_{1c}.[48 49] However, a US based telephone outreach led by trained study nurses under close supervision of primary care physician champions showed a significant reduction in patient lipid profiles compared to usual care.[10] In the Birmingham Own Health study, nurse case managers who undertook telephone coaching achieved significant improvement in HbA_{1c}, blood pressure, and body mass index, particularly among participants with adverse baseline levels.[12] In the US DiaTel study, telephone calls and telehome monitoring by nurse practitioners showed larger reductions in HbA_{1c} compared with telephone calls by study diabetes nurse educators.[17] Similarly, nurse led telephone coaching with or without the addition of a web based system improved glycaemic control.[14] Another telephone coaching intervention in disadvantaged communities in the United States was found to be no more effective than provision of a patient education booklet.[50] These interventions were performed by highly skilled and trained nurses, including nurse practitioners, diabetes educators, and study nurses specifically employed and dedicated to implementation of the coaching. Most of the nurses in these latter studies had authority to prescribe and were not part of the primary care organisations. Indeed, the ability for nurses to independently adjust drugs was a key feature in the effectiveness of these diabetes interventions.[51] The findings are not necessarily generalisable to practice nurses in mainstream practice such as in our study, who were required to take on the additional role as coach within their ongoing generalist role. Our study suggests that adding a goal focused coaching role onto the ongoing generalist role of a practice nurse without the right to prescribe was ineffective.

Explanation of our findings and implications for clinicians and policy makers

The lack of effect of the intervention may in part be explained by the lower intensity of our coaching than originally set out in our protocol. Clearly the intensity of the intervention was a problem in our study as patients who received coaching only received a median of three telephone calls despite support for the practice nurses from the research team. In fact, a quarter of patients in the intervention group did not receive any telephone coaching. A more intensive telephone counselling intervention with more frequent calls, longer interaction, or longer duration of follow-up may lead to better outcomes.[10 52 53] However, in other reported studies in the primary care setting, the intensity of nurse led telephone coaching intervention varied and these studies produced mixed outcomes.[10 14 48-50]

Intervention fidelity also seems to have been compromised. Content analysis of calls showed many consultations did not explicitly address medication intensification, an important part of the coaching programme. Our process evaluation identified varying styles of coaching, with some telephone calls employing a non-directive style with the intended structured, goal focused approach, with a particular focus on medication intensification.[47] There may be several reasons for the low intensity and fidelity of our intervention. The duration of practice nurses' training in the coaching technique may also be a factor. In our study, practice nurses completed an initial 15 hours of telephone coaching training over two days, and further support and training was provided to individual nurses after assessment of their progress. The coaching programme from which we adapted our intervention involved two weeks of training,[25] although other general practice based coaching interventions involved similar training duration to our study. In relation to the scheduled intervals of coaching calls, these were pragmatic, allowing sufficient time for patients to be reviewed by their general practitioners and for changes to their medications to be implemented. These intervals were comparable to those reported in other studies.[48 49]

The lack of focus on medications by the practice nurses may be explained by the nurses not being comfortable or confident with this interference in the existing therapeutic relationship between the patient and doctor. While other studies of telephone coaching by non-prescribing health professionals have been effective, none of these have used existing general practice based nurses to undertake coaching.[51] A recent trial reported similar findings, that drug intensification in type 2 diabetes by non-prescriber nurses was not effective.[48]

Our study was deliberately designed as a pragmatic trial of the effectiveness of embedding a structured, goal focused coaching role within the ongoing generalist role of existing practice nurses. The non-prescribing nature of practice nurses and the interprofessional relationships in the Australian general practice setting are an important element of that context.[54] Despite the rapid growth of the Australian practice nurse workforce in the past decade, no national training standards exist.[55] Over 60% of practice nurses in Australia have a hospital nursing certificate as their highest qualification and face funding and regulatory constraints to expand their role in chronic disease management in primary care, in particular in the area of prescribing.[56] The ongoing generalist role of the practice nurses in our study meant that they had many competing demands in the clinic, despite reimbursement for their participation in the study. They were "time poor" and many even lacked physical space in which to consult with patients. Furthermore, most practice nurses worked part time. Each intervention practice nurse on average managed seven patients and this workload was an additional demand to their current role. They were also dealing with patients who had ongoing competing priorities beyond the management of their diabetes, including multiple comorbidities within their social context.[43] The way the intervention was implemented in practice seems to have been strongly shaped by this context in which the trial was set.

Conclusions

This pragmatic cluster randomised controlled trial of primary care patients with poorly controlled type 2 diabetes found no evidence that telephone coaching by existing generalist practice nurses without prescribing rights was effective compared with usual primary care, either in reaching treatment targets or achieving more intensive treatment. Further research should be undertaken to explore the effectiveness of diabetes management by nurses with a varying mix of generalist and specialist responsibilities, as well as nurses with and without limited prescribing rights, particularly in relation to working with general practitioners. While this study investigated another way to optimise patient outcomes using the existing system and

resources in Australian general practice, a change in this organisational system of care delivery may be required to improve outcomes for people with type 2 diabetes.

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Data sharing: No additional data available.

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What is already known on this topic

Telephone coaching by highly trained nurses can improve glycaemic, blood pressure, and lipid outcomes in type 2 diabetes

No studies have evaluated the effectiveness of practice nurse led telephone coaching intervention in a pragmatic real world general practice

What this study adds

Practice nurse led telephone coaching in a real world general practice was not effective in improving glycated haemoglobin or other biochemical and clinical outcomes

Further research is needed on the balance of generalist and specialist nurses in the workforce, and nurses with and without limited prescribing rights

Optimising patient outcomes in the Australian primary care setting may require a change in the organisational system of care delivery in type 2 diabetes

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Tables

Table 1| Baseline characteristics of practices, general practitioners, and patients with type 2 diabetes by study group. Values are numbers (column percentages) unless stated otherwise

Characteristics	Total	Intervention group	Control group
Practices, No (row percentage)	59	30 (51)	29 (49)
Type of practice:			
Private practice	52 (88)	26 (87)	26 (90)
Corporate practice	3 (5)	2 (7)	1 (3)
Community health centre	4 (7)	2 (7)	2 (7)
Location of practice:			
Urban	25 (42)	13 (43)	12 (41)
Rural	34 (58)	17 (57)	17 (59)
Staff per practice participating in study			
General practitioners:			
1 or 2	22 (37)	12 (40)	10 (35)
3 or 4	28 (48)	13 (43)	15 (52)
5-8	9 (15)	5 (17)	4 (14)
Practice nurses:			
1	49 (83)	26 (87)	23 (79)
2 or 3	10 (17)	4 (13)	6 (21)
General practitioners*, No (row percentage):	176	84 (48)	92 (52)
Mean (SD) age (years)†	48.2 (8.6)	47.6 (8.3)	48.6 (8.9)
Women	55 (31)	25 (30)	30 (33)
Mean (SD) years of practice in Australia‡	19.8 (9.9)	19.2 (9.8)	20.3 (10.0)
Practice nurses, No (row percentage):	70	34 (49)	36 (51)
Women	70 (100)	34 (100)	36 (100)
Patients§, No (row percentage):	473	236 (50)	237 (50)
Mean (SD) age at assessment (years)	62.8 (10.5)	63.6 (10.4)	61.9 (10.5)
Women	204 (43)	109 (46)	95 (40)
Highest level of education:			
Primary or less	100 (23)	53 (24)	47 (21)
Secondary or trade	269 (61)	139 (63)	130 (59)
Tertiary	73 (17)	29 (13)	44 (20)
Unemployed¶	35 (8)	15 (7)	20 (9)
Healthcare card holder	277 (62)	138 (61)	139 (62)
Median (interquartile range) duration of diabetes (years)	10 (5-14)	10 (5-15)	9 (5-13)
Diabetes complications:			
Microvascular	152 (33)	78 (34)	74 (33)
Macrovascular	88 (19)	37 (16)	51 (23)

*One general practitioner worked at two practices, both practices were allocated to control group; patients of this practitioner were recruited from only one practice.

†123 of 176 (70%) general practitioners provided their age; 56 in intervention group, 67 in control group.

‡115 of 176 (65%) general practitioners provided years they had practised in Australia; 48 in intervention group, 67 in control group.

§Discrepancies in totals owing to missing responses.

¶Unemployed compared with participants who were employed, had home duties, were retired, or other.

Table 2| Biochemical, clinical, and psychosocial outcomes at baseline and 18 months by study group. Mean (standard deviations) are used for continuous outcomes and counts (proportions) for binary outcomes

	Intervention group		Control group				
Outcomes	**No**	**Mean (SD)/No (%)**	**No**	**Mean (SD)/No (%)**	**ICC***	**Intervention effect (95% CI)**	**P value**
Biochemical							
Serum HbA_{1c} (%):							
Baseline	235	7.98 (1.22)	236	8.13 (1.34)	0.098		
Follow-up	221	7.85 (1.24)	219	7.91 (1.42)		0.02†§ (−0.20 to 0.24)	0.84
Total cholesterol (mmol/L):							
Baseline	235	4.51 (1.04)	230	4.50 (1.20)	0.062		
Follow-up	200	4.20 (0.95)	200	4.28 (1.05)		−0.08† (−0.27 to 0.11)	0.41
Triglycerides (mmol/L):							
Baseline	226	1.96 (1.61)	225	2.07 (1.56)	0.002		
Follow-up	194	1.83 (1.39)	197	1.92 (1.19)		−0.05†§ (−0.23 to 0.13)	0.61
Low density lipoprotein cholesterol (mmol/L):							
Baseline	218	2.40 (0.89)	208	2.40 (0.85)	0.058		
Follow-up	183	2.22 (0.87)	183	2.26 (0.84)		0.02† (−0.15 to 0.19)	0.86
High density lipoprotein cholesterol (mmol/L):							
Baseline	222	1.22 (0.33)	220	1.13 (0.31)	0.051		
Follow-up	187	1.21 (0.34)	190	1.18 (0.31)		−0.05† (−0.09 to 0)	0.05
Normal ACR¶:							
Baseline	214	153 (72)	202	150 (74)	0.008		
Follow-up	175	125 (71)	188	132 (70)		1.05‡ (0.62 to 1.75)	0.87
Normal eGFR rate**:							
Baseline	224	184 (82)	203	169 (83)	—		
Follow-up	196	158 (81)	201	165 (82)		0.92‡§ (0.55 to 1.53)	0.76
Clinical							
Current smoker:							
Baseline	235	30 (13)	236	27 (11)	0.043		
Follow-up	187	25 (13)	192	23 (12)		1.14‡§ (0.55 to 2.36)	0.72
Healthy weight (BMI <25)††:							
Baseline	233	22 (9)	233	18 (14)	0.024		
Follow-up	189	26 (14)	191	14 (7)		2.19‡§ (1.10 to 4.38)	0.03
Weight (kg):							
Baseline	234	91.0 (19.5)	234	92.2 (20.5)	0.059		
Follow-up	189	90.7 (21.0)	191	92.7 (21.0)		0.12†§ (−1.53 to 1.77)	0.89
Waist circumference (cm)							
Men:							
Baseline	121	109.7 (15.1)	136	112.6 (14.8)	0.063		
Follow-up	94	110.0 (15.9)	110	111.7 (15.0)		0.90†§ (−1.40 to 3.19)	0.44
Women:							
Baseline	105	106.1 (15.1)	89	107.2 (15.5)	0.062		

Table 2 (continued)

Outcomes	Intervention group		Control group		ICC*	Intervention effect (95% CI)	P value
	No	Mean (SD)/No (%)	No	Mean (SD)/No (%)			
Follow-up	81	105.3 (13.9)	69	108.4 (15.5)		−1.52†§ (−4.08 to 1.04)	0.24
Blood pressure (mm Hg)							
Systolic:							
Baseline	234	139 (18)	234	138 (18)	0.096		
Follow-up	189	133 (14)	186	136 (16)		−3.17† (−6.55 to 0.22)	0.07
Diastolic:							
Baseline	233	79 (10)	234	79 (11)	0.088		
Follow-up	188	76 (9)	186	77 (11)		0.13† (−2.23 to 2.49)	0.92
Psychosocial							
Diabetes self efficacy[36]:							
Baseline	202	78.57 (12.29)	208	77.04 (12.98)	—		
Follow-up	175	81.23 (10.96)	194	79.94 (11.46)		−0.06†§ (−2.22 to 2.10)	0.96
Diabetes support[37]:							
Baseline	229	4.31 (0.46)	231	4.28 (0.48)	0.035		
Follow-up	184	4.29 (0.48)	197	4.22 (0.42)		0.09† (−0.01 to 0.18)	0.08
Quality of life[38]:							
Baseline	223	0.78 (0.18)	231	0.78 (0.17)	—		
Follow-up	185	0.79 (0.17)	197	0.77 (0.18)		0.02† (−0.01 to 0.05)	0.16
Major depressive syndrome (PHQ-9)[39]:							
Baseline	216	11 (5)	220	11 (5)	0.013		
Follow-up	186	15 (8)	195	14 (7)		1.09‡ (0.49 to 2.46)	0.83

eGFR=estimated glomerular filtration rate; ACR=urinary albumin to creatinine ratio; BMI=body mass index; PHQ-9=patient health questionnaire-9.

*Intracluster correlations (ICCs) estimated for baseline outcome using one way analysis of variance; ICC values not shown were truncated at zero.

†Intervention effect is the adjusted difference in mean change in outcome before and after intervention between study groups with 95% confidence intervals and P values calculated using marginal linear regression adjusted for baseline outcome measure, practice type, and Australian Primary Care Collaboratives (APCC) programme using generalised estimating equations with robust standard errors to adjust for clustering.

‡Intervention effect is the adjusted odds ratio with 95% confidence intervals and P values calculated using marginal logistic regression adjusted for practice type and APCC programme using generalised estimating equations with robust standard errors to adjust for clustering.

§Analysis does not adjust for clustering because estimated ICC for fitted model was negative.

¶≤2.5 mg/mmol for men and ≤3.5 mg/mmol for women; geometric mean for ACR for intervention and control groups was 1.70 and 1.81 at baseline and 1.83 and 1.88 at follow-up, respectively. Adjusted geometric mean ratio for ACR at follow-up was 1.03 (95% CI 0.82 to 1.28), P=0.82.

**≤60 mL/min per 1.73 m^2; eGFR calculated using CKD-EPI equation.[44]

††One woman in intervention group changed from being obese at baseline to being underweight at last follow-up. She died of cancer 2.5 years after first assessed at baseline; results for body mass index, weight, and waist measures remained relatively unchanged when the woman who was terminally ill was excluded from analysis (results not shown).

Table 3| Association between number of coaching sessions and biochemical, clinical, and psychosocial measures at 18 months. Means (SD) presented unless stated otherwise

No of coaching sessions by measures	Baseline		18 months		Difference in mean change (95% CI)*	P value
	No	Mean (SD)	No	Mean (SD)		
Biochemical						
Serum HbA_{1c} (%):						
0	57	7.44 (1.00)	50	7.53 (1.04)	Reference	0.75
1-4	108	8.29 (1.42)	101	8.06 (1.42)	0.04 (–0.25 to 0.33)	
≥5	70	7.93 (0.84)	70	7.78 (1.05)	–0.05 (–0.43 to 0.32)	
Total cholesterol (mmol/L):						
0	58	4.48 (0.92)	40	4.33 (0.84)	Reference	0.05
1-4	107	4.63 (1.05)	92	4.33 (0.96)	0.04 (–0.37 to 0.45)	
≥5	70	4.36 (1.10)	68	3.95 (0.95)	–0.28 (–0.64 to 0.09)	
Triglycerides (mmol/L):						
0	56	1.74 (1.36)	37	1.55 (0.78)	Reference	0.43
1-4	101	1.91 (1.07)	90	1.88 (0.95)	0.16 (–0.10 to 0.41)	
≥5	69	2.19 (2.30)	67	1.93 (2.02)	0.05 (–0.22 to 0.31)	
Low density lipoprotein cholesterol (mmol/L):						
0	51	2.54 (0.72)	38	2.37 (0.72)	Reference	0.23
1-4	102	2.47 (0.93)	82	2.36 (0.91)	0.01 (–0.34 to 0.35)	
≥5	65	2.16 (0.92)	63	1.94 (0.85)	–0.21 (–0.56 to 0.15)	
High density lipoprotein cholesterol (mmol/L):						
0	53	1.26 (0.35)	38	1.30 (0.37)	Reference	0.54
1-4	103	1.18 (0.32)	83	1.15 (0.28)	–0.03 (–0.14 to 0.08)	
≥5	66	1.24 (0.32)	66	1.23 (0.38)	–0.06 (–0.17 to 0.06)	
Clinical						
Weight (kg):						
0	58	90.22 (18.58)	36	88.02 (20.94)	Reference	0.46
1-4	107	90.00 (18.29)	86	89.96 (18.40)	1.44 (–1.66 to 4.54)	
≥5	69	93.08 (21.93)	67	93.20 (24.05)	2.20 (–1.32 to 5.72)	
Waist circumference (cm):						
0	57	106.23 (15.90)	32	105.02 (15.06)	Reference	0.83
1-4	102	107.99 (13.79)	77	107.62 (13.31)	–0.68 (–2.88 to 1.51)	
≥5	67	109.51 (16.54)	66	109.50 (17.12)	–0.41 (–3.23 to 2.40)	
Blood pressure (mm Hg)						
Systolic:						
0	58	140 (18)	35	136 (15)	Reference	0.14
1-4	106	138 (19)	87	131 (13)	–3.96 (–8.01 to 0.08)	
≥5	70	139 (18)	67	134 (14)	-2.05 (-6.77 to 2.67)	
Diastolic:						
0	58	79 (10)	35	80 (10)	Reference	0.003
1-4	105	79 (10)	86	75 (9)	–4.67 (–7.36 to –1.97)	
≥5	70	78 (10)	67	76 (9)	–2.51 (–5.15 to 0.14)	
Psychosocial						
Diabetes self efficacy[36]:						

Table 3 (continued)

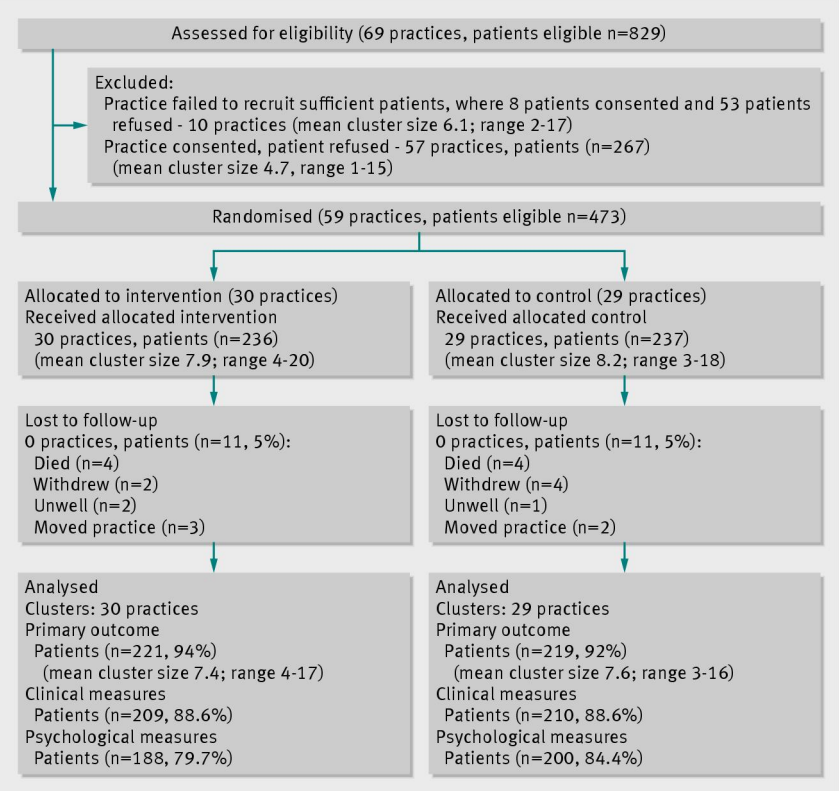
No of coaching sessions by measures	Baseline		18 months		Difference in mean change (95% CI)*	P value
	No	Mean (SD)	No	Mean (SD)		
0	52	78.90 (11.27)	38	80.34 (10.19)	Reference	0.87
1-4	95	79.24 (13.90)	75	81.69 (11.78)	0.87 (–2.40 to 4.14)	
≥5	55	77.11 (10.14)	62	81.23 (10.52)	0.29 (–3.69 to 4.27)	
Diabetes support[37]:						
0	56	4.37 (0.53)	40	4.24 (0.49)	Reference	0.44
1-4	106	4.26 (0.46)	81	4.28 (0.45)	0.07 (–0.14 to 0.29)	
≥5	67	4.33 (0.42)	63	4.35 (0.51)	0.13 (–0.08 to 0.34)	
Quality of life[38]:						
0	55	0.78 (0.19)	40	0.78 (0.19)	Reference	0.64
1-4	102	0.78 (0.18)	81	0.78 (0.19)	0.01 (–0.03 to 0.06)	
≥5	66	0.79 (0.16)	64	0.81 (0.13)	0.03 (–0.28 to 0.08)	
No (%) with major depressive syndrome (PHQ-9)[39]:						
0	52	1 (2)	40	4 (10)	Reference†	0.91
1-4	98	9 (9)	82	7 (9)	0.67 (0.07 to 6.46)	
≥5	66	1 (2)	64	4 (6)	0.91 (0.17 to 4.71)	

PHQ-9=patient health questionnaire-9.

*Unless otherwise indicated, difference in mean change in outcome before and after intervention between each session category and reference group (no coaching sessions) with 95% confidence intervals and P value calculated using marginal linear regression adjusted for baseline outcome measure using generalised estimating equations with robust standard errors to adjust for clustering effect.

†Odds ratio for major depressive syndrome for each session category and the reference group (no coaching sessions) with 95% confidence intervals and P value calculated using marginal logistic regression adjusted for baseline outcome measure using generalised estimating equations with robust standard errors to adjust for clustering effect.

Figure



Flow of practices and patients through study