A cluster randomised controlled trial of the effectiveness and cost-effectiveness of Intermediate Care Clinics for Diabetes (ICCD)

Executive Summary

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Executive Summary

Background

In the UK, community based intermediate care clinics for diabetes (ICCD) are an increasingly popular method of supporting primary care management of type 2 diabetes (T2DM). This approach has the potential to improve control of diabetes, enhance the patient experience, and reduce hospital outpatient attendance not only among patients referred to the ICCD service but also among other patients, as the practices gradually increase their expertise in managing diabetes. However to date there is little evidence of effectiveness or cost effectiveness of these services, and none has been evaluated in a randomised trial.

Aims

Aims of the study aims were to (1) compare clinical outcome in people with T2DM registered with practices that have access to an ICCD service with those that have access only to usual hospital care; (2) assess the cost-effectiveness of the ICCD service intervention; and (3) explore the views of users and other stakeholders.

Methods

A two arm cluster randomised trial was conducted in three English Primary Care Trusts. GP practices in the intervention arm had the opportunity to refer patients to ICCD; a multidisciplinary team led by a specialist nurse and a diabetologist with the aim of supporting practices in their management of patients with T2DM. Those patients referred to the ICCD service were managed for a short period with a goal of improving diabetes control, and then referred back to their practice. Patients of control group practices continued to receive standard GP care, with referral to secondary care as required, but no access to ICCD. The ICCD clinics were available for an 18 month period.

The primary outcome was the percentage of all trial participants reaching three risk factor targets: HbA1c ($\leq 7.0\%$); blood pressure ($<140/80$); and cholesterol ($<4 \text{ mmol/l}$), referred to as ‘combined control’, at the end of the 18 month intervention period. The main secondary outcomes were the
proportion of patients reaching individual risk factor targets, the mean change in risk factors and overall 10 year risks for CHD and stroke assessed by the UKPDS risk engine. Additionally, the impact of the intervention was assessed using routine GP data. Participants were assessed in their practices by a researcher at baseline and follow up. Questionnaires were used to assess psychological stress caused by diabetes and continuity of care.

The study included a cost effectiveness analysis and qualitative interviews with patients, primary care practitioners and other stakeholders, transcribed and analysed using the framework approach.

Results

A total of 49 practices were randomised, 24 to the intervention and 25 to the control arm. All patients with T2DM in these practices (n=12,340) were eligible to take part in the trial, of whom 1997 (16%) agreed to take part. Of these, 1280 (61%) provided follow-up data. At baseline, the intervention and control groups were similar with respect to gender, smoking status, co-morbidities and achievement of NICE defined blood pressure, HbA1c and total cholesterol targets. There was some difference in combined control at baseline, with 11% of intervention vs. 9% of control patients achieving all targets; P=0.09. The 3 PCT sites were similar with respect to baseline characteristics. Of the 1057 patients in the intervention arm, 199 (19%) were seen by the ICCD service. The proportion of trial participants referred at each site ranged from 5% to 34%.

At follow up, combined control was achieved by 92 (14.3%) of patients in the intervention arm and 59 (9.3%) in the control arm. A mixed multiple logistic regression analysis, with adjustment for clustering using a random effect to allow for GP practice based variation, plus fixed effects to allow for potentially confounding variables was undertaken, which found that the difference between groups just failed to reach statistical significance (P = 0.059). The only variable in the model statistically significant at the 5% level was baseline control of diabetes. The odds ratio (95% CI) for the intervention was 1.56 (0.98 to 2.49) suggesting over 50% increased odds of achieving combined control in the intervention group. The odds ratio for achievement of control of individual risk factors were: HbA1c 1.45 (1.07, 1.96), blood pressure 1.23 (0.88, 1.73), cholesterol 1.48 (1.08, 2.03). Mean values of these variables at follow up were slightly lower in the intervention group, but this reached statistical significance only for cholesterol (p=0.014). There was no significant difference in CHD risk as
assessed by the UKPDS risk engine. There were no differences between intervention and control groups in psychological stress or perceived continuity of care. In the subset of practices able to provide routine data on achievement of control at baseline and follow up, there was no difference between control and intervention groups.

The health economic analysis showed that the average cost of an ICCD consultation was £102.18, ranging from £74.01 to £154.75 across the three sites. Average general practitioner and practice nurse costs were higher in the intervention group (mean £26.56 vs £20.07, p =0.012) as were community clinic costs (£1.46 vs £0.49, p 0.025). There was no significant difference in hospital or total healthcare costs.

Qualitative interviews were conducted with 17 primary health care professionals (GPs and practice nurses) who had experience of referring patients to the intermediate care clinics, 15 intermediate care staff and other stakeholders who had worked in the clinics in some capacity and/or had been involved in setting them up, and 13 patients who had attended the clinics. Professionals saw ICCD services as having two valuable roles; the up-skilling of staff and short term inputs to patient care. They emphasised the role of ICCD in capacity building in primary care. Two key features of the service identified were coordination with primary care and accessibility to patients. Patients welcomed the service, particularly the extra time given to their care and input from a team that was felt to have additional skills. They felt their care was coordinated without loss of continuity.

Conclusions

Providing practices with access to an ICCD service was associated with higher proportion of patients achieving recommended control of risk factors, although this difference just failed to reach statistical significance for the primary outcome of control of all three blood pressure, cholesterol and HbA1c (odds ratio 1.56 (0.98 to 2.49). The intervention had only a small effect on mean values of HbA1c, blood pressure and cholesterol, and the difference was only statistically significant for the last of these. Primary care and community clinic costs were significantly higher in the intervention group, but there was no significant difference in hospital and total healthcare costs. There was substantial variation in costs and clinical outcomes between the three sites. Despite potential biases due to low recruitment and loss to follow up, we conclude that intermediate care clinics...
can make a contribution to improving target achievement in patients with diabetes.

This improvement was seen despite a lower than expected number of referrals to ICCD in two of the three PCTs. Services using case management had higher referral rates, and this approach is likely to be needed to maximise their potential. However, ICCD services appeared to improve the overall management of T2DM in practices with which they worked, and so the number of patients seen by ICCD services should not be the only metric for judging their impact.

The qualitative interviews identified components of ICCD services that were important to patients and practitioners. These included close integration and communication with primary care, active involvement in identifying patients who could benefit from referral and an accessible location.

Future ICCD services should be developed and monitored in collaboration with primary care, a process that will be facilitated by clinically led commissioning.