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Research

Building the evidence for integrated care for type 2 diabetes: a pilot study

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Abstract. Integrated care models have the potential to reduce fragmentation in the health system and improve outcomes for people with type 2 diabetes. A pilot evaluation of an integrated care model for people with type 2 diabetes in Melbourne, Australia, is reported on. Two studies were conducted: (1) a 6-month pilot randomised controlled trial ($n = 56$) evaluating the impact of the integrated care model relative to hospital outpatient clinics; and (2) a cross-sectional study ($n = 92$) of patients attending the two services. The primary outcome was diabetes-specific distress; secondary outcomes were perceived quality of diabetes care, diabetes-specific self-efficacy and glycated haemoglobin (HbA1c). There was no effect of service setting on diabetes-specific distress. Participants from the integrated care setting perceived the quality of diabetes care to be higher than did participants from the hospital clinics. Significant HbA1c improvements were observed over time, but with no effect of service setting. The model holds promise for people with type 2 diabetes who need more specialist/multidisciplinary care than can be provided in primary care. Patients' evaluations of the quality of diabetes care received at the integrated care service are very positive, which is likely to be one of the key strengths of the integrated model.

Additional keywords: patient satisfaction, quality of care, questionnaire, randomised controlled trial.

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Introduction

Type 2 diabetes negatively impacts both quality (Rubin and Peyrot 1999) and quantity (Fagot-Campagna *et al*. 2005) of life. Traditionally, health-care services for type 2 diabetes have provided episodic, reactive care, but increasingly are required to provide proactive monitoring and effective long-term management (Bodenheimer *et al*. 2002). Integrated care models hold promise for reducing fragmentation in the health system and improving outcomes for people with type 2 diabetes (Ouwens *et al*. 2005). They coordinate care provided by various health professionals in a seamless and continuous manner, using a person-centred approach to tailor health care to individuals' needs, and are supported by a variety of funding streams (Mur-Veeman *et al*. 2003).

The Integrated Diabetes Education and Assessment Service (IDEAS) is an integrated, multidisciplinary type 2 diabetes health-care service currently operating at a small number of sites in the eastern suburbs of Melbourne. The service was developed in 2008 as a partnership between Carrington Health (CH; previously Whitehorse Community Health Service) and the Eastern Health (EH) Endocrinology Department, driven by aligned goals to improve the provision of services for people with diabetes. Organisational reviews of community-based chronic disease management services and diabetes outpatient services pointed to a need for more effective, integrated, multidisciplinary care based in the community, as well as a need to respond to the current and pending financial pressure and increasing waitlists for acute diabetes services. Consequently, CH and EH redesigned their services to provide multidisciplinary, community-based 'joined-up' health care within the limits of existing resources. Providing integrated health care in one setting, the team includes an endocrinologist and registrar (from EH) working directly with a diabetes nurse educator, podiatrist and community health nurse (from CH). The funding model utilises Medicare Benefits Schedule-funded specialist medical services and core Community Health-funded allied health professionals, with support for start-up provided by the state-funded EH Hospital Admission Risk Program (HARP).

What is known about the topic?

- Integrated care models hold promise for reducing fragmentation in the health system and improving physical health outcomes for people with type 2 diabetes.

What does this paper add?

- The current study adds knowledge about the impact of integrated type 2 diabetes care on psychosocial outcomes and the patient experience.

People receiving services provided by IDEAS include those who have been referred for assessment and support by their primary care provider, or who have been discharged from hospital inpatient or ambulatory services. With demand for specialist clinics in acute services increasing by 51% in the local area over the past 3 years, IDEAS provides a timely alternative model of care delivery, and is enabling redirection of ~33% of diabetes outpatient referrals. However, there is a need to investigate the effectiveness and acceptability of the IDEAS model before significant investment of resources is made into a full randomised controlled trial (RCT) and expansion of services, if appropriate.

We report on the results of a pilot evaluation of the IDEAS model. Two separate but related studies were conducted, with the aim of assessing the psychosocial and biomedical outcomes of adults with type 2 diabetes attending IDEAS relative to hospital-based outpatient diabetes clinics.

Methods

Design

Two studies were conducted: (1) a real-world, 6-month, multi-site pilot randomised trial evaluating the impact of the IDEAS model relative to usual care at hospital-based outpatient clinics; and (2) a cross-sectional study of patients attending IDEAS and hospital-based outpatient clinics.

Both studies were undertaken at two IDEAS sites (Whitehorse Community Health Service (WH) and Knox Community Health Service (KX)) and two hospital outpatient clinics in the same geographical region (Box Hill Hospital (BH) and Maroondah Hospital (MA)).

Participants and recruitment

Participants in both studies were adults with type 2 diabetes living in Melbourne's eastern suburbs. The inclusion criteria were: age $\geq$18 years; proficiency in English; absence of severe diabetes-related complications, pregnancy, cognitive impairment, severe mental illness; new referral into system (randomised trial only); and having attended the service at least twice (cross-sectional study only).

For the randomised trial, new referrals were screened for eligibility via telephone by a diabetes educator, who also explained the objectives and methods of the study (including randomisation). Following verbal consent, a computerised random number generator was used to assign the participant to receive their health care via the intervention condition (IDEAS) or control condition (hospital clinics). After being assigned to a condition, participants were then assigned to the site closest to where they lived.

For the cross-sectional study, researchers approached patients in waiting rooms to invite them to take part in the study. Researchers obtained informed consent before proceeding with study activities.

Study outcomes

The main focus of both studies was the assessment of psychosocial outcomes (via self-report survey), with the primary outcome of interest being diabetes-specific distress. Secondary outcomes were perceived quality of diabetes care, diabetes-specific self-efficacy and HbA1c.

Diabetes-specific distress

The Problem Areas in Diabetes (PAID) scale (Polonsky *et al.* 1995) is a reliable and valid 20-item scale (Polonsky *et al.* 1995; Delahanty *et al.* 2007). Each item represents a diabetes-related issue (e.g. 'Worrying about the future and the possibility of serious complications'), and respondents indicate on a five-point Likert scale whether each issue is 'not a problem' (0) through to a 'serious problem' (4). Raw scores range from 0 to 80, and are converted to a standardised score (range 0–100). Higher scores reflect greater distress.

Perceived quality of diabetes care

The Patients' Evaluation of the Quality of Diabetes Care (PEQD) is a reliable and valid (Pouwer and Snoek 2002) 14-item scale that is scored on a five-point Likert scale (1 = poor, 5 = excellent). Each item addresses a different aspect of care (e.g. waiting time, usefulness of consultation). Scores are summed, then transformed to a 0–100 scale using the formula [(raw score – 14)/56] $\times$ 100. Higher scores indicate more positive perceptions of quality of diabetes care. The language was revised slightly to reflect the structure of care models assessed in this study. For the randomised trial, this scale was only administered at Time 2 (after participants had gained some experience of care at their allocated site).

Diabetes-specific self-efficacy

The Diabetes Empowerment Scale Short Form (DES-SF) is a reliable and valid eight-item scale that assesses self-efficacy in relation to managing diabetes (Anderson *et al.* 2003). Respondents indicate the extent to which they agree with statements (e.g. 'I am able to turn my diabetes goals into a workable plan') on a five-point Likert scale (from 'Strongly disagree' to 'Strongly agree'). Higher scores indicate higher self-efficacy.

Glycated haemoglobin (HbA1c)

Neither the pilot randomised trial nor the cross-sectional survey were powered to detect clinically significant differences in HbA1c ($\geq$ 0.5%). However, because HbA1c is an important diabetes clinical indicator, results are reported here to provide information about relative trends in HbA1c between the two groups. A central laboratory assay was not used.

Basic demographic and clinical data (e.g. age, employment, living arrangements, complications, diabetes duration, diabetes treatment) were extracted from participants' medical records for the purposes of describing the sample.

Data collection

Data collection procedures were consistent across conditions and sites, and were as follows:

Randomised trial

Time 1 (baseline) A researcher met participants in the waiting room at their allocated site when they arrived for their first appointment. Written consent was obtained, and then the participant completed a survey booklet, which served as the baseline assessment of psychosocial outcomes. Clinical staff then conducted an initial assessment and all other activities according to usual care. The most recent HbA1c was provided by the referring GP but if this was dated more than 3 months before study entry, the participant was referred for an HbA1c assessment. Clinic staff extracted other relevant clinical and biomedical information from participants' medical records after the appointment, and this information was provided to the researcher in a de-identified format. Participant questionnaires were matched with their clinical and biomedical data using a numerical identifier to protect anonymity.

Time 2 (6-month follow up) The second data collection took place during the participants' 6-monthly review appointment. Participants completed the follow-up survey in the waiting room, and clinical indicators were recorded and obtained, all as per Time 1. All other appointment activities were as per usual care. Participants were referred to pathology for a follow-up HbA1c. Participants who did not attend their follow-up appointment were reminded once (by telephone or letter) by service administration staff to reschedule their appointment before being considered lost to follow up. Participants who were willing to take part in the follow-up phase but unable to attend a clinical appointment (e.g. had moved out of the area) were mailed a survey and a reply-paid envelope, with a request to return their completed form within 2 weeks. No follow-up biomedical or clinical data were available for those who did not attend a review appointment at the service.

Cross-sectional study

Clinic attendees at each site were approached in the waiting room by a researcher who invited them to take part in the study. If eligibility was confirmed and informed consent was given, participants completed a questionnaire in the waiting room and returned it to the researcher. If they did not finish the questionnaire before being called for their clinical appointment, they were asked to complete it at a later time and return it by post using a reply-paid envelope. All survey data were anonymous, and were identified only with a unique participant number. Clinic staff extracted relevant biomedical and demographic information from participants' medical records, and provided this information to the researcher in a de-identified format.

Data analysis

Data from the various sites (i.e. WH, KX, BH, MA) within each service setting (i.e. IDEAS *v.* hospital) were pooled, as there was no evidence of clustering (variance components estimation indicated that the proportion of site variance from total variance was less than 2%).

For both studies, there was substantial missing data. For the randomised trial, the proportion of missing data ranged from 0% for age and several PAID items at Time 1 to 48% for HbA1c at Time 2. For the cross-sectional study, the proportion of missing data ranged from 0% for several PAID items to 27% for diabetes duration. Little's MCAR test indicated that the data were not missing completely at random (all $P < 0.01$). Missing data were imputed using expectation maximisation techniques. For both the PAID and PEQD, all questionnaire items were used to predict missing data points on other questionnaire items for both Time 1 and Time 2 data separately. Age and diabetes duration missing data points were predicted by themselves and each another, and missing HbA1c data points at Time 1 were predicted by age and diabetes duration. Time 1 HbA1c data, along with age and diabetes duration, were used to predict missing HbA1c data at Time 2. Missing data about number of appointments attended was imputed using age, diabetes duration and HbA1c as predictor variables. The imputation models used were acceptable, on the basis that imputed variable data ranges and means were not meaningfully different from the original dataset.

Independent samples *t*-tests were used to compare baseline characteristics of the two groups in the randomised trial study, and to compare sociodemographic characteristics between the two groups in the cross-sectional study. Outcome data for the randomised trial were analysed using analysis of covariance (ANCOVA), with Time 2 data for each outcome variable entered as the dependent variable, and condition entered as the independent variable. Three separate ANCOVAs were conducted on each of: diabetes-specific distress, diabetes-specific self-efficacy and HbA1c values. Baseline values of the outcome variable, along with age, diabetes duration and primary treatment, were entered as covariates. Repeated-measures analysis of variance (ANOVAs) were also conducted on diabetes distress, diabetes self-efficacy and HbA1c for each condition separately, to assess change over time.

For the cross-sectional study, separate ANCOVAs were conducted on diabetes-specific distress, diabetes-specific self-efficacy and HbA1c data, with age, diabetes duration and number of appointments attended entered as covariates for each analysis.

As the randomised trial participants only completed the PEQD at Time 2, and univariate tests demonstrated no significant difference in scores between each study sample, PEQD data from both studies were pooled. An ANCOVA, controlling for age and diabetes duration, was conducted to assess differences in perceived quality of diabetes care between the two service settings.

All statistical analyses were performed on an intention-to-treat basis and were conducted using SPSS 22 (IBM, New York, NY, USA). $P < 0.05$ was considered significant.

Results

Randomised trial study sample characteristics

A total of 64 participants were recruited into the study by clinic staff. No data are available regarding the total number of patients approached or for those who refused to take part, on the basis that consent was not given for personal information to be extracted from health records. Eight of these 64 individuals were subsequently excluded by the researcher at the eligibility assessment. Reasons for exclusion were: having previously attended the service ($n = 4$), insufficient English language literacy

skills to complete the questionnaire ($n = 2$), presenting with a major psychiatric condition ($n = 1$) and not having type 2 diabetes ($n = 1$). Thus, the final sample size was $n = 56$ (IDEAS: $n = 27$; hospital: $n = 29$). Participants were evenly distributed across each service setting, but unevenly distributed across sites (Table 1). Eleven participants (20%) were lost to follow up between Time 1 and Time 2 (IDEAS: $n = 5$; hospital: $n = 6$).

Table 2 presents key sample characteristics at baseline and demonstrates that randomisation was largely successful, with the exception of significant differences on treatment type and HbA1c.

Cross-sectional study sample characteristics

Of 127 eligible patients who were invited to take part in the study, a total of 96 (76%) participated. No data are available for those who refused, on the basis that consent was not given for personal information to be extracted from health records. Four individuals were subsequently excluded from the study on the basis that they had insufficient English language skills to complete the questionnaire, leaving a final sample size of $n = 92$ (IDEAS: $n = 59$; hospital: $n = 33$). Participants were evenly distributed across sites of the same type, but unevenly distributed across service settings (Table 1). Participant demographic and clinical characteristics were equivalent between the IDEAS and hospital groups. However, IDEAS participants reported more service visits (representing a higher 'dosage' of care) than participants at the hospital clinics (Table 3).

Table 1. Number of trial and cross-sectional study participants by condition and study site

Data presented as *n* (%). IDEAS, Integrated Diabetes Education and Assessment Service; WH, Whitehorse Community Health Service; KX, Knox Community Health Service; BH, Box Hill Hospital; MAR, Maroondah Hospital

Clinic type	Site	Trial study ($n = 56$)	Cross-sectional study ($n = 92$)
IDEAS	WH	18 (32)	28 (48)
	KX	9 (16)	31 (52)
	Total	27 (48)	59 (64)
Hospital	BH	18 (32)	16 (49)
	MAR	11 (20)	17 (51)
	Total	29 (52)	33 (36)

Psychosocial outcomes

The results relating to all psychosocial outcomes for both studies are presented in Table 4. In the randomised trial, while diabetes-specific distress scores appeared to decrease over time in both IDEAS and hospital services, the trend was non-significant. After controlling for covariates, diabetes-specific distress was equivalent between the IDEAS and hospital groups at Time 2, indicating that there was no effect of service setting on distress scores in the randomised trial. For the cross-sectional study, while the mean PAID score of the hospital group was almost eight points higher (indicating greater diabetes-specific distress) than the IDEAS group, this difference was not significant.

Diabetes-specific self-efficacy did not change significantly over time as a result of receiving care, and there was no effect of service setting at Time 2. For the cross-sectional study, no between-group differences in diabetes-specific self-efficacy was detected.

Participants who were attending IDEAS perceived the quality of diabetes care they received as significantly better than did those attending the hospital clinics. To further explore which aspects of care were perceived to be better at IDEAS as compared with the hospital clinics, mean item scores were compared across groups (Table 5). Consistency of advice received from health

Table 2. Baseline characteristics of trial participants ($n = 56$)[A]

Data are presented as mean ± s.d. (range) or *n* (%). OHA, Oral hypoglycaemic agents; IDEAS, Integrated Diabetes Education and Assessment Service; HbA1c, glycated haemoglobin

Sample characteristics	IDEAS	Hospital	*P*-value	Total sample
Age (years)	54 ± 14 (30–78)	58 ± 11 (36–78)	0.26	56 ± 12 (30–78)
Diabetes duration (years)	8 ± 8 (0–27)	9 ± 6 (0–25)	0.96	8 ± 7 (0–27)
Women	10 (37)	8 (28)	0.50	18 (32)
Primary treatment[B]				
Insulin injections	7 (26)	18 (62)	<0.01	25 (45)
OHA	18 (67)	6 (21)		24 (43)
Diet and exercise only	1 (4)	2 (7)		3 (5)
Employment status				
Employed	16 (59)	10 (35)		26 (55)
Unemployed	7 (26)	3 (10)	0.24	10 (21)
Retired	4 (15)	7 (24)		11 (23)
Living alone	5 (19)	2 (7)	0.24	7 (15)
No. of diabetes complications	1.07 ± 1.38 (0–5)	1.86 ± 1.94 (0–6)	0.09	1.5 ± 1.7 (0–6)
HbA1c (%)	8.61 ± 1.36 (6.0–10.9)	9.61 ± 2.01 (6.3–13.5)	0.04	9.13 ± 1.78 (6–13.5)
Diabetes distress[C]	27.18 ± 20.04 (1–71)	29.25 ± 23.50 (0–89)	0.71	28.25 ± 21.73 (0–89)
Diabetes-specific self-efficacy[D]	3.89 ± 0.56 (3–5)	3.64 ± 0.73 (2–5)	0.15	3.76 ± 0.66 (2–5)

[A]Missing data on some categorical variables; frequencies do not always add to total sample size of $n = 56$.
[B]Combination treatments not reported here.
[C]Measured by the Problem Areas in Diabetes scale (Polonsky *et al.* 2005).
[D]Measured by the Diabetes Empowerment Scale-Short Form (Anderson *et al.* 2003).

Table 3. Demographic and clinical characteristics of cross-sectional study participants ($n = 92$)[A]
Data are presented as mean ± s.d. (range) or *n* (%). IDEAS, Integrated Diabetes Education and Assessment Service

Sample characteristics	IDEAS	Hospital	*P*-value	Total sample
Age (years)	63 ± 10 (38–81)	63 ± 9 (39–77)	0.87	63 ± 10 (38–81)
Diabetes duration (years)	12 ± 9 (1–40)	14 ± 7 (3–41)	0.29	13 ± 9 (1–41)
Women	28 (48)	19 (58)	0.35	47 (51)
Primary treatment[B]				
Insulin injections	37 (63)	22 (67)		59 (64)
Oral hypoglycaemic agents	15 (25)	9 (27)		24 (26)
Diet and exercise only	7 (12)	2 (6)	0.11	9 (10)
Employment status				
Employed	20 (34)	7 (21)		27 (29)
Unemployed	13 (22)	7 (21)	0.32	20 (22)
Retired	23 (39)	18 (55)		41 (45)
Living alone	19 (32)	11 (33)	0.97	30 (34)
No. diabetes complications	1.9 ± 1.9 (0–6)	1.1 ± 1.9 (0–4)	0.29	1.8 ± 1.8 (0–6)
No. clinic visits	6.0 ± 2.9 (2–15)	4.7 ± 1.4 (3–9)	<0.01	5.5 ± 2.5 (2–15)

[A]Missing data on some categorical variables; frequencies do not always add to total sample size of $n = 92$.
[B]Combination treatments not reported here.

Table 4. Descriptive and test statistics on outcome variables for randomised control trials (RCT; $n = 56$) and cross-sectional studies ($n = 92$)
All means adjusted for covariates. Data are presented as adjusted mean ± s.d. score. IDEAS, Integrated Diabetes Education and Assessment Service; HbA1C, glycated haemoglobin. *Significant change from Time 1 to Time 2

			F	*P*-value
Diabetes-specific distress[A]				
RCT study ($n = 56$)	Time 1	Time 2		
IDEAS	27.18 ± 20.04	26.44 ± 19.16	0.91	0.35
Hospital	29.25 ± 23.50	27.23 ± 19.26		
Cross-sectional study ($n = 92$)				
IDEAS	22.63 ± 19.43		2.81	0.10
Hospital	30.38 ± 19.89			
Diabetes-specific self-efficacy[B]				
RCT study ($n = 56$)	Time 1	Time 2		
IDEAS	3.89 ± 0.56	3.95 ± 0.68	0.40	0.53
Hospital	3.64 ± 0.73	3.71 ± 0.67		
Cross-sectional study ($n = 92$)				
IDEAS	3.73 ± 0.71		0.35	0.56
Hospital	3.54 ± 0.99			
HbA1c (%)				
RCT study ($n = 56$)	Time 1	Time 2		
IDEAS	8.61 ± 1.36	7.62 ± 1.56*	0.79	0.38
Hospital	9.61 ± 2.01	7.15 ± 0.54*		
Cross-sectional study ($n = 92$)				
IDEAS	7.95 ± 1.37		1.66	0.20
Hospital	8.28 ± 1.45			
Perceived quality of diabetes care[C]				
Pooled data from the RCT and cross-sectional studies ($n = 148$)				
IDEAS	70.18 ± 18.48		6.15	0.01
Hospital	62.38 ± 19.10			

[A]Measured by the Problem Areas in Diabetes scale (Polonsky *et al.* 2005).
[B]Measured by the Diabetes Empowerment Scale-Short Form (Anderson *et al.* 2003).
[C]Measured by the Patient Evaluation of Perceived Quality of Diabetes care (Pouwer and Snoek 2002).

professionals was rated as significantly better by the IDEAS participants. There was a marginally significant difference between groups regarding ease of making appointments, with IDEAS participants also rating this aspect of care as better than the hospital clinic participants.

Glycated haemoglobin (HbA1c)

HbA1c results for both studies are presented in Table 4. In the randomised trial, HbA1c decreased significantly from Time 1 to Time 2 in both groups, indicating an effect over time on glycaemic control. However, there was no effect of service setting; HbA1c at Time 2 was equivalent between groups after controlling for covariates. No significant between-group difference in HbA1c was observed in the cross-sectional study.

Discussion

This pilot study was the first to evaluate the IDEAS model of care: a new, integrated type 2 diabetes health-care service currently operating in a small number of sites in the eastern suburbs of Melbourne. In respect of the designated primary outcome, diabetes-specific distress, there was a trend in favour of IDEAS but this did not reach significance in either the randomised trial or cross-sectional study. Nor was there a significant difference between service settings in terms of diabetes-specific self-efficacy. There was, however, a significant difference between service settings in terms of perceived quality of diabetes care, favouring IDEAS. After 6 months of clinical intervention in the randomised trial, HbA1c had improved significantly, with both groups being nearer the target of ≤7% (Colagiuri *et al.* 2009). However, there was no effect of service setting, as the IDEAS and hospital participants had equivalent glycaemic control at follow up after controlling for covariates. Furthermore, existing IDEAS and hospital clinic patients had equivalent HbA1c values, as demonstrated by the findings of the cross-sectional study.

While previous studies of community-based diabetes services have used objective process measures of service quality (e.g.

Table 5. Perceived quality of care: descriptive statistics and between-group differences on Patients' Evaluation of the Quality of Diabetes Care (PEQD) item scores ($n = 148$)

Data are presented as mean ± s.d. IDEAS, Integrated Diabetes Education and Assessment Service

Item	IDEAS	Hospital	*P*-value
1. The waiting time before your consultations	3.16 ± 1.13	3.03 ± 1.14	0.49
2. The duration of the consultations	3.78 ± 0.89	3.66 ± 0.89	0.43
3. The time I have to wait between appointments	3.43 ± 0.96	3.60 ± 1.08	0.31
4. The clarity of information I receive	3.77 ± 1.07	3.79 ± 0.88	0.90
5. The amount of information I receive	3.76 ± 0.87	3.66 ± 0.96	0.53
6. The usefulness of the information I receive	3.74 ± 0.85	3.62 ± 0.98	0.44
7. The opportunity to ask questions during the consultations	3.80 ± 0.90	3.93 ± 0.90	0.39
8. The extent to which I feel supported by the health-care professionals	3.86 ± 0.94	3.90 ± 0.98	0.80
9. The competence of the health-care professionals in helping me achieve good diabetes outcomes	3.80 ± 0.87	3.80 ± 0.86	0.98
10. The extent to which the health-care professionals remember what has been discussed during previous visits	3.76 ± 1.05	3.44 ± 1.08	0.08
11. The extent to which the advice and care I receive is consistent across health-care professionals at this service	3.90 ± 0.83	3.58 ± 0.90	0.03
12. The opportunity for me to be involved in decisions about the treatment of my diabetes	3.66 ± 0.90	3.39 ± 0.98	0.09
13. The ease of making new appointments	3.87 ± 0.83	3.58 ± 0.94	0.05
14. The overall quality of my diabetes care	3.80 ± 0.91	3.65 ± 0.89	0.30

adherence to guidelines) (Chin *et al*. 2000; Brown *et al*. 2005), in the current study, we used a series of patient-reported outcome measures to determine subjective quality of diabetes care from the patients' perspective. Participants attending IDEAS rated the quality of diabetes care they received more highly than did participants attending the hospital clinics. In particular, IDEAS participants perceived that they received more consistent advice from their health professionals, and found it easier to make appointments (and therefore gain access to their health professionals) than did hospital participants. It is perhaps unsurprising that the IDEAS model of care was evaluated more positively by attendees, given its explicit focus on person-centred care. Previous research has shown that people with diabetes have strong views about what constitutes quality diabetes care (Tabrizi *et al*. 2007), and that positive evaluations of quality of care are associated with improved diabetes outcomes such as fewer treatment-related problems and diabetes complications (Pouwer and Snoek 2002). Therefore, ensuring that people with diabetes have a positive experience, fostering engagement with the service, needs be a priority for diabetes health care.

While neither service setting was instrumental in achieving significant reductions in diabetes-specific distress or improvement in diabetes-specific self-efficacy, this may be a function of several limitations (to be discussed later). In addition, it may also be reflective of the treatment priorities during the first months of clinical care at IDEAS and hospital clinics. Follow up in the randomised trial was restricted to 6 months. While the integrated service might be expected to improve perceptions regarding continuity and consistency of care, the priorities targeted (which contributed to improved HbA1c) may well have had a neutral or even deleterious effect (due to increased treatment burden) on diabetes-specific distress and self-efficacy. In the randomised trial, average HbA1c was well above target for both groups at baseline, and therefore in all likelihood, reducing HbA1c became the top priority for clinical intervention in the first instance. This is consistent with clinical care guidelines (Colagiuri *et al*. 2009). The nature of the clinical care provided to each participant was not mandated by the trial protocol. The focus of clinical care might conceivably turn to other priorities after HbA1c was optimised. Therefore, a longer follow-up time may have been required for the randomised trial to detect change on psychosocial outcomes. Alternatively, it may be that neither the hospital-based clinics nor the integrated care service offered through IDEAS truly offer support for, and intervention on, the psychosocial aspects of living with diabetes, a criticism that has previously been levelled at disease-specific programs (Ferrer and Goodwin 2014).

In this study, we: (a) assessed the relative impact of IDEAS versus hospital outpatient clinics on psychosocial and clinical outcomes using a small trial design; and (b) compared outcomes of existing service attendees using a cross-sectional study design. This two-pronged approach was a key strength of the pilot study, as it allowed for concurrent assessment of effectiveness, while also taking a snapshot of existing patients whose usual care experience had not been impacted by trial protocol requirements. However, the studies reported here were limited by small sample sizes (especially the randomised trial study) and uneven sample distributions across sites (especially in the cross-sectional study). It is likely that these limitations resulted in the studies being underpowered to detect an effect on the outcomes of interest and thus, results must be interpreted with caution. Furthermore, the small sample sizes prohibited sub-sample analyses or advanced modelling to explore for whom the intervention was most effective, though this will be an important issue to address in future research.

While the randomisation procedure for the trial study was largely successful, some anomalies were apparent. Participants in the hospital group had higher HbA1c, were more likely to be managing their diabetes with insulin and there was a trend towards them having more diabetes-related complications (non-significance likely due to insufficient power). Based on this information, it could be argued that participants in the hospital group had more advanced diabetes than those in the IDEAS group, despite equivalent diabetes duration. These anomalies are the result of chance bias, which can occur when smaller samples (i.e. $n < 100$) are used. For example, in the case of HbA1c in the current trial, these between-group differences resulted from a small number of outlying data points (e.g. in the case of HbA1c, just four participants had an HbA1c of >11% (i.e. 12.8%, 12.9%,

13.3% and 13.5%), which inflated the mean value of the outpatient group. The implication for the current trial is that it may have been more difficult to detect improvements in key outcomes in the IDEAS group relative to the hospital group, but we do not believe this has been the case. A larger sample size would likely overcome this issue. For future studies, we would consider stratifying the samples with regard to HbA1c and diabetes treatment type.

Other limitations include not being able to report a response rate for the trial. Variations in interpretation of the trial protocol by the diabetes educators who conducted the telephone eligibility screening meant that they each kept slightly different records, which could not be compiled to produce an overall response rate or a rate per site. This is an unfortunate but understandable by-product of conducting a real-world study. We were unable to assess potential bias in the sample (due to not having access to demographic or clinical data for those who declined to participate) and variability in the measurement of HbA1c (due to not using a central laboratory). Finally, we were unable to translate our study materials into languages other than English, which likely limited recruitment in this multicultural area of Melbourne.

The pilot evaluation studies reported here are the first to assess the effectiveness and patients' experiences of IDEAS. Further research is needed, in the form of a large RCT adequately powered to detect change on relevant psychosocial and clinical outcomes. Our findings suggest that the IDEAS model holds promise for people with type 2 diabetes who need more specialist or multidisciplinary care than can be provided by a primary care practitioner. Patients' own evaluations of the quality of diabetes care received at IDEAS are very positive, and this is likely to be one of the key strengths of the IDEAS model of care.

Conflicts of interest

None declared.

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