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Title Page

Title: *A pilot study of an integrated mental health, social, and medical model for diabetes care in an inner-city setting: Three Dimensions for Diabetes (3DFD)*

Short title: *Integrated diabetes care: 3DFD study*

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Conflicts of interest

KI has received honorarium for educational lectures from Sanofi, Novo Nordisk, Janssen, and Eli Lilly. KI and DS received partial funding from the NIHR Biomedical Research Centre for Mental Health at the South London and Maudsley NHS Foundation Trust and IoPPN, King's College London. The authors have no other conflicts of interest to declare.

Novelty statement

- There are few evidence-based models of diabetes care that include mental health and social care
- The Three Dimensions for Diabetes (3DFD) model integrated social care, mental health and diabetes care into one service
- This is a non-randomised, observational study, set in three diverse boroughs in London, UK, and recruited adults with suboptimal glycaemic control and mental health and/or social problems
- 3DFD was associated with clinically significant reductions in glycaemic control but as they were already a very expensive and high-risk group there was no evidence of reduction in the costs compared to the control

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Author Contributions

KI with CG developed the 3DFD model of care, supervised the study, supervised the analysis and manuscript development. KR contributed to the data collection. EB conducted the study and data collection and preliminary analyses. RF contributed to data collection. DS contributed to the statistical analyses. KS contributed to the statistical analyses and writing of the manuscript. PM contributed to the economic portion of the study. CG with KI developed the 3DFD model of care, implemented and supervised the study. AMD led the delivery of 3DFD and supervised the data collection and initial manuscript draft. All authors commented on and contributed to the manuscript development.

Guarantor

KI takes responsibility for the contents of the article.

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Data sharing statement

Data are available upon reasonable request to the corresponding author.

Abstract

Aims: We examined the effectiveness of a service innovation, Three Dimensions for Diabetes (3DFD), that consisted of a referral to an integrated mental health, social care, and diabetes treatment model, compared with usual care in improving biomedical and health economic outcomes.

Methods: Using a non-randomised control design, the 3DFD model was offered in two inner-city boroughs in London, UK, where diabetes health professionals could refer adult residents with diabetes, suboptimal glycaemic control ($\text{HbA1c} \geq 75\text{mmol/mol} (\geq 9.0\%)$) and mental health and/or social problems. In the usual care group, there was no referral pathway and anonymised data on individuals with $\text{HbA1c} \geq 75\text{mmol/mol} (\geq 9.0\%)$ were collected from primary care records. Change in HbA1c from baseline to 12 months was the primary outcome and change in healthcare costs and biomedical variables were secondary outcomes.

Results: 3DFD participants had worse glycaemic control and higher healthcare costs than control participants at baseline. 3DFD participants had greater improvement in glycaemic control compared to control participants (-14 mmol/mol (-1.3%) v. -6 mmol/mol (-0.6%), respectively, $p<0.001$), adjusted for confounding. Total follow-up healthcare costs remained higher in the 3DFD group compared to the control group (mean difference=£1,715, 95% CI=591 to 2,811), adjusted for confounding.

Conclusions: Integrating mental health and social care in routine diabetes treatment can aid the identification of individuals at high risk of complications and lead to improvements in glycaemic control.

Keywords

Glycaemic control; Integrated care; Mental health; Social care

1. Introduction

In the UK, around 4 million people have diabetes, costing almost £10 billion/year in direct costs alone, 80% of which are for complications.¹ Psychiatric morbidity, diabetes-related distress, and social problems (e.g., debt, unemployment, isolation, and poor housing) are common barriers to diabetes self-care and associated with reduced self-management, which leads to suboptimal glycaemic control, increased risk of diabetes complications, premature mortality, and increased healthcare costs.²⁻⁸ National guidance recognises that integrating social and psychological care with medical care could lead to better health outcomes.⁹

Integrating the treatment of depression with diabetes care improves outcomes for both conditions and reduces costs^{10,11}, but studies that have attempted to integrate social welfare are almost non-existent. The highest prevalence rates of diabetes and worst diabetes outcomes occur in inner-city settings.^{12,13} While there have been several interventions to intensify medical and educational interventions in inner-city settings to improve self-management and glycaemic control, there have been no interventions that address social problems with the aim of improving glycaemic control.^{14,15} We found in a feasibility pre-post observational study design that integrating diabetes, mental health, and social care into one service, the Three Dimensions For Diabetes (3DFD) model, was associated with improvements in biomedical, mental health, social, and cost outcomes.¹⁶

The primary aim of this pilot study was to further test whether 3DFD was associated with greater change in glycaemic control, other diabetes-related biomedical outcomes, and in healthcare costs compared to a control group receiving usual care over 12 months. Our secondary aim was to assess the change in psychological and subjective measures of healthcare use in the 3DFD group only from referral to 12-month follow-up.

2. Material and Methods

2.1 Design

We used a non-randomised control design where we compared individuals who were referred to 3DFD with a contemporaneous control group receiving usual care.¹⁷ The rationale for a non-randomised design was that the funding body had requested a control group but not a randomised controlled trial (RCT) as the results were to inform the commissioners as to whether there was any clinical and economic evidence to translate this model into routine

care. Evidence from non-randomised studies is useful when confounders are well-understood, measured, and controlled and we were able to do this using a variety of statistical methods.^{18,19}

2. 2 Setting

3DFD was set in Lambeth and Southwark, London, UK, which are adjacent inner-city boroughs with populations of 324,431 and 308,401 residents and with high levels of ethnic diversity and significant socioeconomic deprivation, as measured by the English Indices of Multiple Deprivation (IMD) 2010.²⁰ The contemporaneous control group was set in Lewisham, a neighbouring borough with 275,900 residents and similar levels of ethnic diversity and deprivation. This borough did not have the 3DFD service or any diabetes-specific mental health or social care services, but shared the same diabetes clinical pathways as Lambeth and Southwark and therefore had a comparable healthcare profile.²¹ We invited all primary care practices in Lewisham to participate. The study was granted ethical approval by the East Kent Research Ethic Committee (Reference 13/LO/0101; NHS Research & Development number RJ113/N306) to collect data after informed consent for the 3DFD group and for the control group general practices to screen their registers for eligible individuals and generate anonymised diabetes-related data.

2.3 Participant selection

For the 3DFD group, we used a referral form with the following criteria of: (a) HbA1c ≥ 75 mmol/mol ($\geq 9.0\%$) and (b) the presence of psychiatric morbidity (including depression, psychosis, eating or anxiety disorder, substance misuse, or diabetes adherence problems) and/or social problems (housing, debt, literacy problems, unemployment) as diagnosed and judged by the referring clinician contributing to reduced self-management. We excluded individuals who were already registered under mental health services, as 3DFD aimed to identify participants with unmet or previously unidentified mental health or social needs or who did not meet the clinical criteria for mental health services. We did not distinguish between type of diabetes. Participants could be referred from any point on the care pathway from primary to secondary care.²¹

For the control group, we could not use a referral form as there was no service to offer. Instead, consenting practices collected sociodemographic and biomedical data from their electronic medical records to identify individuals who met the first 3DFD referral criterion, which was having a current HbA1c ≥ 75 mmol/mol ($\geq 9.0\%$). We could not include the

secondary referral criteria of presence of mental health or social problems as this would have involved a clinical judgement by the diabetes health professional and we did not have the ethical approval or funds to collect data from this group of participants and the data were anonymised to the researchers.

2.4 Interventions

2.4.1 Usual care

This consisted typically of a diabetes multi-disciplinary team (MDT), which included a general practitioner, diabetologist, diabetes specialist nurse, and dietitian in three settings of increasing severity: primary, intermediate, and secondary care. The pathway in all three boroughs was aligned with the principles of the Diabetes Guide for London²¹ in which there was no provision for mental health or social care.

2.4.2 3DFD intervention

The 3DFD team consisted of a full-time consultant liaison psychiatrist and two full-time community support workers from a third-sector (or non-governmental organisation), voluntary organisation, Thames Reach, that provided social welfare. Thames Reach helps homeless and vulnerable people to be rehoused and rebuild their lives (thamesreach.org.uk). This combination of specialists was selected based on our pilot study¹⁶ which observed higher levels of severe psychiatric morbidity. The psychiatrist was also trained to deliver brief psychological therapies.

From 01-10-2012 to 30-09-2013, any professional from the diabetes MDT in Lambeth and Southwark (i.e., a general practitioner, diabetologist, diabetes specialist nurse, or dietitian) could refer adult individuals to 3DFD via a standardised online or paper referral form. Each referral was discussed and triaged at weekly 3DFD team meetings attended by the psychiatrist and community worker and allocated to: (a) the liaison psychiatrist (if the referral indicated pressing safety concerns or presence of multiple psychiatric morbidities) for a diagnostic assessment and initiation and monitoring of psychotropics; (b) assessment for psychological therapy; and/or (c) the community support worker if social problems were recorded. All individuals who were referred and met the criteria were included as participants. The 3DFD clinics were integrated into diabetes teams and clinics and the third-sector support workers delivered outreach work from their offices or participants' homes. The final follow-up took place 17-06-2015.

Following a clinical psychiatric assessment using the International Classification of Disorders-10 criteria for psychiatric disorders²² and identifying the barriers to optimal diabetes control, the treatment options consisted of: diabetes-focused cognitive behaviour therapy (CBT)²³; initiation and monitoring of psychotropics; and/or social interventions, which involved advocacy in housing, debt problems, childcare, domestic violence, immigration, and/or signposting to employment training. These were integrated into their routine diabetes care by ensuring 3DFD clinics were co-located with the diabetes MDT clinics via joint consultations with the key diabetes healthcare professionals or weekly feedback at the generic diabetes MDT meetings. The 3DFD liaison psychiatrist and/or community worker met the participant in weekly-to-monthly appointments, depending on their needs, for a period of up to six months. Separate weekly 3DFD MDT team meetings provided an opportunity to discuss challenges in treatment and for supervision. Discharge into routine diabetes care was planned with the generic diabetes MDT.

2.5 Measures

At baseline and 12 months for all participants, we collected the following data from medical records: sociodemographic variables (age, gender, self-reported ethnicity, postcode for IMD 2010 score and quintile), biomedical variables (HbA1c, serum cholesterol, estimated glomerular filtration rate (eGFR), albumin:creatinine ratio (ACR), body mass index (BMI), and blood pressure (BP)), macrovascular and microvascular complications, and prescribed medications.

For both groups, the primary outcome was change in HbA1c from baseline (time of referral for 3DFD group) to 12-month follow-up (i.e., six months after discharge from the 3DFD intervention). Secondary outcomes were the remaining biomedical outcomes (serum cholesterol, eGFR, ACR, BMI, and BP). Service use was coded and costed as number of emergency department (ED) visits, inpatient admissions, and outpatient visits, length of inpatient bed stays, and number of outpatient appointments offered and attended in the previous 12 months at baseline and follow-up. We calculated the cost of the intervention as £209,785.50, based on the salaries of one psychiatrist (£76,761/year), one senior (£32,802/year) and junior Thames Reach worker (£30,294/year) for the duration of the intervention's implementation (18 months).

We could collect self-report psychological, social, and service use measures at baseline and 12 months in the 3DFD group only. These included: the Patient Health Questionnaire (PHQ-9), a nine-item questionnaire that screens for severity and number of depressive symptoms (range: 0–27) with a score of ≥ 10 representing case threshold for likely depressive disorder²⁴; the Generalized Anxiety Disorder-7 (GAD-7) scale, a seven-item questionnaire for screening for the presence and severity of anxiety (range: 0–21), with scores ≥ 10 indicating possible anxiety disorder²⁵; and the Diabetes Distress Scale (DDS), a 17-item instrument for the assessment of diabetes-related emotional distress with a score of ≥ 40 representing clinical significance.²⁶ For social functioning, we used the Independent Living Star™, a multidisciplinary tool originating in the third-sector which has been since adapted and validated for measuring the outcomes of social and psychological interventions.²⁷ Participants rate eight areas of social functioning on a Likert scale, where higher scores indicate higher levels of functioning: *Where you live, Looking after yourself, Health, Being treated with dignity, Meaningful activity, Social life, Managing money, How you feel.*

2.6 Power calculation

The power calculation was informed by the effect size observed in the earlier study¹⁶, however, we anticipated a more conservative between-group difference. We estimated that the improvement in HbA1c in the 3DFD group would be 4 mmol/mol greater than the control group (with a pooled standard deviation of 15 mmol/mol), corresponding to a small effect size of 0.25 (Cohen's *d*). At a power of 80% and two-sided significance level of 0.05, a per group sample size of 252 was required for comparing two means.

2.7 Statistical analysis

We included 3DFD participants who were accepted into the intervention and controls that were identified anonymously. We described the baseline characteristics as means (SD) for continuous variables and as counts (percentages) for categorical variables. Baseline characteristics of each group were compared using Student's *t*-test or χ^2 -test for continuous and categorial variables, respectively. We compared the change in biomedical outcomes from baseline to 12 months between groups with *t*-tests. For the self-report measures collected in the 3DFD group only, paired *t*-tests were used to investigate changes from baseline to follow-up. Distributions of continuous variables were checked with histograms and QQ-plots; skewed variables were analysed with non-parametric tests (i.e., Mann-Whitney *U*-test).

Using linear regression models, our primary analyses compared the change in HbA1c and the other biomedical outcomes in the 3DFD versus control group. We adjusted for relevant potential confounders (age, gender, ethnicity, IMD 2010 score, type of diabetes, and diabetes duration). Residual plots were visually checked to see if the regression models fit the data and if any assumptions were violated.

We recorded health service use (inpatient admissions, ED visits, and outpatient clinic attendance) and calculated costs by estimating the cost per contact with the service based on staff and other expenditure data, overheads, and activity levels. Other service costs were calculated by combining the data collected from hospital and primary care records with appropriate unit cost information.²⁸

For our economic analysis, we compared total follow-up healthcare costs between groups in a regression model, adjusting additionally for baseline costs and change in HbA1c. We used a bootstrapped model with 1,000 replicates, which makes no assumptions about the underlying data distribution, to estimate the 95% confidence intervals of coefficients, as regression analyses of cost data often result in non-normally distributed residuals.²⁹ We did not transform the data as this would distort the true spread of morbidity and costs. For 3DFD participants only, total follow-up costs included the per-participant cost of the intervention.

The incremental cost-effectiveness ratio (ICER) was calculated for the ratio of follow-up total costs to HbA1c, adjusting for baseline values, as follows: $(\text{cost}_{3\text{DFD}} - \text{cost}_{\text{control}}) / (\text{HbA1c}_{3\text{DFD}} - \text{HbA1c}_{\text{control}})$. The ICER was bootstrapped with 1000 replicates, its 95% CI calculated, and uncertainty around the estimate was shown by plotting the replicates on the cost-effectiveness plane.

We performed a per-protocol sensitivity analysis as well because a small group of participants were recruited with HbA1c <75 mmol/mol (<9.0%), as they had serious psychiatric and/or social problems. The above primary and cost analyses were redone excluding these participants.

2.7.1 Propensity Score Analyses

In addition to the regression analyses, we conducted a propensity score analysis (PSA) with stratification to investigate the effect of the 3DFD intervention on change in HbA1c and total follow-up healthcare costs to reduce the potential bias in our estimation of the treatment effect due to the observational and non-randomised design. A PSA allows for the balancing of measured covariates between the control and treatment groups in an observational study.³⁰ An advantage of the PSA over multiple regression is that by matching by propensity scores we do not rely on the linearity assumptions between confounders and outcome as in multiple regression. However, PSA does not allow extrapolation and we may not be able to make inferences about certain groups.

Participants with complete data on the relevant variables were used for the PSA. Propensity scores for change in HbA1c and healthcare costs were calculated by predicting treatment group status from five (age, gender, ethnicity, 2010 IMD score, and baseline HbA1c) and eight variables (additionally complications, type of diabetes, and baseline total costs), respectively, in a logistic regression model. Participants were then stratified based on quintiles of the propensity scores to create five, relatively equal-sized groups. Treatment effects on change in HbA1c and costs were estimated within each stratum and pooled across strata. We checked the balancing of covariates.

Data were analysed using SPSS for Windows (version 22) and, for the PSA and bootstrapped cost statistics, R (version 3.4.1).

2.8 Participant involvement

ThinkPublic, a social enterprise that supports qualitative research co-design projects in the community, conducted semi-structured interviews with participants after our pilot study to inform the content of the intervention for this project. They asked for participant feedback as to the key facilitators for improving their care and suggested improvements (report available from authors).^{16,31}

3. Results

3.1 Comparison of 3DFD and control groups

During the study period, we received 307 referrals of which 277 individuals met the 3DFD criteria. In the control group, the five largest general practices in Lewisham agreed to

participate and 292 individuals were anonymously identified from the diabetes registers who met the first eligible criterion of HbA1c ≥ 75 mmol/mol ($\geq 9.0\%$) (Fig. 1).

Table 1 presents baseline characteristics. The 3DFD group overall had greater morbidity and greater risk of diabetes complications. On average they were ten years younger, more likely to be female or from an ethnic minority, and slightly less likely to be living in the most deprived areas. The 3DFD group had poorer glycaemic control, longer duration of diabetes, and a higher proportion of participants with type 1 diabetes. In addition, the 3DFD group had more type 2 diabetes participants receiving current insulin therapy. The 3DFD group also had higher mean eGFR values but a lower mean BMI.

In the 3DFD group, 47 (17.0%) participants were offered all three dimensions of care (prescribed psychotropic medication, CBT, and social support). Seventeen (6.1%) participants were prescribed medication and offered social support and 77 (27.8%) were offered CBT and social support. Ten (3.6%) participants were offered CBT only and 48 (17.3%) were offered social support only. 78 (28.2%) did not receive any of the 3DFD services.

Supplemental Table 2 presents the unadjusted between-group difference in change in biomedical outcomes from baseline to 12 months; the mean reduction in glycaemic control in the 3DFD group was significantly greater than in the control group, with no other differences observed for the other biomedical outcomes.

3.1.1 Primary analyses

In the multivariate analysis adjusting for potential confounders, the change in HbA1c was significantly greater in the 3DFD group compared to the control group (Table 2). Additionally, we observed that the 3DFD group had greater decreases in ACR values over time. Residual plots indicated that the models fit the data well.

3.1.2 Economic analyses

Table 3 reports health service use and costs by group at baseline and follow-up. The mean baseline total costs were about three times higher in the 3DFD group than the control group. In both groups, the costs of diabetes care had increased, while the rate of increase in the 3DFD group appeared less than in the control group, the difference between the two groups

remained significant at follow-up. In the multivariate analysis, total follow-up costs were significantly greater in the 3DFD group than the control group (Table 2).

After adjusting for baseline values, the between-group differences in total follow-up costs and follow-up HbA1c values were £1,987.61 and 5.07 mmol/mol, respectively, yielding an ICER of £392 per mmol/mol unit decrease in HbA1c. In other words, every 10 mmol/mol (1.1%) decrease in HbA1c costs £3,920 in additional healthcare use, including the cost of the 3DFD intervention over 12 months, compared to usual care. The bootstrapped results almost entirely fell within the north-east quadrant of the plane (Supplemental Fig. S1), strongly suggesting that the 3DFD intervention was more expensive and more effective.

3.1.3 Sensitivity analyses

For the per-protocol analyses, 58 participants were excluded for having a baseline HbA1c <75 mmol/mol (<9.0%), leaving 240 (37 excluded) participants in the 3DFD group and 274 (18 excluded) in the control group remaining. The baseline characteristics of each group were similar to those in the original sample. The results of this analysis closely resembled the above results, namely that, compared to the control group, the 3DFD group from baseline to follow-up had a significantly greater reduction in HbA1c; no statistically different changes in other biomedical variables; greater healthcare costs in absolute units; and statistically significant improvements in the psychological and social measures (Section 3.2).

3.1.4 PSA

There were 452 participants (3DFD group n=203, 44.9%) with complete data on the variables for the PSA. Five strata were created, with sizes of 90 or 91 participants each, and a minimum of 20% participants from one group in each stratum. In the lowest, second, and fourth strata, 3DFD participants had significantly greater decreases in HbA1c (Supplemental Table S2). When pooling across strata, the 3DFD treatment effect was also significant. When checking the balance diagnostics of the covariates, some group differences remained within strata: age (higher in control group in the top stratum), baseline HbA1c (higher in control group in the third stratum), IMD 2010 score (higher in 3DFD group in the third stratum).

For the PSA comparing follow-up total healthcare costs, 556 participants across the two groups (3DFD group n=270, 48.6%) with complete data on the relevant variables were included. Five strata were created, of 111-112 participants each, and a minimum of 16%

participants from one group in each stratum. Within each and across all strata, follow-up costs were not different between groups (pooled estimate=£212, 95% CI=£-302 to 727).

3.2 3DFD group only

On the self-report measures, 3DFD participants indicated experiencing high levels of psychological difficulties (Supplemental Table S3). In the pre-post analysis in the 3DFD group, there were statistically significant improvements in each psychological and social outcome (Supplemental Table S3).

4. Discussion

This study tested the potential effectiveness of a service that integrated mental health and social care into the diabetes care pathway. We found that individuals actively being identified by diabetes health providers referred into to the 3DFD service were at higher risk of diabetes complications and costing the health system three times more than using the HbA1c cut-off of 75 mmol/mol (9.0%) alone as in the control group. We also found that the integrated 3DFD service was effective, but not cost-effective, in reducing glycaemic control after adjusting for baseline potential confounders compared to the control group. We also found in the 3DFD group only that measures of psychological and social functioning improved.

4.1 Strengths

We used a study design that allowed us to model a service innovation at a cluster level in the real-world setting of an inner-city with very high levels of socioeconomic deprivation. The criteria were broad and simple to be inclusive to all types of mental health and/or social problems and to ensure that they were user-friendly by busy clinician referrers. This contrasts with other models of integrated care which focused only on depression in diabetes, thus limiting the generalisability of their findings to one comorbidity.^{10,11} We also had ethics committee approval to collect routine clinical data anonymously from the control group, as it was recognised that commissioning/purchasing of health services required comparative evidence of cost-savings. We also achieved high follow-up rates for our primary outcome, HbA1c.

4.2 Limitations

The main limitation is the non-randomised design. An RCT was not appropriate as the service innovation was funded in only two boroughs. As an unexpected consequence, due to the non-randomised design, having a referral system in the intervention group led to

recruitment of participants who were sicker than the control group; they had worse glycaemic control, were younger, more likely to have type 1 diabetes, and at greater risk of health disparities. Although we did not have psychiatric or social data for the control group, we appear to have selected a less sick group and we thus likely underestimated the cost-effectiveness of the intervention. For the 3DFD group, having a referral system that explicitly includes a mental health or social problems appears to encourage health professionals to select individuals for whom they had more concerns. Although we selected a minimum cut-off for HbA1c of ≥ 75 mmol/mol (9.0%) for both groups to identify those who were most likely to be struggling with self-management, the 3DFD clinical teams referred individuals with much higher HbA1c levels. The referring clinician judged whether psychiatric and social morbidity contributed to reduced self-management and this may have resulted in selection bias.

Second, we had a smaller number of practices agreeing to participate in the control borough and their diabetes population may have had better health status. We adjusted for the baseline differences between the 3DFD and control group in the multivariate analysis and used a PSA and the effect of the 3DFD intervention on glycaemic control remained significant. A further limitation is that many 3DFD participants were missing outcome data on psychological measures at 12-month follow-up as these data were being collected as participants presented routinely, potentially biasing our findings towards positive effects on mental health. A fourth limitation is that inner London setting is potentially different from other inner-city settings across the UK, for instance, in its ethnic and socioeconomic diversity. We were not able to adjust for some potential confounders such as marital status. Finally, we conducted several statistical analyses with a relatively small sample size, thus some of our findings may be false positives. Overall our findings are to be interpreted with caution with these caveats and need further validation.

4.3 Interpretation

While there have been many clinical trials of treating depression and diabetes distress in people with diabetes^{10,32–34}, there have been almost no published literature evaluating the benefits on biomedical, psychological and social outcomes of integrating mental health and social care into a diabetes service.³² The cost of diabetes is greater for those who are diagnosed earlier and therefore have a longer duration.³⁵ We observed this in our 3DFD group where costs before treatment were three times higher. The control group shows that the

annual cost of diabetes increases rapidly and the 3DFD intervention suggests that it can slow down this inevitable year-on-year increase in costs.

The cost of 3DFD was £757.35 per person over 12 months and associated with a reduction of 10 mmol/mol (1.1%) in HbA1c. This is favourable compared to adding a second or third diabetes drug, for instance, the cost of adding liraglutide 1.8 mg/day for 12 months would cost the NHS an additional £1,433.24 per person.³⁶ However, as well as knowing the cost of pharmacological interventions, we would also need to establish their effectiveness in comparison to 3DFD as healthcare decisions cannot be made on the basis of cost alone.

The added value of integrating mental health and social care into patient management seems to result in multidimensional improvements in outcomes and of a larger magnitude than those observed in clinical trials of collaborative care.³⁷ Referral processes and pathways of care that include an assessment of mental health and social problems encourage clinicians to identify a group of much higher risk individuals, rather than using poor glycaemic control alone as an indicator of psychological or social distress or greater healthcare utilisation. Another added value is that 3DFD crossed organisational boundaries from primary care to specialist diabetes services, overcoming many communication barriers. There are very few similar models to compare with 3DFD. The Rapid, Assessment, Interface and Discharge (RAID) model is a specialist multidisciplinary mental health service for rapid discharge of mentally ill individuals presenting in ED settings and was associated with significant cost savings, and despite lacking the RCT gold-standard evidence, has been widely disseminated.³⁸ A recent pragmatic cluster RCT of integrated psychological and biomedical approach to multi-morbidity in primary care did not lead to improved quality of life, possibly because social factors were not included.³⁹ Our findings suggest there is now a need for a cluster RCT to test the effectiveness and cost-effectiveness of integrated psychiatric and social care in diabetes services.

5. Conclusions

In summary, a biomedical, psychological, and social criteria-based referral system for identifying and managing high-cost and high-risk individuals with poor glycaemic control can lead to improved health in all three dimensions. The cost of the intervention was lower than second-line diabetes drugs.

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7. Figure legends

Figure 1. Study flow diagram.

8. Tables

Table 1. Baseline characteristics of 3DFD and control participants.

Baseline characteristics		3DFD (n=277) ¹	Control (n=292) ²	p-value
Age (years)		46.8 (15.0)	57.2 (14.2)	p<0.001
Gender (female)		168 (60.7%)	137 (47.7%)	p=0.003
Ethnicity	White	114 (41.2%)	150 (51.4%)	p=0.003
	African/ Caribbean	127 (45.9%)	93 (31.9%)	
	Asian/Mixed/Other	36 (13.0%)	49 (16.8%)	
IMD 2010 quintile	1 – least deprived	2 (0.7%)	0	p<0.001
	2	6 (2.2%)	0	
	3	22 (8.0%)	48 (16.4%)	
	4	147 (53.3%)	108 (37.0%)	
	5 – most deprived	99 (35.9%)	136 (46.6%)	
Type of diabetes	Type 1	90 (32.5%)	23 (8.0%)	p<0.001
	Type 2	187 (67.5%)	264 (92.0%)	
Duration of diabetes (years)		11.4 (8.8)	9.4 (7.3)	p=0.015³
Current insulin therapy		183 (66.3%)	119 (40.8%)	p<0.001
HbA1c (mmol/mol) / (%)		97 (21) / 11.0 (1.9)	93 (17) / 10.7 (1.6)	p=0.01
Serum cholesterol (mmol/L)		4.77 (1.33)	4.69 (1.23)	p=0.53
eGFR (ml.min/1.73m ²)		80.2 (25.6)	74.6 (15.5)	p=0.007
ACR (mg/mmol)		8.4 (17.5)	10.8 (37.9)	p=0.30³
BMI (kg/m ²)		30.0 (7.7)	31.5 (6.4)	p=0.03
BP systolic (mmHg)		130.3 (18.7)	132.4 (15.8)	p=0.21
BP diastolic (mmHg)		77.4 (10.1)	78.9 (9.7)	p=0.12
Macrovascular complications	None	87 (43.3%)	112 (41.0%)	p=0.69
	At least one	114 (56.7%)	161 (59.0%)	
Microvascular complications	None	66 (32.2%)	80 (30.4%)	p=0.76
	At least one	139 (67.8%)	183 (69.6%)	

Data are mean (SD) or n (%), as appropriate. Percentages were calculated after the missing data for the respective variable were excluded.

¹Number of missing cases for the 3DFD group is: Gender=5, IMD quintile=1, Type of diabetes=5, Macrovascular complications=76, Microvascular complications=72.

²Number of missing cases for the control group is: Gender=5, Type of diabetes=5, Macrovascular complications=19, Microvascular complications=29.

³Diabetes duration and ACR values were skewed and non-parametric tests were used.

IMD=Index of Multiple Deprivation; eGFR= estimated glomerular filtration rate; ACR= albumin:creatinine ratio; BMI=body mass index; BP=blood pressure.

Table 2. Results of the regression analyses predicting change in HbA1c and other biomedical outcomes and total follow-up healthcare costs.

	HbA1c (mmol/mol)	Serum cholesterol (mmol/L)	eGFR (ml.min/1.7 3m ²)	ACR (mg/mmol)	BMI (kg/m ²)	BP systolic (mmHg)	BP diastolic (mmHg)	Total follow-up costs (£)
<i>Model coefficients</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)</i>	<i>Estimate (95% CI)¹</i>
Treatment group (control v. 3DFD)	-10.5 (-15.16 to -5.84)	-0.11 (-0.54 to 0.32)	0.66 (-2.67 to 3.99)	-12.08 (-22.24 to -1.93)	-0.04 (-0.63 to 0.56)	0.29 (-3.88 to 4.47)	0.53 (-1.91 to 2.96)	1336.65 (242 to 2351)
Age (years)	-0.37 (-0.55 to -0.19)	0 (-0.01 to 0.02)	-0.11 (-0.24 to 0.02)	-0.14 (-0.51 to 0.24)	0.01 (-0.01 to 0.03)	0.04 (-0.12 to 0.19)	-0.03 (-0.12 to 0.06)	-5.62 (-43.82 to 32.16)
Gender (male v. female)	-0.38 (-4.71 to 3.95)	-0.39 (-0.78 to -0.01)	-1.99 (-4.96 to 0.98)	3.72 (-4.74 to 12.17)	-0.07 (-0.61 to 0.47)	-2.39 (-6.17 to 1.39)	1.03 (-1.18 to 3.23)	-521.48 (-1382.2 to 525.3)
Ethnicity (white v. black)	1.54 (-3.29 to 6.37)	-0.05 (-0.48 to 0.37)	-0.16 (-3.47 to 3.15)	-0.84 (-10.21 to 8.53)	0.09 (-0.51 to 0.69)	-0.13 (-4.34 to 4.09)	-0.8 (-3.26 to 1.66)	-1532.02 (-2664 to -492)
Ethnicity (white v. other)	7.21 (1.16 to 13.27)	0.1 (-0.46 to 0.67)	-0.19 (-4.51 to 4.14)	2.34 (-9.51 to 14.18)	0.42 (-0.33 to 1.18)	0.62 (-4.65 to 5.89)	-0.42 (-3.51 to 2.67)	-1153.53 (-2252 to -163)
Type of diabetes (type 1 v. type 2)	6.10 (-1.18 to 13.38)	-0.33 (-1 to 0.33)	1.21 (-4.12 to 6.54)	-17.69 (-33.29 to -2.09)	-0.47 (-1.42 to 0.48)	-0.21 (-6.74 to 6.32)	1.71 (-2.11 to 5.53)	-1451.17 (-2963 to 657)
IMD 2010 score	0.05 (-0.27 to 0.36)	0.01 (-0.02 to 0.04)	0.01 (-0.22 to 0.23)	0.08 (-0.57 to 0.73)	0 (-0.04 to 0.04)	0.01 (-0.27 to 0.3)	-0.02 (-0.19 to 0.14)	-6.07 (-60.34 to 46.47)
Diabetes duration (years)	0.52 (0.22 to 0.81)	0.01 (-0.02 to 0.03)	0.01 (-0.2 to 0.21)	0.19 (-0.42 to 0.79)	0.01 (-0.03 to 0.05)	-0.31 (-0.57 to -0.06)	-0.1 (-0.25 to 0.05)	27.03 (-38.75 to 83.31)
Change in HbA1c (mmol/mol)								-11.47 (-31.78 to 8.53)
Total baseline costs (£)								0.39 (0.27 to 0.94)
<i>Model statistics</i>								
Adjusted R ²	0.06	0.00	-0.01	0.02	-0.01	0.00	-0.01	0.33

Note: for HbA1c and other biomedical outcomes, negative coefficient estimates indicate decreases in that variable from baseline to 12-month follow-up.

¹Bootstrapped percentile 95% CI's are presented.

Table 3. Healthcare use and costs per-participant in the preceding 12 months from baseline and from 12-month follow-up in the 3DFD versus control group.

	Baseline							
	3DFD			Control			<i>Mean difference in costs (95% CI)²</i>	<i>p-value³</i>
	<i>Number of participants (%)</i>	<i>Number of visits/Length of stay</i>	<i>Cost (£)</i>	<i>Number of participants (%)</i>	<i>Number of visits/Length of stay</i>	<i>Cost (£)</i>		
Inpatient admissions	100 (36.1%)	2.33 (2.14)	2,324 (11,875)	39 (13.4%)	5.79 (26.53)	652 (3,645)	-1,672 (-3,137 to -207)	<i>p<0.001</i>
ED attendance	118 (42.6%)	2.89 (3.40)	150 (316)	65 (22.3%)	1.60 (1.73)	43 (122)	-107 (-147 to -68)	<i>p<0.001</i>
Outpatient clinic attendance	223 (80.5%)	9.92 (10.66)	1,012 (1,555)	228 (78.1%)	4.18 (3.92)	370 (466)	-642 (-833 to -450)	<i>p<0.001</i>
Total			3,486 (12,253)			1,065 (3,870)	-2,421 (-3,936 to -905)	<i>p<0.001</i>
	Follow-up							
Inpatient admissions	103 (37.2%)	3.06 (2.66)	2,365 (7,549)	61 (20.9%)	4.16 (21.34)	1,025 (5,446)	-1,339 (-2,428 to -250)	<i>p<0.001</i>
ED attendance	125 (45.1%)	2.52 (2.78)	140 (285)	82 (28.1%)	1.71 (1.02)	59 (116)	-81 (-117 to -45)	<i>p<0.001</i>
Outpatient clinic attendance	238 (85.9%)	11.46 (11.84)	1,203 (1,418)	221 (75.7%)	5.44 (5.52)	487 (657)	-716 (-900 to -532)	<i>p<0.001</i>
3DFD intervention ¹			757.35					
Total			4,465 (8,214)			1,571 (5,760)	-2,893 (-4,068 to -1,719)	<i>p<0.001</i>

Data are mean (SD) or n (%).

ED = emergency department. No missing data. Length of stay is given in days.

¹Cost of 3DFD intervention per-participant is based on total delivery cost of £209,785.50 for 277 participants.

²3DFD costs are subtracted from control costs.

³All variables were heavily skewed and Mann-Whitney U-tests were used to compare groups.