

Appendix 11: Secondary outcomes measured and results

Number	Study	Mental health outcomes	Psychosocial outcomes	Adherence outcomes	Other physical outcomes	Healthcare utilisation outcomes	Medication related outcomes
1	Anzaoldo-Campos	Depression (PHQ-9): Unclear of MD between two intervention groups (PD or PD-TE groups) and control group. Unadjusted MD was -1.83 favouring the PD group to control and -1.84 for PD-TE group to control.	<p>Self efficacy (Spanish Self-Efficacy): Unclear of MD between two intervention groups (PD or PD-TE groups) and control group. Unadjusted MD was -2.42 favouring the PD group to control and -0.54 for PD-TE group compared to control.</p> <p>Lifestyle (IMEVID): Unclear of MD between two intervention groups (PD or PD-TE groups) and control group. Unadjusted MD was 2.3 favouring the PD group to control and 2.7 favouring the PD-TE group to control.</p> <p>Quality of life (Diabetes 39): Unclear of MD between two intervention groups (PD or PD-TE groups) and control group. Unadjusted MD was -8.88 favouring the PD group to control and -4.87 favouring the PD-TE group to control.</p> <p>Diabetes knowledge (DKQ24): Unclear of MD between two intervention groups (PD or PD-TE groups) and control group. Unadjusted MD was 2.05 favouring the PD group to control and 2.09 favouring the</p>		<p>Triacylglyceride: Unclear of MD between two intervention groups (PD or PD-TE groups) and control group.. Unadjusted MD was -21.46 favouring the PD group to control and -4.55 for PD-TE group compared to control.</p> <p>BMI: Unclear of MD between two intervention groups (PD or PD-TE groups) and control group.. Unadjusted MD was +0.33 comparing the PD group to control and +0.31 for PD-TE group compared to control.</p>		Significantly higher insulin use in PD and PD-TE groups

			PD-TE group to control.				
2	Basudev				Weight MD 0 (p = NS) eGFR -3.9 (p = 0.1)	Care destination: NS change Frequency of contact: NS change	Medication change: 54% of intervention group had a change in glycaemic medication versus 46% in the control group (p=0.04). No other significant change in medications. Medication optimization: NS change
3	Blackberry	Major depression 1.09 (0.49 to 2.46) p= 0.83	Quality of life 0.02 (CI -0.01 to 0.05) p =0.16 Diabetes self efficacy -0.06 (CI -2.22 to 2.10) p 0.96 Diabetes support -0.09 (CI -0.01 to 0.18) p 0.08				
4	Capozza		Patient interaction and satisfaction (CSQ8) with the program by means of survey-intervention patients all scoring over 3 on a four point satisfaction scale. No clear comparison with usual care.				
5	Choe					Process measures: (% before, % after, p value) Rate of HbA1c measurement: 82.9% 92.3% 0.21 Dilated retinal examination: 74.3% 97.3% p= 0.004 Urine ACR or use of ACE Inhibitors: 85.7% 94.9% p= 0.18	

						Monofilament testing for diabetic neuropathy by chart review over 24 months: 62.9% 92.3% p=0.002	
6	Crowley	Depression (PHQ-9): mean difference was not significant.	Diabetes self-management (Self-care inventory revised) SCI-R: mean difference was +7.0 (p=0.047) in favour of intervention	Self reported medication adherence (Morisky medication adherence scale 4): nonsignificant difference		Adverse events similar in both groups	
7	Dale		<p>Diabetes distress (PAID) adjusted score showed no significant difference for two intervention groups versus control.</p> <p>Self efficacy (DMSES) adjusted score showed no significant difference for two intervention groups versus control. PS-CG, +4.17, p=0.28 DSN-CG, +0.38, p=0.94.</p> <p>Self efficacy (DMSES) improved for the patients in the peer support group but there were no significant differences between groups; diabetes related problems (PAID) reduced for those in the diabetes nurse specialists group. In all groups the HbA1c improved, but there were no significant differences between groups</p>		<p>Normal ACR: 1.05 (0.62 to 1.75) p= 0.87</p> <p>Normal eGFR: 0.92 (0.55 to 1.53) p 0.76</p> <p>Current smoker 0.043 (0.55 to 1.53) p 0.72</p> <p>Healthy weight (BMI<25) 2.19 (1.1 to 4.38) p=0.03</p> <p>Weight 0.12 (-1.53 to 1.77) p=0.89</p> <p>Waist circumference Men 0.90 (-1.40 to 3.19) p=0.44</p> <p>Waist circumference Women -1.52 (-4.08 to 1.04) p=0.24</p>		
8	DePue		Mean perceived competence score significant difference 1.6 (CI: 0.9 to 2.4) p< 0.001	Adherence: self reported medication adherence			

			Physical activity Adapted measures of diabetes beliefs; no data reported.	Nonsignificant difference.			
9	Edelman 2010		Self-efficacy using the Perceived Competence Scale Nonsignificant difference	Adherence to medications ??? Morisky self-reported medication adherence scale Nonsignificant difference	BMI nonsignificant differences	Adverse events through structured self report and medical record review Health utilization Cost data	
10	Edelman 2015		Self-efficacy- but no report in Results section Health literacy- but no report in Results section.	Medication adherence (via self report) - but no report in Results section.	No significant differences weight or physical activity.	45.2% of intervention group had GP management plan for diabetes V's 35.5% of controls (non-significant)	
11	Farmer		Functional status as per SF 12 Physical and SF 12 Mental Diabetes treatment satisfaction and satisfaction with nurse <u>SF 12 Physical</u> 46.3 (9.0) V's 44.6 (11.1) MD -0.7 (CI -2.7, 1.4) p = 0.52 <u>SF 12 Mental</u> 49.5 (10.4) V's 52.6 (8.8) MD -1.6 (CI -3.9, 0.6) p = 0.15	MARS Self reported adherence (range 5-25) with a higher score indicating higher levels of adherence Nonsignificant difference	BMI dietary nonsignificant difference.	% reporting hypoglycaemia nonsignificant difference Treatment satisfaction nonsignificant difference	Primary outcome % days over a 12 week period on which the correct number of doses of main glucose lowering medication was taken each day as prescribed. 77.4% (26.3) & days taking correct dose V's 69% = 8.4% MD (P = 0.044)
12	Forjough		Self care data not given				
13	Frosch		Diabetes knowledge: (23 point Diabetes knowledge test) - nonsignificant difference. Self-care behaviours (SDSCA) - nonsignificant difference				Prescribed medications measured: taking most prescribed medications (P = .01; interaction, P = .41), and taking all prescribed medications (P .001; interaction, P=.75).

			Diabetes knowledge and behavioural outcomes by group over time: Exercise was statistically significantly reduced				Nonsignificant difference.
14	Guerci					Symptomatic hyoglycaemia Any hypoglycaemia: 53 (10.4%) in SMBG and 25 (5.2%) in control p= 0.003	Medications nonsignificant difference
15	Heisler		Diabetes social support score - nonsignificant difference Diabetes distress Diabetes QoL -nonsignificant difference	Medication adherence nonsignificant difference Medication intensification: Significant increase in insulin and oral diabetic medication prescribing .	BMI nonsignificant difference		Medication intensification: Significant increase in insulin and oral diabetic medication prescribing .
16	Jacobs				Weight and diet nonsignificant difference	Intervention group had more screening parameters performed (retinal screening, nephropathy and neuropathy)	Medication sse; intervention group had higher use of antiplatelet, diabetic and statin medications.
17	Jameson						Intervention group- 28.8% commenced basal bolus insulin V's 1 (2%) patient in the control group.
18	Jovanovic				HbA1c < 7% 35% V's 21% (but p = 0105)		Medication usage Increase in oral agents in intervention group, without any increase in numbers on insulin. Control group- no change.
19	Keogh		The intervention group reported better personal control, a better understanding of diabetes and an increased belief in treatment effectiveness. They also had fewer symptoms and lower levels of diabetes concern and		Statistically more patients in intervention group achieved at least 1.0% improvement in HbA1c.		

			<p>distress. They also had better psychological well being, adherence to lifestyle factors, self efficacy and family support.</p> <p>Illness perceptions (Brief illness Perception Questionnaire)- statistically significant improvement</p> <p>Psychological wellbeing (12-item Well-Being questionnaire)- statistically significant improvement</p> <p>Diabetes self management (Summary of Diabetes Self-care Activities Questionnaire) Self Efficacy (UK version Diabetes Self-Efficacy Scale)- statistically significant improvement</p> <p>Family support (Diabetes Family Behaviour Checklist)- statistically significant improvement</p>				
20	Kim	<p>Depression (Kim Depression Scale for Korean Americans) nonsignificant difference</p> <p>Quality of Life (Diabetes Quality of Life Measure (DQOL) nonsignificant difference</p>	<p>Diabetes knowledge test (DKT) statistically significant difference</p> <p>Self efficacy (Stanford Chronic Disease Self-Efficacy scale) statistically significant difference</p> <p>Self care (Diabetes self care activitiis (SDSCA) statistically significant difference</p>		<p>% participants achieving HbA1c goals</p> <p>% participants achieving HbA1c goals & achieving HbA1c less 6.5, 7 and 7.5 greater in intervention group (Fig 3). statistically significant. But data not shown.</p> <p>BMI- nonsignificant</p>		

					difference		
21	Krein		General satisfaction score and rating of diabetes provider score was marginally better and statistically better in the intervention group.		BMI nonsignificant difference		
22	Long				BMI nonsignificant difference	Uptake of intervention Peer mentoring: Aiming to have 4 calls per month for 6 months. The Results showed 38% mentors talked 4 times per month and by Month 6, that reduced to 16%.	No difference in hypoglycaemia
23	Maisios					Adherence to follow up: 41/48 and 23/34 patients returned for follow up. 29% intervention group non-compliant.	Use of insulin nonsignificant difference INT: 25% to 40% CONTROL: 15 to 17%
24	Mathers		Decisional conflict: Mean difference between intervention and control groups on the total score for decisional conflict on the total score was -7.72 (CI -12.5, -2.97) Realistic expectations: Were better in intervention group Preferred option: - Proportion undecided: No significant difference Participation in decision-making: Statistically significant difference, intervention group had higher participation rates.				

			<p>Regret score. No significant difference.</p> <p>Acceptability: Most found PDA useful.</p>				
25	McDermott		<p>Test of Functional Health Literacy for Adults (TOFHLA)- unclear if significant result present</p> <p>Assessment of Quality of Life (AQoL) instrument- unclear if significant result present</p>	<p>Waitlist patients had better self-report adherence</p> <p>Adherence: SS reduction</p>	<p>Slight non-significant reductions in rest of other physical outcomes (BMI, ACR, eGFR)</p>	<p>Intervention group patients statistically significantly more likely to have seen a dietician and dentist, be taking inculin and have influenza vaccination.</p>	
26	McMahon					<p>Frequency of data uploads on web-based care management system (used to look at effect on HbA1c primary outcome)</p>	
27	Mons	<p>Symptoms of depression: Geriatric depression scale GDS: No difference between groups.</p>	<p>Health related quality of life (Short Form General Health Survey: SF-12)</p> <p>No difference <u>between</u> groups at 12 months.</p> <p>Statistically significant change at 18 months.</p>				
28	O'Connor			<p>No significant difference between groups regarding medication adherence (one prescription fill within 60 days of prescription date)- 88% in intervention group vs 86% in control group.</p> <p>Similarly there was no significant difference</p>			<p>Medication persistence (two or more prescription fills within 180 days)</p>

				between groups regarding medication persistence (two or more prescription fills within 180 days)			
29	Odegard			No improvement on self reported adherence.			No significant difference in MAI (medication appropriateness) at end of study.
30	Palmas						
31	Phillis-Tsimikas	Self management behaviours and Depression (in separate publication) - not published at time of search so not included	Self management behaviours and Depression (in separate publication)- not published at time of search so not included				
32	Polonsky		GWB WHO-5 - nonsignificant difference			<p>Treatment intensification</p> <p>Changes in treatment: 75.5% of STG patients received a medication change at month 1 V's 28% of ACG patients (p <0.0001).</p> <p>Twice as many STB patients started on insulin between month 1 and 12. Heightened attention paid to subjects.</p> <p>Free meters: Requirement to bring meters to all study visits</p> <p>More frequent study visits STG physicians trained on a treatment algorithm SMBG: Lower test use in</p>	

						STG group (0.77) V's ACG group 1.05 (nonsignificant difference)	
33	Protheroe	<p>Warwick- Edinburgh Mental Well-Being: Adjusted MD was -0.17 (p=0.87)</p> <p>Health Status Measure (from Sf12) Adjusted MD for mental health score was 5.46 (p=0.049)</p>	<p>Diabetes self care (Summary of Diabetes Self-Care Activities Measure) : Adjusted MD was 0.33 (p=0.2)</p> <p>Diabetes Quality of Life (Diabetes Quality of Life Inventory) : Adjusted MD was -4.24 (p=0.46)</p> <p>Diabetes UK Scale Items: Adjusted MD was 0.4 (p=0.22)</p> <p>Health-related Quality of Life (EQ5D) : Adjusted MD was 0.1 (p=0.135)</p> <p>Illness Perception (Brief Illness Perception Score) : Adjusted MD was -5.74 (p=0.04)</p>			No significant difference in resource use (inpatient nights, Emergency Department visits, Outpatient visits, GP visits or practice nurse visits)	
34	Quinn	PHQ-9 depression - nonsignificant difference	<p>Diabetes distress scale - nonsignificant difference</p> <p>Diabetes diabetes inventory - nonsignificant difference</p>		BMI unclear if statistically significant	Hypoglycaemic events and hospitalizations were infrequent in all groups.	
35	Rothman		<p>Diabetes knowledge Satisfaction:</p> <p>(Diabetes Treatment Satisfaction Questionnaire) MD in scores (INT V's control)</p> <p>Diabetes knowledge: +14 (CI 9 to 20)</p> <p>Diabetes treatment satisfaction +3 (CI 1 to 6) statistically significant reduction</p>			Process measures (time spent with patients) and medication changes. But did not factor in any changes made by PCP. Aspirin use higher in intervention group at 12 months. Statin use equal. No statistically significant increase in services in intervention group.	
36	Schillinger		SF-12 instrument for QoL			Functional outcomes:	

			<p>nonsignificant difference</p> <p>Patient assessment of chronic illness care (PACIC) score out of 100</p> <p>Statistically significant difference ATSM +12.2 V's control GVC +12.6 V's control Data present</p> <p>Diabetes Quality Improvement Program (100 score)</p> <p>Self management behavior statistically significant difference ATSM +0.6 V's control GVC +0.3 V's control Data present</p> <p>Diabetes self efficacy statistically significant difference ATSM +6.0 V's control GVC +5.5 V's control Data present</p>			<p>Bed days: ATSM significant reduction</p> <p>Restricted activity, ATSM significant improvement</p> <p><u>Interpersonal Processes of Care</u> for Diverse Populations (IPC) instrument to capture reports of provider's communication. Statistically significant difference ATSM +9.0 V's control</p>	
37	Sen					<p>Primary outcome was adherence to biometric tests:</p> <p>At three months; total adherence rates were 81% in the low incentive arm V's 58% in control (p 0.007) and 77% in high incentive arm V's 58% (p0.02).</p> <p>No difference between the incentive arms.</p> <p>But no difference in the high incentive group V's</p>	

						control at month 6 (at 3 month post intervention follow up).. But the low incentive group still had significant improvement in adherence at month 6 Vs control (62% V's 27%, p 0.002).	
38	Sugiyama	Change Mental Component Summary Score (MCS-12) from the SF-12: A mean difference of +1.6 between intervention and control which was statistically significant	Secondary outcomes: Social support score from the Diabetes Care Profile: non-significant change				
39	Tang		Satisfaction/ Psychosocial wellbeing Intervention group had higher treatment satisfaction (statistically significant) and lower treatment distress scores. Other scales of diabetes distress had no change between groups.		BMI nonsignificant difference	Healthcare utilisation - nonsignificant difference in total physician visits.	Significant increase in new medications started and insulin commencement in intervention group. Patients already on insulin- the intervention group had a statistically significant higher number of dose increases.
40	Taylor		Psychosocial (SF 26 for QoL and Duke Activity Status): Nonsignificant difference in psychological variables Patient and physician satisfaction nonsignificant difference			Medical utilization (physician visits) nonsignificant difference in physician or ED visits	
41	Thom				10-year framingham risk nonsignificant difference		

42	Wild	<p>EQ-5D index: Adjusted MD was 0.00 (non-significant)</p> <p>Total HADS score: Adjusted MD was -0.31 (non-significant)</p>	<p>Self-efficacy: Adjusted MD was +0.69 (non-significant)</p> <p>Self-reported total physical activity score (IPAQ): Adjusted MD was -467.31 (non-significant)</p> <p>Diabetes Knowledge (first 14 items only): Adjusted MD was +0.04 (non-significant)</p>	Medication adherence	<p>Weight: adjusted MD supporting telemonitoring group - 0.35 (p = 0.6)</p> <p>No significant differences in alcohol use, smoking, or urinary sodium/creatinine ratio.</p>	<p>Greater number of telephone calls in intervention group (rate ratio 7.5 p<0.0001)</p>	<p>No significant change in use of insulin or other medications (from Supplementary File 1).</p> <p>No change in forgetfulness taking medications or carelessness taking medications.</p>
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