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Process- and Outcome-Based Financial Incentives to Improve Self-Management and Glycemic Control in People with Type 2 Diabetes in Singapore: A Randomized Controlled Trial

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Abstract

Background Sub-optimally controlled diabetes increases risks for adverse and costly complications. Self-management including glucose monitoring, medication adherence, and exercise are key for optimal glycemic control, yet, poor self-management remains common.

Objective The main objective of the Trial to Incentivize Adherence for Diabetes (TRIAD) study was to determine the effectiveness of financial incentives in improving glycemic control among type 2 diabetes patients in Singapore, and to test whether process-based incentives tied to glucose monitoring, medication adherence, and physical activity are more effective than outcome-based incentives tied to achieving normal glucose readings.

Methods TRIAD is a randomized, controlled, multi-center superiority trial. A total of 240 participants who had at least one recent glycated hemoglobin (HbA1c) being 8.0% or more and on oral diabetes medication were recruited from two polyclinics. They were block-randomized (blocking factor: current vs. new glucometer users) into the usual care plus (UC +) arm, process-based incentive arm, and outcome-based incentive arm in a 2:3:3 ratio. The primary outcome was the mean change in HbA1c at month 6 and was linearly regressed on binary variables indicating the intervention arms, baseline HbA1c levels, a binary variable indicating titration change, and other baseline characteristics.

Results Our findings show that the combined incentive arms trended toward better HbA1c than UC +, but the difference is estimated with great uncertainty (difference -0.31; 95% confidence interval [CI] -0.67 to 0.06). Lending credibility to this result, the proportion of participants who reduced their HbA1c is higher in the combined incentive arms relative to UC + (0.18; 95% CI 0.04, 0.31). We found a small improvement in process- relative to outcome-based incentives, but this was again estimated with great uncertainty (difference -0.05; 95% CI -0.42 to 0.31). Consistent with this improvement, process-based incentives were more effective at improving weekly medication adherent days (0.64; 95% CI -0.04 to 1.32), weekly physically active days (1.37; 95% CI 0.60-2.13), and quality of life (0.04; 95% CI 0.0-0.07) than outcome-based incentives. **Conclusion** This study suggests that both incentive types may be part of a successful self-management strategy. Process-based incentives can improve adherence to intermediary outcomes, while outcome-based incentives focus on glycemic control and are simpler to administer.

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1 Introduction

Sub-optimally controlled diabetes increases risks for a host of adverse and costly complications, including heart attacks, strokes, kidney failure, lower limb amputation(s), blindness, and nerve damage [1]. There is a strong consensus that optimal glycemic control is essential to minimize risks for these complications [2]. Many studies have shown that careful self-management, including regular glucose monitoring, medication adherence, regular exercise, and weight

Key Points for Decision Makers

A lack of diabetes self-management practices remains common.

This study highlights the challenges in achieving improvements in glycemic control and provides only limited evidence that incentives may be part of a successful multicomponent intervention to improve glycemic control and self-management.

More research is required to determine the strategy, size, and type of incentives that may cost-effectively improve self-monitoring and glycemic control among those with type 2 diabetes.

control, supports optimal glycemic control [3–6], resulting in improved health outcomes and lower healthcare utilization and costs, including a reduction in emergency department visits and hospitalizations [7, 8]. Yet, poor self-management remains common [9, 10].

From a behavioral economics perspective, poor self-management is thought to partly arise from people's bias towards the present. Indeed, the cost of self-management, primarily in terms of time and effort, is immediate and certain, whereas the health benefits are distant and uncertain [11, 12]. One strategy to address present bias and improve shortterm glycemic control and long-term health outcomes is to provide people with a near-term benefit, such as a financial incentive. Financial incentives, implemented either alone or as part of multi-component interventions, have been used in many health-related interventions in efforts to overcome present bias [13–23]. However, the literature provides little guidance on what objective one should tie the incentives to. In this study, we explored whether it is more effective to tie the incentives to intermediary processes supporting the desired outcome, or whether it is more effective to incentivize the outcome directly.

Process-based incentives focus on motivating near-term behaviors associated with optimal glycemic control, such as self-monitoring of blood glucose, with the underlying idea that incentivizing these behaviors can overcome people's present bias [24, 25]. However, the challenge with this approach is that individuals could engage in only a subset of behaviors such that overall glycemic control is not effectively improved [26]. An alternative approach is to focus on near-term health outcomes, such as having glucose readings within the acceptable range. This approach also addresses present bias, while providing flexibility on how to attain the objective. Tying incentives to health outcomes is expected to be a more cost-effective strategy than tying it to self-management processes, as incentives are only paid out upon success. However, outcome-based incentives might be less effective than process-based incentives if many people find the specified goals too challenging to make an effort to reach them and/or do not see enough of a direct link between changes in behavior and changes in the target of the incentives (i.e., overall glycemic control) [27].

The aim of the Trial to Incentivize Adherence for Diabetes (TRIAD) study was to test these competing approaches to incentives via a three-arm randomized controlled trial. The first arm, usual care plus (UC+), merely added monitoring devices to diabetes usual care (glucometer, medication tracker, and pedometer) to create a control group. The second arm applied a process-based strategy that tied incentives to regular glucose monitoring, medication adherence, and physical activity. The third arm was outcome based and tied incentives solely to having self-monitored blood glucose readings in the acceptable range. We hypothesized that providing either form of incentive would be more effective than UC+in improving glycemic control. We did not hypothesize which incentive strategy would have the largest effect on glycemic control, as competing arguments can be made supporting each strategy.

2 Methods

2.1 Study Design

A detailed description of the TRIAD study protocol has been published previously [28]. In brief, 240 participants were block-randomized (blocking factor: current vs. new glucometer users) into the UC +, process-based incentives, and outcome-based incentives arms in a 2:3:3 ratio. Our sample size was calculated to detect an effect size of 1.0% in glycated hemoglobin (HbA1c) at a 5% significance level. The study was registered on ClinicalTrials.gov (ID: NCT02224417). Written informed consent was obtained from all participants.

2.2 Participants

Participants were recruited from two polyclinics in Geylang and Bedok estates in Singapore between February 2015 and December 2017. The participant timeline is described in detail in Fig. 1. Recruited participants had sub-optimally controlled diabetes—defined as having at least one HbA1c within the last 6 months of 8.0% or more. Participants were on at least one oral diabetes medication (had been for at least 3 months), were aged 21–70 years, were Singapore citizens or permanent residents, and were able to converse in English or Mandarin. Patients who were on insulin, were unable to take their oral medication independently, were pregnant, or had a physical condition that could be made worse with exercise were excluded from the study.

2.3 Randomization

Prior to recruitment, randomization numbers were generated by the principal investigator and the project coordinator (PC) using Stata 13.2. Participants were block-randomized into one of the three study arms in a ratio of 2:3:3 based on whether they were current glucometer users or not. The PC

Fig. 1 Participant timeline



and a witness external to the study enclosed the assignments in sequentially numbered, opaque, sealed randomization envelopes, which were handed over to the Clinical Research Coordinators (CRCs) at the polyclinics. Upon informed consent, the CRCs drew the next sequential envelope based on the participant's glucometer use status. The allocation was then revealed to both the CRC and participant. The study arm assignment was not revealed to the laboratory staff assessing the primary outcome (i.e., HbA1c).

2.4 Intervention

All participants received usual care, as per the SingHealth Polyclinics structured framework for diabetes patients, including information on the recommended guidelines on blood glucose monitoring, acceptable blood glucose range, medication adherence, and physical activity (see Fig. 2).

To tease out the independent effect of incentives, each participant, regardless of which arm they were assigned, received a TRUEresultTM glucometer to measure their blood glucose if they did not already have one, an eCAPTM to track their medication adherence, and a Fitbit ZipTM to monitor their physical activity. Participants also received regular arm-specific text messages (7, 28 and 56 days after the baseline visit and 28 and 56 days after the month 3 visit) to remind them to exercise regularly, take their medications as prescribed, and monitor their blood glucose regularly (see Fig. 3). Because of these additions to usual care, we called the control arm UC + .

The process-based incentive participants earned financial incentives contingent on meeting specified intermediary health behaviors: 3.50 Singapore dollars (S\$) (S\$1 = US\$0.74, as at 11 November 2020) weekly if they measured their blood glucose on three non-consecutive days each week, S\$0.50 daily if they took their medication as prescribed, and S\$1 daily if they completed 8000 steps as recorded by the Fitbit ZipTM. The outcome-based incentive participants earned S\$2 weekly if they had one pre-meal glucose reading within the acceptable range of 4-7 mmol/L (72-126 mg/dL), S\$7 if they had two pre-meal glucose readings within the acceptable range, or S\$14 if they had three pre-meal glucose readings within the acceptable range in a week. The maximum amount of incentives that participants in the process and outcome arms could earn per week was S\$14 (US\$10.36). This is a relatively small amount but more than enough to offset the additional cost of buying test strips and lancets for three glucose measurements per week, which ranges from S\$2.25 to S\$5.52 (prices as of 11 November 2020) depending on the glucometer brand and model. Participants in the control arm did not receive any financial incentive but received a S\$75 non-contingent payment at the end of month 6 for participating in the study. Incentives

•	 Aim to have blood sugar levels between 4.0 and 7.0mmol/L before your meals. 				
•	Measure your blood sugar levels at least on 3 non-consecutive days in the week.				
•	The best time to test your blood sugar is before you take your breakfast.				
•	 You are also recommended to test your blood sugar <u>2 hours</u> <u>after your meals</u>. readings should be below 8.5 mmol/L if you have type 2 diabetes. 				
•	Aim to take 8,000 steps every day. Take your diabetes medication(s) as				
•	The Site Study Coordinator will note in the table below when you should take your medication:				
Nan	ne of diabetes medication	Breakfast	Lunch	Dinner	

Recommendations to optimally manage your diabetes

Fig. 2 Sample of the study leaflet on self-management

were paid out in the form of supermarket vouchers at month 3 and month 6. The intervention lasted for 6 months, from March 2015 to June 2018. Although a longer post-incentive follow-up period was originally planned, due to the enactment of a new regulation on human biomedical research, only a 6-month evaluation was possible.

2.5 Data Collection

Participants were assessed at baseline, month 3, and month 6. At each assessment, information from their pedometer, medication tracker and glucometer were uploaded to the study website and participants' HbA1c was recorded. Paper-based survey questionnaires were also administered at baseline and month 6. The baseline questionnaire assessed the socio-demographic characteristics of the participants. Both baseline and month 6 questionnaires included the European Quality of Life–5 Dimensions–5 Levels (EQ-5D-5L), Brief Illness Perception Questionnaire (BIPQ), Self-Monitoring of Blood Glucose (SMBG), and Beliefs about Medication Questionnaire (BMQ).

Fig. 3 Text messages sent to participants. *CRC* Clinical Research Coordinator, *SMS* short message service, *SGD* Singapore dollars, *TRIAD* Trial to Incentivize Adherence for Diabetes, *UC* + usual care plus

SMS Schedule to participants				
Time which	ID			
	UC +	Process	Outcome	
Week 1	1	1	1	
Month 1	2-1	2-2	2-3	
Month 2	3-1	3-2	3-3	
Month 4	2-1	2-2	2-3	
Month 5	3-1	3-2	3-3	
Day 21 of each month where no step activity is recorded	4	4	4	

ID	Text Message
1	Dear participant, many thanks for taking part in the TRIAD study. Please remember that regular physical activity, taking medication as recommended and monitoring your glucose level will help manage your diabetes. For assistance, please contact (CRC name) at (CRC contact).
2-1	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will receive SGD15 for attending the Month 3 Visit. You will also receive SGD90 at the end of the study for recording your data and attending the Month 6 Visit. For assistance, please contact (CRC name) at (CRC contact).
2-2	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will earn SGD14 weekly for meeting all activity, medicine-taking and glucose testing goals. For assistance, please contact (CRC name) at (CRC contact).
2-3	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will earn SGD14 weekly for meeting your glucose level goals. For assistance, please contact (CRC name) at (CRC contact).
3-1	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will receive SGD90 at the end of the study for recording your data and attending the Month 6 Visit. For assistance, please contact (CRC name) at (CRC contact).
3-2	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will earn SGD14 weekly for meeting all goals. For assistance, please contact (CRC name) at (CRC contact).
3-3	Dear TRIAD participant, please remember that regular physical activity, taking medication as advised and glucose level monitoring will help manage your diabetes. You will earn SGD14 weekly for meeting your goals. For assistance, please contact (CRC name) at (CRC contact).
4	Dear TRIAD participant, A gentle reminder that if you have not yet synced your Fitbit you have 1 week left to sync. If you wish you can sync at the Polyclinic, please contact (CRC name) at (CRC contact). Thank you.

2.6 Outcomes

The primary outcome was the mean change in HbA1c at month 6 from baseline. Secondary outcomes included mean number of glucose readings within the acceptable range (4–7 mmol/L), mean number of glucose readings (i.e., with a minimum of three non-consecutive testing days in a week as per SingHealth Polyclinics recommendation), mean number of medication adherent days (i.e., taking all the medication doses in a day within the pre-defined time windows, as verified by the eCAPTM medication tracker), and mean number of physically active days (i.e., logging at least 8000 steps per day on the Fitbit ZipTM) on the last week of intervention.

Exploratory outcomes included the proportion of participants whose oral medication was titrated up and/or who switched to another medication, including insulin, during the intervention, and mean changes from baseline in EQ-5D-5L, BIPQ, SMBG, and BMQ scores.

2.7 Statistical Analysis

All analyses were carried out as pre-specified in the study protocol and followed an intention-to-treat approach. As such, all missing data in both independent and dependent variables were filled using Markov chain Monte Carlo multiple imputation.

2.7.1 Primary Analyses

We first tested the effectiveness of financial incentives, either process or outcome based, in reducing HbA1c levels. Change in HbA1c readings from baseline to month 6 was linearly regressed on a binary variable indicating participation in the incentive arms, with UC as the reference category, baseline HbA1c readings, the interval (in days) between baseline and month 6 HbA1c test date, and baseline characteristics, including gender, age, education level, employment status, income, EQ-5D-5L, BIPQ, SMBG, and BMQ scores, and number of comorbidities. The analysis was performed using an intention-to-treat approach.

To measure the difference in effectiveness between incentive strategies, we used the same model as above but restricted the sample to the participants in the incentive arms and changed the reference category of the binary variable to the process-incentive arm.

As sensitivity analyses, we ran a regression analysis carrying forward the last measured HbA1c level (baseline or month 3), and a regression with no imputation of the missing HbA1c observations.

2.7.2 Secondary Analyses

Using the same approach as for the primary analyses, we tested the effectiveness of financial incentives in improving treatment adherence as measured by the mean number of glucose readings within the acceptable range, mean number of glucose readings, mean number of medication-adherent days, and mean number of physically active days on the last week of the intervention. These were separately regressed against the same set of independent variables used in the primary analyses.

2.7.3 Exploratory Analyses

To test whether the intervention encouraged changes in medication adherence, we estimated separate logistic regressions of binary variables indicating whether the participants had a titration/change of their oral medicine or whether they switched to insulin therapy during the intervention. We also ran separate linear regressions on the changes from baseline in EQ-5D-5L, BIPQ, SMBG, and BMQ scores at month 6. For all models, the covariates were the binary variables indicating the incentive arms and the same baseline characteristics used in the primary analyses.

We also analyzed the effect of potential moderators, including gender, age, language spoken, education, occupation, income, EQ-5D-5L, BIPQ, SMBG, and BMQ scores, and number of comorbidities on the change in HbA1c at month 6. To do so, the model used in the primary analysis was extended by adding interaction terms (in separate regressions) between each potential moderator and the binary variables indicating study arms.

3 Results

A total of 1387 patients were assessed for eligibility (Fig. 4). Eight hundred and eighty-four (63.7%) were found eligible to participate. Among the eligible, 240 (27%) responded to the invitation to participate and were consented and randomized into the three arms, 61 into UC +, 87 into the process-based incentive arm, and 92 into the outcome-based incentive arm. Twenty-eight participants (11.7%) withdrew from the study before the month 6 assessment, while 14 (5.8%) were discontinued due to insulin initiation. The proportion of participants who were lost to follow-up, either due to insulin initiation or other reasons, is not statistically different across study arms (*p* value 0.71). A summary of missing observations is reported in Fig. 5.

Baseline participant characteristics are shown in Table 1. On average, participants were 55 years old, had two children, and had a baseline HbA1c of 9.1%. Only 19% reported that their health was excellent or very good. Thirty-four percent reported that they were self-monitoring their blood glucose. There were no observed statistical differences in socio-demographic characteristics between the incentive and control arms.

Table 2 shows the estimated incremental effects of incentives, either outcome or process based. The mean difference is in the hypothesized direction, a greater reduction in HbA1c (difference - 0.31; 95% confidence interval [CI] -0.67 to 0.06) compared to UC +, but the difference is estimated with great uncertainty (p value 0.11). Consistent with incentives having an effect, the proportion of participants who had any improvement in HbA1c is higher in the incentive arms by 18% (95% CI 4–31) than in UC +. Incentive arm participants, on average, also had 0.32 more glucose readings within the acceptable range (out of three tests per week) (95% CI 0.07-0.57), had 0.40 more glucose readings (out of three tests per week) (95% CI 0.04-0.76), were more adherent to their medication by 0.72 days (95% CI 0.05-1.38), and were more physically active by 1.12 days (95% CI 0.38–1.86). Participants in the incentive arms also had higher treatment control scores by 0.62 (95% CI - 0.02)to 1.26) compared to control group participants, but this result was also estimated with great uncertainty. Other outcome and process measures showed no consistent trends and were associated with large CIs.

The incremental effects of outcome- compared to process-based incentives are reported in Table 3. The difference in HbA1c between the process and outcome arms was small and estimated with great uncertainty (difference -0.05; 95% CI -0.42 to 0.31). This conclusion holds for the secondary outcomes considered: the proportion of participants who had any improvement in HbA1c (difference -0.02; 95%



CI – 0.14 to 0.11), the mean number of glucose readings within the acceptable range (out of three tests per week) (difference 0.07; 95% CI – 0.21 to 0.34), and the mean number of glucose readings (out of three tests per week) (difference – 0.06; 95% CI – 0.45 to 0.32). The mean incentive payout on the last week of the intervention was also similar between the two arms (process = S\$5.43 [95% CI 4.22–6.62] vs. outcome = S\$6.21 [95% CI 4.47–7.95]).

Lending some support to the hypothesis that processbased incentives improve intermediate outcomes, outcome-arm participants had fewer medication adherent days (difference -0.64; 95% CI -1.32 to 0.04) and were less physically active during the last week of the intervention (difference -1.37 days; 95% CI -2.13 to -0.60), although these results were again estimated with great uncertainty. Further, self-reported EQ-5D-5L scores worsened among outcome-arm participants compared to process-arm participants (difference -0.04; 95% CI -0.07 to -0.004). There were no clear differences between groups in the treatment control domain ("How much do you think your treatment can help your diabetes?") or in the other exploratory outcomes considered.

We tested the robustness of our primary and secondary outcome estimates using [1] regressions not controlling for

Table 1 Participants' baseline characteristics		All participants	UC + arm	Incentive arms	
characteristics				Process	Outcome
		(N=240)	(N=61)	(N=87)	(N=92)
	Socio-demographic characteristics				
	Age, mean (SD)	55.23 (8.3)	54.8 (8.4)	54.7 (8.2)	56.1 (8.3)
	Gender, <i>n</i> (%)				
	Male	130 (54.2)	35 (57.4)	49 (56.3)	46 (50.0)
	Female	110 (45.8)	26 (42.6)	38 (43.7)	46 (50.0)
	Highest level of education, n (%)				
	No formal education/primary	41 (17.1)	10 (16.4)	14 (16.1)	17 (18.5)
	Secondary	105 (43.7)	26 (42.6)	35 (40.2)	44 (47.8)
	Post-secondary	94 (39.2)	25 (41.0)	38 (43.7)	31 (33.7)
	Ethnicity, n (%)				
	Chinese	117 (48.8)	22 (36.1)	44 (50.6)	51 (55.4)
	Malay	60 (25.0)	18 (29.5)	16 (18.4)	26 (28.3)
	Indian/others	63 (26.3)	21 (34.4)	27 (31.0)	15 (16.3)
	Married, n (%)	175 (72.9)	45 (73.8)	64 (73.6)	66 (71.7)
	No. of children, mean (SD)	2.1 (1.3)	2.2 (1.1)	2.1 (1.4)	1.9(1.3)
	Housing type, <i>n</i> (%)				
	HDB/JTC flat (1–3 room)	85 (35.4)	17 (27.9)	35 (40.2)	33 (35.9)
	HDB/JTC flat (4 room)	85 (35.4)	26 (42.6)	21 (24.1)	38 (41.3)
	HDB/JTC flat (5 room)/condominium/bun- galow/semi-detached/terrace house	70 (29.2)	18 (29.5)	31 (35.6)	21 (22.8)
	Household's average monthly income, n (%)				
	No income/below S\$2000	71 (29.6)	12 (19.7)	28 (32.2)	31 (33.7)
	S\$2000–S\$3999	58 (24.2)	18 (29.5)	19 (21.8)	21 (22.8)
	S\$4000 and over	60 (25.0)	16 (26.2)	20 (23.0)	24 (26.1)
	Refused	51 (21.3)	15 (24.6)	20 (23.0)	16 (17.4)
	Currently employed, n (%)	143 (59.6)	34 (55.7)	58 (66.7)	51 (55.4)
	Self-monitoring of blood glucose	82 (34.2)	20 (32.8)	33 (37.9)	29 (31.5)
	Primary outcome				
	HbA1c reading, mean (SD)	9.1 (1.3)	9.1 (1.4)	9.0 (1.2)	9.3 (1.4)
	Exploratory outcomes				
	EQ-5D-5L, mean (SD)	0.91 (0.14)	0.89 (0.15)	0.92 (0.13)	0.92 (0.15)
	BIPQ total score, range 8-80, mean (SD)	38.7 (9.6)	38.4 (10.3)	37.8 (9.9)	39.9 (8.9)
	SMBQ score, range 6–54, mean (SD)	26.5 (4.7)	25.9 (4.5)	27.1 (4.5)	26.4 (4.9)
	BMQ General score	23.2 (4.5)	22.6 (4.2)	23.2 (4.8)	23.5 (4.4)
	Number of comorbidities ^a	1.3 (0.9)	1.4 (0.96)	1.3 (0.86)	1.4 (0.90)

BIPQ Brief Illness Perception Questionnaire, BMQ Beliefs about Medication Questionnaire, EQ-5D-5L European Quality of Life-5 Dimensions-5 Levels, HDB Housing and Development Board, HbA1c glycated hemoglobin, JTC Jurong Town Corporation, S\$ Singapore dollars SMBQ Self-Monitoring of Blood Glucose, UC+usual care plus

^aThirty-four participants had missing/don't know/refused answers

confounders, [2] last observation carried forward and [3] using a per protocol approach. Results from these estimation methods were similar to the reported estimates in Tables 2 and 3. Lastly, we tested for a range of moderators for the incentive effect and found no clear signs of effect for any of those tested, although this may be due to a lack of statistical power for testing such hypotheses (please refer to Supplementary Information Tables 1.1-1.3 and 2.1-2.3 in the supplementary electronic material).

Table 2 Estimated effects of the intervention by arms and the incremental effect of incentive^a (N=240) Source: Author calculations using the data collected from the study

	Study arms		Incremental effect of incen- tive	
	UC+	Incentive	Estimate	[95% CI]
Primary outcome				
Mean change in HbA1c at month 6	- 0.73	- 1.04	- 0.31	[-0.67 to 0.06]
Secondary outcomes				
Mean no. of glucose readings within acceptable range (out of 3 tests) during the last week of intervention	0.16	0.48	0.32	[0.07 to 0.57]
Mean no. of glucose readings (out of 3 tests) during the last week of intervention	0.73	1.12	0.40	[0.04 to 0.76]
Mean no. of medication adherent days during the last week of intervention	0.97	1.69	0.72	[0.05 to 1.38]
Mean no. of physically active days during the last week of intervention	1.24	2.35	1.12	[0.38 to 1.86]
Exploratory outcomes				
Proportion of participants who titrated up their oral medication during the intervention	0.35	0.39	0.04	[-0.1 to 0.18]
Proportion of participants who switched to insulin treatment during the intervention	0.09	0.05	- 0.04	[-0.12 to 0.04]
Mean change in EQ-5D-5L at month 6	0.01	0.01	0.002	[-0.03 to 0.04]
Mean change in overall BIPQ score at month 6	- 1.59	- 1.91	- 0.32	[-3.02 to 2.38]
Mean change in BIPQ Treatment Control score at month 6	- 0.31	0.31	0.62	[-0.02 to 1.26]
Mean change in SMBG score at month 6	0.49	0.50	0.01	[-0.12 to 0.13]
Mean change in BMQ Specific score at month 6	- 0.35	0.33	0.68	[-0.59 to 1.94]
Additional outcomes				
Proportion of participants who had improvement in HbA1c at month 6	0.64	0.81	0.18	[0.04 to 0.31]

BIPQ Brief Illness Perception Questionnaire, BMQ Beliefs about Medication Questionnaire, CI confidence interval, EQ-5D-5L European Quality of Life-5 Dimensions-5 Levels, HbA1c glycated hemoglobin, SMBQ Self-Monitoring of Blood Glucose, UC+usual care plus

^aCalculated as the difference in change from baseline at month 6 between intervention and control groups

4 Discussion

The first objective of this study was to quantify the effect of financial incentives on glycemic control among polyclinic patients with sub-optimally controlled diabetes. We found that financial incentives reduced HbA1c by 0.31 compared to a control group receiving usual care and monitoring devices. Even though this result was associated with a fairly large p value (p value 0.11), there are several reasons to suggest that incentives had an effect. First, we calculated an additional outcome for the proportion of participants who improved their baseline glycemic control at month 6 and found that 18% more participants improved their HbA1c in the incentive groups (p value 0.013). Moreover, we also found evidence consistent with the effectiveness of incentives for the number of glucose readings within the acceptable range (0.32), number of glucose readings (0.40), weekly medication adherent days (0.72), and weekly physically active days (1.12).

Our results are consistent with other studies that aimed to achieve a reduction in HbA1c through financial incentives. These studies showed significant behavior changes, i.e., improvements in medication adherence, regular physical activity, and/or glucose monitoring but did not show clinically significant improvements in glycemic control [18, 29–31], or had clinically significant improvements that were not statistically significant based on conventional p values [32, 33]. Overall, evidence suggests that financial incentives alone have a small to moderate effect on glucose control and, consequently, that a larger sample size than that used in our study is needed to confirm this effect.

A notable finding is that only 34% of the participants in our sample engaged in self-monitoring of blood glucose at baseline. The low rate of monitoring and lack of regular monitoring may be due to patients' negative perception and attitude towards glucose self-monitoring. The discomfort associated with testing and potential frustration with high glucose readings could be some of the barriers to regular self-monitoring [34]. Cost could also be an additional barrier as the approximate cost of glucose monitoring three times a week incurred by a patient ranges from S\$2.25 to S\$5.52 (prices as of 11 November 2020) depending on the glucometer brand and model. Despite the low level of glucose monitoring at baseline, financial incentives were effective in increasing glucose monitoring. However, the glucose monitoring incentive may have inadvertently encouraged process-arm participants to overemphasize testing in lieu of behavior change. Several authors have noted that it is not **Table 3** Estimated effects of the intervention by incentive arms and the incremental effect of outcome-based incentive^a (N=240) Source: Author calculations using the data collected from the study

	Incentive arms		Incremental effect of outcome-based vs. process- based incentives	
	Process	Outcome	Estimate	[95% CI]
Primary outcome				
Mean change in HbA1c at month 6	- 1.04	- 1.10	- 0.05	[-0.42 to 0.31]
Secondary outcomes				
Mean no. of glucose readings within acceptable range (out of 3 tests) during the last week of intervention	0.44	0.51	0.07	[-0.21 to 0.34]
Mean no. of glucose readings (out of 3 tests) during the last week of intervention	1.20	1.14	- 0.06	[-0.45 to 0.32]
Mean no. of medication adherent days during the last week of intervention	2.02	1.38	- 0.64	[-1.32 to 0.04]
Mean no. of physically active days during the last week of intervention	3.12	1.76	- 1.37	[-2.13 to -0.60]
Mean incentive payout during the last week of intervention	5.43	6.21	0.79	[-1.62 to 3.19]
Mean time (in minutes) taken by the intervention during the last week of intervention	15.74	12.91	- 2.84	[-4.84 to -0.83]
Exploratory outcomes				
Proportion of participants who titrated up their oral medication during the intervention	0.43	0.36	- 0.08	[-0.22 to 0.07]
Proportion of participants who switched to insulin treatment during the intervention	0.05	0.05	0.00	[-0.07 to 0.07]
Mean change in EQ-5D-5L at month 6	0.03	- 0.01	- 0.04	[-0.07 to -0.004]
Mean change in BIPQ at month 6	-0.78	- 3.09	- 2.31	[-4.92 to 0.31]
Mean change in BIPQ Treatment Control score at month 6	0.35	0.51	0.16	[-0.42 to 0.73]
Mean change in SMBG score at month 6	0.49	0.51	0.02	[0.10 to 0.14]
Mean change in BMQ Specific score at month 6	0.06	0.43	0.37	[-0.90 to 1.64]
Additional outcomes				
Proportion of participants who had improvement in HbA1c at month 6	0.82	0.80	- 0.02	[-0.14 to 0.11]

BIPQ Brief Illness Perception Questionnaire, BMQ Beliefs about Medication Questionnaire, CI confidence interval, EQ-5D-5L European Quality of Life–5 Dimensions–5 Levels, HbA1c glycated hemoglobin, SMBQ Self-Monitoring of Blood Glucose

^aCalculated as the difference in change from baseline at month 6 between that adherence outcome and process groups

uncommon for people who are testing their blood glucose to be proficient at and feel confident in their ability to perform tests, but to not use the results to influence their diet and exercise choices [35–38].

Our results do not show any significant difference in effectiveness between process- and outcome-based incentives on glycemic control. However, process-based incentives were statistically significantly more effective at improving medication adherence and physical activity at the 10% and 5% level, respectively, behaviors which are necessary for good glycemic control. Furthermore, process-based incentives participants reported an increase in their quality of life compared to UC + and outcome-based incentives participants. This increase in perceived well-being could possibly be due to the reinforcing effect of incentives on healthy self-management behaviors such as increased physical activity [39]. While there was no difference in incentive payouts between incentive groups, process-group incentives took more time to administer in the context of this trial and required more monitoring devices.

Although our goal was to tease out the independent effectiveness of process versus outcome incentives, it is likely

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that neither strategy is sufficient as a stand-alone intervention. Our study coupled the incentives with technology (i.e., monitoring devices), reminders, and other program features. However, since those in the control group received these intervention components as an addition to usual care, we cannot state whether the combined intervention would have been more effective relative to usual care alone. This should be an area of future research. Future studies could also test incentivizing both processes and outcomes to see whether or not this approach is more effective than incentivizing just one or the other [18, 19, 40].

Our study has many strengths, including the rigorous trial design, but also several weaknesses. Our statistically insignificant HbA1c results may be due to the lack of power given by our sample size calculation. Our results may have been stronger if we recruited participants who had higher HbA1c values at baseline, as they have more ability to improve. However, that would have limited our ability to recruit the required number of participants in the time available. Another challenge was in using blood glucose as an outcome to be incentivized. The advantage of blood glucose, over HbA1c, is that it is modifiable and measurable in the near-term. However, intraday fluctuations in glucose readings suggest that an incentive scheme integrating blood glucose outcomes with HbA1c outcomes may better translate into long-term glycemic control. Our results are also likely driven by the size and type of incentives offered [20, 41]. This is a problem with all incentive-based studies. It is also important to consider in interpreting our results that our study participation rate is low. Only 27% of the eligible participants joined the study, thus our results may not be generalizable. Finally, we deviated from the protocol by not analyzing the changes from baseline in HbA1c at month 12 and month 18 due to recent changes in the regulations on human biomedical research in Singapore that made it infeasible to collect information beyond the month 6 assessment. A longer duration would have enabled us to observe the intervention's full effect on HbA1c [42, 43].

5 Conclusion

Our results highlight the challenges in achieving improvements in glycemic control, yet provide suggestive evidence that incentives may be part of a successful multicomponent intervention strategy [18, 20]. While there was no significant difference in effectiveness between process- and outcomebased incentives, process-based incentives improved medication adherence, physical activity level, and quality of life. On the other hand, process-based incentives are potentially more costly to administer due to the number of devices they require. More research is needed to determine the most costeffective strategies for implementing incentives for management of diabetes and other chronic diseases.

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Declarations

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Conflict of Interest The authors do not have any conflicts of interest to declare.

Ethics Approval The study was approved by the SingHealth Centralised Institutional Review Board E (Ref. Numbers 2013/830/E & 2018/2162) and conducted in accordance with the ethical standards of the Declaration of Helsinki.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication All authors have reviewed and approved the manuscript and consent to its publication.

Availability of data and material Access to de-identified data will be granted to entities with an IRB approval for use that is consistent with Singapore's data privacy laws and the study research protocol.

Code availability The code can be made available upon request for non-commercial use.

Trial Registry The ClinicalTrials.gov Identifier is NCT02224417. The trial was registered 22 August 2014.

Trial Protocol The protocol is available from https://trialsjournal-biome dcentral-com.libproxy1.nus.edu.sg/articles/10.1186/s13063-017-2288-6.

Authors' Contribution MB and EAF conceived and designed the study, conducted the analysis and interpretation of the data, and led the manuscript preparation. MS and NCT contributed to the conception and design of the study and helped oversee recruitment, data acquisition, and implementation on site. CYLT assisted with overseeing recruitment and the implementation of the study on site. FGB contributed to the analysis and interpretation of data and helped draft and finalize the manuscript. JB helped amend the study protocol, coordinate the study, collect data, and draft and finalize the manuscript. All authors reviewed and approved the final manuscript.

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