Original Article

Economic evaluation of a mobile phone text-message intervention for Australian adults with type 2 diabetes

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Background: The rising prevalence of type 2 diabetes in Australia is a public health concern, contributing to significant disease burden and economic costs. Text-message programs have been shown to improve health outcomes for people with type 2 diabetes, however they remain underutilized, and no evidence exists on their cost-effectiveness or costs of scale up to a population level in Australia. This study aimed to determine the cost-effectiveness and cost-utility of a 6-month text-message intervention (DTEXT) to improve glycated hemoglobin (HbA1c) and self-management behaviors for Australian adults with type 2 diabetes.

Methods: A within-trial economic evaluation was conducted on the DTEXT randomized controlled trial. Incremental cost-effectiveness ratios (ICERs) were determined per 11 mmol/mol (1%) reduced HbA1c and per quality adjusted life year (QALY) gained, compared to usual care. Cost-effectiveness acceptability curves (CEAC) determined the probability of the intervention being cost-effective over a range of willingness to pay thresholds. A scenario analysis was conducted to determine how cost-effectiveness was impacted by using current implementation costs.

Results: The DTEXT intervention cost AU$36 (INT$24) per participant, with an ICER of AU$311 (INT$211) per 11 mmol/mol (1%) reduced HbA1c. Based on HbA1c outcomes, DTEXT had a 33% probability of being effective and cost-saving. Based on the QALY outcomes, the intervention had only a 24% probability of being cost-effective. Scenario analysis indicated costs per participant of AU$13 (INT$9) to deliver the intervention, with a reduced incremental cost effectiveness ratio of AU$151 (INT$103) per 11 mmol/mol (1%) reduced HbA1c and a 38% probability of being effective and cost-saving.

Conclusions: DTEXT was low cost and potentially scalable, but only had a low to moderate probability of being effective and cost saving. Further research should determine more targeted approaches that may improve cost-effectiveness.

Trial Registration: ACTRN12617000416392.

Keywords: Economic evaluation; cost-effectiveness; diabetes; text-messages; self-management

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Introduction

Diabetes prevalence in Australia is rising, having almost tripled between 2000 and 2020 with an estimated 1.3 million (1 in 20) people with the disease, which is reported to be an underestimation of true prevalence (1). Accounting for around 90% of all diabetes cases (2), type 2 diabetes attributed 2.3% of the total burden of disease in Australia in 2018 (3), being ranked the 12th leading contributor to disease burden (1) making it a public health concern that will worsen if rates continue to increase by a further 25% in 2030 and 51% by 2045 as predicted (2). The total burden of type 2 diabetes is largely attributable to modifiable risk factors such as overweight and obesity (36%), diet (19%), physical inactivity (13.8%) and tobacco use (2%) (1). Self-management education for adults with type 2 diabetes has been shown to improve health outcomes (4), however access and attendance in Australia is poor (5,6), and only half of those with the disease meet the recommendations for type 2 diabetes management (7).

The economic burden from type 2 diabetes on the healthcare system is significant (8) costing the Australian government $1.9bn in 2018–2019 (1), with the largest expenditure attributed to government subsidized medications (44%) and hospital services (40%) (9). Predictions show that for the hospital system in New South Wales (NSW) alone, Australia's most populated state, costs are expected to become unsustainable totaling $21.7bn over the next decade if no changes to current practices occur (10). Reductions in glycated hemoglobin (HbA1c) have been shown to delay the onset and slow the progression of type 2 diabetes, and reduce diabetes-related complications and death (11). To better support people with type 2 diabetes manage their condition, and reduce the economic burden on the Australian health system, new cost-effective treatment strategies are required (12,13).

Text-message programs for people with type 2 diabetes have been shown to improve health outcomes and self-management behaviors, are relatively inexpensive and provide a highly accessible mode of communication with the potential to address health disparities in diabetes care (14). A meta-analysis of 1,701 participants with type 2 diabetes receiving unidirectional text-messages showed a significant reduction in HbA1c of 0.38% (15), and a recent review on text-message programs for people with type 2 diabetes demonstrated a consistent moderate effect size on improvements in HbA1c (14). Despite this, text-message programs are an underutilized adjunct to clinical care (14), and there is no evidence on their cost-effectiveness or costs of scale-up to a population level in the Australian context. Economic evidence is crucial to inform decision makers which interventions represent value for money to ensure limited health care budgets are well spent (16,17). In 2017–2018 we conducted a pragmatic 2-armed, parallel, non-blinded randomized controlled trial (RCT) to determine the effectiveness of a 6-month text-message intervention (DTEXT: ACTRN12617000416392) compared to usual care, for people with type 2 diabetes (18). The intervention was highly accepted and resulted in significant improvements in consumption of vegetables, fruit and sweet discretionary foods, and a non-significant trend for improved HbA1c (19). The present study aimed to determine the cost-effectiveness and cost-utility of DTEXT to improve HbA1c and self-management behaviors for Australian adults with type 2 diabetes. We present the following article in accordance with

Highlight box

Key findings

- The cost of delivering a text message intervention to people with type 2 diabetes in Australia was AU$36 per participant. The intervention had a 33% probability of being effective and cost-saving based on glycated hemoglobin outcomes. It had a 24% probability of being cost-effective based on quality adjusted life year outcomes.

What is known and what is new?

- Text message programs have been shown to improve the health outcomes for people with type 2 diabetes. Our study is the first to provide evidence on the cost-effectiveness of a text message intervention to improve the health of people with type 2 diabetes in Australia.

What is the implication, and what should change now?

- There is the need for new cost-effective treatment strategies due to the significant economic burden from type 2 diabetes. Research is needed to examine the costs and cost-effectiveness of the intervention with key populations.

the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting checklist (20) (available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-26/rc).

Methods

We conducted a within-trial economic evaluation on the RCT to determine the cost-effectiveness and cost-utility of DTEXT (intervention arm), compared to usual care only (control arm), on diabetes management for Australian adults with type 2 diabetes. A detailed study protocol for DTEXT has been published elsewhere (18). Whilst the observed difference in HbA1c between the intervention and control groups was non-significant, we proceeded with the planned economic evaluation, including a cost-utility analysis, to determine if the intervention could be cost saving, and to quantify the probability of it being cost-effective. A health funder plus patient perspective was used for the evaluation as costs are borne by both the Australian health system and the person living with type 2 diabetes in terms of out-of-pocket healthcare costs.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Wollongong & Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (No. 2016/343) and informed consent was taken from all individual participants.

Subjects

Participants were community dwelling residents of New South Wales (NSW), Australia, with type 2 diabetes and HbA1c ≥53 mmol/mol (7%), aged ≥18 years, who were able to read and speak English, could provide written informed consent, owned a mobile phone and were not pregnant. Medical clearance was obtained from participants' doctors. Recruitment occurred primarily through Facebook and a mass mail-out, but also included referral from health professionals and advertisements in newspaper, radio and community noticeboards (21).

Intervention and control arms

DTEXT intervention arm received a mobile phone text-message program providing six months of self-management behavior change and diabetes care support. The text-messages were developed by an expert panel, with appropriate readability and using the behavior change theory and technique taxonomy (18). Text-messages were unidirectional and semi-personalized, with delivery occurring daily for months 1–3, and four times per week for months 4–6. The message content included nutrition, physical activity, diabetes care, weight management, medication adherence and smoking cessation. The control arm received usual care from their treating doctor and associated health professionals. HbA1c and quality of life measures for both arms were taken at baseline, 3 and 6 months. All participants could withdraw from the study at any time by texting STOP.

Health outcome measures

HbA1c

The primary outcome of the DTEXT study was the difference in HbA1c between intervention and control at 6 months, determined by non-fasting blood test taken at the participant's local pathology collection center.

Quality-adjusted life years (QALYs)

Quality of life was determined by the Short Form 12-item Health Survey (SF12v2), a multi-purpose survey measuring quality of life by functional health and wellbeing (22). To calculate QALYs, health utilities were converted to a preference-based measure of quality of life, the Short Form Six Dimension (SF-6D) health index (23), using the UK valuation algorithm (24). QALYs over the 6-month period of the trial were determined for intervention and control arms using utilities at baseline, 3 and 6 months. QALYs were summed over each 3-month period from duration of time multiplied by mean utility. For the 6% of participants with a missing utility measurement at 3 months, QALYs were calculated from the baseline and 6-month measurements. If participants were missing a baseline or 6-month measure they were excluded from the analysis.

Measurement and valuation of resource use

The cost of delivering the intervention and the healthcare costs of participants were collected and valued in 2018 Australian dollars (AUD). Conversions to an international dollar value (INT$) were calculated using the World Bank PPP conversion factor (25). As the intervention ran for less than one year, discounting was not applied. The cost of delivering the intervention included text-message costs, staffing costs and consumables which were calculated to determine total intervention costs for the trial, and a cost

per participant. Out-of-hospital costs of health services and medications were determined by individual patient data linkage to Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. Medicare is a universal healthcare system that provides Government subsidies for out-of-hospital health care services, tests and interventions. The MBS is a listing of the Medicare health care services subsidized by the Australian federal government. The PBS claims data lists all the medicines dispensed to patients subsidized by the Australian government. All Australian residents who hold a Medicare card are eligible for the PBS. All MBS items, and PBS items relevant to type 2 diabetes management (26) were included in the analysis. Items were checked by experts in the field for relevancy in the analysis. Health care costs relating to hospital admissions were not captured as the short 6-month duration of DTEXT was not anticipated to impact on these.

Economic evaluation

The economic evaluation included a cost-effectiveness analysis and cost-utility analysis. The cost-effectiveness analysis utilized the intervention mean costs and health outcomes of each trial arm to determine the incremental costs per 11 mmol/mol (1%) reduced HbA1c, compared to usual care. The cost-utility analysis estimated the incremental cost per QALY gained.

Incremental cost-effectiveness ratios (ICERs) were calculated for HbA1c and QALY outcomes. Each ICER was calculated by dividing the difference in per participant mean cost (intervention minus control) by the difference in outcome measures.

$$ICER = \frac{Cost\ of\ intervention\ arm - cost\ of\ control\ arm}{Outcome\ of\ intervention\ arm - outcome\ of\ control\ arm} \quad [1]$$

Bootstrapping techniques used 1,000 replications with replacement to estimate the joint uncertainty of costs and health outcomes, which were plotted on an incremental cost-effectiveness plane. Cost-effectiveness acceptability curves (CEAC) determined the probability that the DTEXT intervention was cost-effective over a range of willingness to pay thresholds.

A scenario analysis was conducted to determine if the ICERs and probability of cost-effectiveness changed markedly when the cost of text-messages was adjusted to reflect the current market costs of text-message (7 cents rather than 12 cents at the time of the trial) and consumables specific to the study were removed (a NSW Health database storage fee specific to this study that would not be charged if the intervention was translated into practice).

Results

Three hundred and ninety-five participants (mean age 62 years, 50% male) were randomized to either the intervention (n=197) or control (n=198) arm of the DTEXT intervention. The majority (88%, n=348) of participant data was included in the economic evaluation [intervention (n=176), control (n=172)], with exclusions due to consent not provided for MBS/PBS data linkage (2%); and missing data for the 6-month HbA1c measures (6%) and the SF12v2 questionnaire (4%). Baseline demographics, clinical measures, and health utility scores for participants of the economic evaluation were similar between the intervention and control arms (*Table 1*).

Costs and outcomes

The total cost of delivering the 6-month text-message intervention (DTEXT) to 197 participants was AU$7,106 (INT$4,827), which equates to AU$36 (INT$24) per participant. The delivery of text-messages contributed to almost half of the costs. There were no intervention costs associated with the control arm as this arm received usual care only (*Table 2*).

The mean healthcare costs over 6 months (health funder plus patient out-of-pocket expenses) for the intervention and control arms were similar, costing AU$1,982 (INT$1,346) and AU$1,974 (INT$1,341) per participant respectively. The mean difference in HbA1c at 6 months between the intervention and control arms was 1.1 mmol/mol (95% CI: −1.4 to 4.5), 0.1% (95% CI: −0.13 to 0.41), favoring the intervention group. The corresponding incremental QALY was −0.004 (95% CI: −0.02 to 0.01), favoring the control arm (*Table 3*).

Economic evaluation

Cost-effectiveness

The ICER at 6 months was AU$311 (INT$211) per 11 mmol/mol (1%) reduced HbA1c (95% CI: −10,800 to 5,559). Most bootstrapped replicates fell in the northeast quadrant, indicating that the intervention was more effective and more costly (*Figure 1*). The probability of DTEXT being more effective and cost-saving than usual care for improvements in HbA1c was 33% (*Figure 1A*).

Table 1 Baseline demographics, clinical measures, and health utility scores of participants in the health economic evaluation (n=348)

Outcome	Control (n=172)	Intervention (n=176)
Demographic		
Males	91 (52.9)	84 (47.7)
Age (years)	62.83±10.29	62.10±9.59
Born in Australia	129 (75.0)	129 (73.3)
Aboriginal or Torres Strait Islander origin[†]	9 (5.2)	9 (5.1)
Education level of year 12 or less	50 (29.1)	58 (33.0)
Paid employment	67 (39.0)	61 (34.7)
Smoker	12 (7.0)	11 (6.3)
Taking medication for diabetes[†]	169 (98.3)	167 (94.9)
Self-reported health fair/poor	67 (39.0)	61 (34.7)
Objective clinical measures		
HbA1c [mmol/mol (%)]	66 (8.19)±1.15	66 (8.16)±1.16
Total cholesterol (mmol/L)[†]	4.10±1.11	4.16±1.13
Body mass index (kg/m^2)[†]	33.88±7.46	33.42±6.41
Health Utility Score—SF12v2		
Quality of life (mental)[†]	50.28±11.27	50.42±10.51
Quality of life (physical)[†]	41.84±11.11	42.06±10.89
Excluded from analysis		
Participants with missing data	26 (15.1)	21 (11.9)

Data are expressed as n (%) or mean ± SD. [†], n<348. HbA1c, glycated hemoglobin; SD, standard deviation.

The CEAC (*Figure 2A*) showed a 75% probability of the intervention being cost effective at a nominal willingness to pay threshold of AU$1,800 (INT$1,223) per 11 mmol/mol (1%) reduced HbA1c, compared to usual care.

Cost-utility

A mean ICER for QALYs was not calculated as the control arm dominated the intervention for this measure. The probability of DTEXT being more effective and cost-saving than usual care for QALYs was 15% (*Figure 1B*), with mean QALYs slightly higher in the control arm than the intervention. The CEAC for QALYs (*Figure 2B*) showed a 24% probability that the intervention was cost-effective compared with usual care at the commonly used willingness to pay threshold in Australia of AU$50,000 (27) per QALY gained.

Scenario analysis

Based on more realistic costs of text-messaging reflecting the current market cost per text-message and no study database storage fees, scenario analysis indicated the cost per participant reduced from AU$36 (INT$24) to AU$13 (INT$9). The corresponding ICER reduced from the base case value of AU$311 (INT$211) per 11 mmol/mol (1%) reduced HbA1c over the 6-month period to AU$151 (INT$103). The probability of the intervention being effective and cost-saving increased from 33% to 38%. The probability that the intervention was cost-effective at a willingness to pay threshold of AU$50,000 per QALY increased slightly to 25%. A mean ICER for QALYs was not calculated as the control arm dominated the intervention.

Discussion

This health economic evaluation provides the first evidence on the costs and cost-effectiveness of a text-message intervention for people with type 2 diabetes in Australia. The cost of delivering DTEXT intervention was low at

Table 2 Cost of delivering the 6-month DTEXT

Resource item	Resource use	Units	Unit cost (AUD)	Cost (AUD)	Source of unit costing
Equipment and overhead					
Delivery of text messages	135 messages per participant (n=197)	26,595	0.12	3,191	Message media
Account activation and licence fee	One-off payment	1	49	49	Message media
Access fee	Monthly basis	6	50	300	Message media
Dedicated mobile number activation	One-off payment	1	150	150	Message media
Dedicated mobile number/alpha tag licence fee	Monthly basis	6	25	150	Message media
Maintenance of text message database and delivery system	Monthly fee for IT server	6	197	1,182	NSW Health internal cost
Database storage fee	One-off payment	1	1,989	1,989	NSW Health internal cost
Staff time					
Data entry	Administrative task, 1 min per participant	197	0.48	95	NSW Health award for Administration Officer (level 3) at hourly rate of $29.02
Total intervention cost	–	–	–	7,106	–
Total cost per participant	–	–	–	36	–

DTEXT, text message intervention; AUD, Costs in Australian dollars for the year 2018; IT, information technology; Min, minutes.

Table 3 DTEXT healthcare costs and health outcomes per participant over 6 months (n=348)

Costs and health outcomes	Mean (bootstrapped 95% CI)			AUD per health gain (bootstrapped 95% CI)
	Control (n=172)	Intervention (n=176)	Incremental[†]	ICER
Costs				
Intervention costs (AUD)	0	36		
Patient costs (AUD)	303	273		
Health funder cost (AUD)	1,671 (1,512, 1,884)	1,709 (1,530, 1,903)	38 (–207, 302)	
Health funder plus patient cost (AUD)	1,974 (1,808, 2,145)	1,982 (1,789, 2,187)	8 (–250, 289)	
Total costs (AUD)	1,974 (1,808, 2,145)	2,018 (1,825, 2,223)	44 (–214, 325)	
Health outcomes				
HbA1c (mmol/mol) at 6 months	65 (63, 68)	64 (62, 66)	1.1 (–1.4, 4.5)	311 (–10,800, 5,559) per 11 mmol/mol HbA1c reduction
HbA1c (%) at 6 months	8.1 (7.94, 8.33)	8.0 (7.81, 8.17)	0.1 (–0.13, 0.41)	311 (–10,800, 5,559) per 1% HbA1c reduction
QALYs over 6 months	0.367 (0.36, 0.38)	0.363 (0.35, 0.37)	–0.004 (–0.02, 0.01)	Not calculated*

[†], intervention minus control, except for HbA1c which is control minus intervention to allow for calculation of HbA1c percentage points saved; *, an ICER could not be calculated as mean QALYs were higher in the control group than in the intervention group. DTEXT, text-message intervention; ICER, incremental cost effectiveness ratio; AUD, Australian Dollars for the year 2018; CI, confidence interval; HbA1c, glycated hemoglobin; QALY, quality adjusted life year.

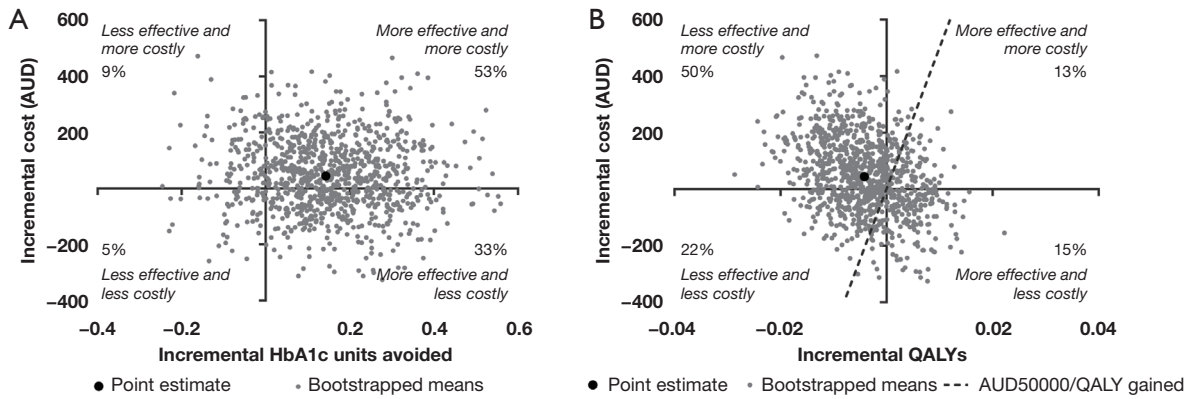

Figure 1 Incremental cost effectiveness planes of n=1,000 bootstrapped replications for (A) incremental cost per 11 mmol/mol (1%) reduction in HbA1c and (B) incremental cost per QALY gained. HbA1c, glycated hemoglobin; QALY, quality adjusted life year; AUD, Australian Dollar.

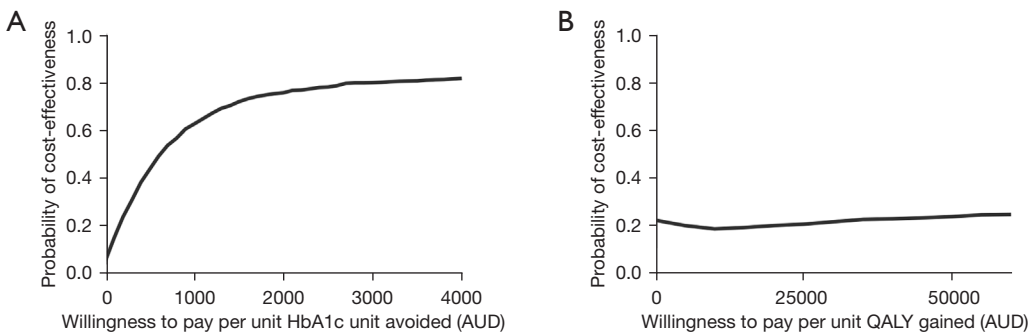

Figure 2 Cost-effectiveness acceptability curves showing probability of cost-effectiveness at different willingness to pay for (A) 11 mmol/mol (1%) reduction in HbA1c and (B) QALYs gained. HbA1c, glycated hemoglobin; AUD, Australian Dollar; QALY, quality adjusted life year.

AU$36 (INT$24) per participant in study conditions, and AU$13 (INT$9) per participant based on scenario analysis. The highly accepted DTEXT text-message intervention providing self-management support and diabetes care for Australian adults with type 2 diabetes, showed a non-significant trend to reduce HbA1c compared to usual care, and statistically significant improvements in the type 2 diabetes nutritional risk factors of vegetables, fruit and sweet discretionary food consumption (19). The cost-effectiveness analysis showed that DTEXT had a 33–38% probability of being effective and cost saving over 6 months, with an ICER of AU$311 (INT$211)–AU$151 (INT$103) per 11 mmol/mol (1%) HbA1c reduction. DTEXT did not result in higher QALYs than the control, and had only a 24–25% probability of being cost-effective based on usual cost/QALY thresholds.

The evidence for economic evaluations of type 2 diabetes text-message interventions is limited (28), making comparisons with DTEXT outcomes challenging. To the best of our knowledge, no similar studies exist, except for one from Bangladesh that reported a text-message program delivery cost of INT$24 per patient, an incremental cost of INT$38 per 11 mmol/mol (1%) reduction in HbA1c and an ICER of INT$2,406 per QALY gained (29). This represents a similar cost of intervention delivery as DTEXT and a similar incremental cost per HbA1c reduction as our scenario modelling outcome. The ICER for QALYs for the Bangladesh study was reported to be cost-effective, however in our study the intervention had only a 24% probability of being cost-effective for the QALY outcome. This may be explained by our study being powered to detect HbA1c outcomes and not costing or quality of life measures (4), or that 6 months duration is not long enough to show significant improvements in diabetes complications (30) and

complex constructs (29), which affect quality of life. More economic evaluations of text-message programs for people with type 2 diabetes are required to provide an adequate comparison of DTEXT outcomes.

As the cost-effectiveness comparison data for DTEXT is currently limited, considering the costs required for scale-up by the Australian Government may be useful. Our scenario modelling suggests this would cost the health services AU$13/person to provide 6 months of supportive text-messages, which is considerably cheaper than the government cost to cover one single standard general practitioner (AU$38.75) or allied health (AU$54.60) consultation (31). Interventions similar to DTEXT have been deemed scalable and most cost-effective when implemented at a large or national scale (32), which may further reduce DTEXT costs and support scale-up potential. It has been shown that programs that reduce HbA1c over the short term can lead to substantial savings, and that reductions in HbA1c of less than 11 mmol/mol (1%) still lead to costs-savings in health care (33). Single technology interventions such as DTEXT have reported acceptability due to being user friendly, with lower costs, and less complexity (16).

Our study had several strengths including its robustness using costs and outcomes from the largest randomized controlled trial (19) to date of participants for a type 2 diabetes text-message intervention on self-management strategies and diabetes care. The use of data linkage from the MBS/PBS provided accurate and objective measures of out-of-hospital health care utilization and costs which is currently lacking from the existing evidence (29). The pragmatic study design enabled an economic evaluation to be conducted in a real-world setting allowing for realistic assessment of population scale-up suitability (34). The text-message program was highly accepted by people with type 2 diabetes, an important consideration for implementation (4). The study limitations include the short 6-month follow-up period, however, HbA1c improvement (32) and long-term health outcomes and cost savings may be observed at longer follow-up (29). Modelling was not undertaken which may have provided an indication of long term effects, and validated disease progression models offer the best prospective for evaluating the cost-effectiveness of self-management support interventions (4). Furthermore, our intervention costing did not include costs beyond the timeframe of the trial, such as IT system upgrades and text message adaptations. While it is not appropriate for an economic evaluation to include costs incurred beyond the timeframe that the outcomes are measured, it may be important to consider these costs when integrating such a program in the health system.

Our findings have implications for future research and the Australian health system. Important future research might investigate if the cost-effectiveness of DTEXT differed among different aged participants, culturally and linguistically diverse populations, those with differently controlled HbA1c or those with newly diagnosed type 2 diabetes as it is plausible that its effectiveness and cost-effectiveness is heterogenous. For example, it is suggested that the early years of living with the disease is the optimal time to support behavior change and educational reinforcement (14), can provide greater treatment effects (14) and benefits to the individual and health system (35). Depending on its effectiveness and cost-effectiveness in key population groups, implementation of DTEXT may be worth consideration in targeted populations as the simple and low cost delivery of automated text-messages can deliver ongoing support and provide an equitable adjunct to usual care. From a health system perspective, DTEXT is an affordable intervention that is feasible to deliver, with a 33–38% probability of being cost-saving and effective. Moreover, the intervention was highly accepted by community dwelling adults with type 2 diabetes (19) can reach people anywhere in their everyday lives and benefit care (32). Future research prior to implementation would also have to consider cultural and linguistically diverse populations and the need to adapt the content for people of different health literacy.

Conclusions

This study provides high quality evidence to the limited pool of health economics research on text-message programs for people with type 2 diabetes. The intervention was low cost but had low to moderate probability of being cost-saving and effective. In light of its affordability and acceptability, there is potential for a targeted approach to its implementation as an adjunct to usual care but further research is needed to examine its effectiveness and cost-effectiveness in key populations.

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Footnote

Reporting Checklist: The authors have completed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) reporting checklist. Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-26/rc

Data Sharing Statement: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-26/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the University of Wollongong & Illawarra Shoalhaven Local Health District Human Research Ethics Committee (Health and Medical) (No. 2016/343) and informed consent was taken from all individual participants.

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