Griffith UNIVERSITY

Centre for Applied Health Economics

Townsville Broadband Diabetes Telehealth Trial

EVALUATION REPORT

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EXECUTIVE SUMMARY

BACKGROUND

In Queensland, the direct healthcare costs to treat diabetes were estimated to cost $370 million in 2011-2012, with diabetes expenditure expected to increase five-fold over the 30 years to 2032-2033. Among the range of disease groups, this represents the largest single cause of expected proportional expenditure increase [1]. For the Townsville area, hospitalisation rates and death rates due to diabetes were higher than the Queensland rates.

Research from large scale programs have shown that the use of telehealth technologies combined with a care coordination model can be effective in helping people manage their chronic health condition. However, the role of telehealth has not been established in the Australian health system as an alternative to combat the increasing prevalence and demands of diabetes and other chronic conditions. This trial was funded to examine the effect of a telehealth intervention based in primary care on the control of Type 2 diabetes and subsequent potential cost savings to the health system.

Study Aims: The overarching question and sub-questions for the research were: does remote access to clinicians supported by telehealth technologies over broadband lead to improved diabetic control in a way that benefits patients, carers and clinicians, and improves the overall health system? Specifically:

- Does it improve health outcomes?
- Does it improve the care or experience for the patients, carers and clinicians?
- Does it improve primary care capacity and integration of care?
- Does it improve service utilisation and efficiency of the healthcare workforce?
- Does it utilise ubiquitous high-speed broadband?

METHODOLOGY

The study was a two-arm prospective randomised controlled trial in which adults with Type 2 diabetes were randomised to either the intervention (diabetes program) or control (usual care)

arm. The primary outcome used for indication of this was the measure of glycated haemoglobin (HbA_{1c}), a clinical marker of diabetes control.

The intervention consisted of an additional in-home broadband monitoring and communication device which also captured clinical measures. The system allowed for video conferenced communication with the care coordinator nurse (and other health professionals when required). The care coordinator nurse offered regular contact with the participant for health coaching, advice and information. General Practitioners and their teams continued to manage their patients' care in partnership with the care coordinator nurse who developed a care plan consistent with the Diabetes Australia Type 2 diabetes Guidelines. Additional health or other services (e.g. allied health) were implemented by the GP according to patient need or the participant, as per usual care.

The home telehealth devices supplied to participants consisted of a tablet computer (ASUS, Lenovo), a bluetooth-compatible blood pressure monitor (A&D Medical, Omron), and bluetooth–compatible glucometer (MyGlucoHealth). Blood pressure and blood glucose measurements were taken regularly by participants with results appearing on the tablet loaded with vital signs monitoring software (Tunstall myclinic). Patients in the usual care group continued to receive usual care from their GP and other health providers, and participated in the clinical measurement and quality of life components of the evaluation.

After some changes to the protocol, eligibility for inclusion in the trial was HbA_{1c} measure of ≥ 58 mmol/mol (7.5%). An expected effect size of a decrease in HbA_{1c} of 15 mmol/mol (0.8%) meant that complete data for 120 participants (60 in each group) were required to be recruited into the trial.

A number of outcome measures were recorded including clinical factors (e.g. weight, blood pressure, neuropathy tests, vision loss, cholesterol) as well as acceptance and utilisation of technology (e.g. the UTAUT scale), patient reported outcomes (the SF-12 for quality of life, Kessler 10 for psychological distress e.g. anxiety, depression, acute grief reactions), Patient Assessment of

Chronic Illness Care (a measure of satisfaction of services), and a comprehensive suite of utilisation of health services measures (e.g. number of GP visits, admissions to hospital, length of stay for hospital stays), diagnosis and various hospital codes. Costs for the intervention were meticulously recorded for a sample of participants in the intervention group, and costs for GP visits and admissions to hospital were obtained from administrative databases.

Follow-up for 6-months, the minimal time sufficient to detect a change in HbA_{1c}, was undertaken for all 120 participants and all outcome measures were repeated.

Qualitative analysis was undertaken for the process evaluation, including interviews with GPs and participants. Clinical data were analysed comparing the intervention group with the usual care group; the primary outcome measure was HbA_{1c}. Several other secondary clinical outcome factors were also tested for differences between groups. An economic evaluation (cost-effectiveness analysis) to identify the value for money of the intervention was undertaken. The economic evaluation involved a Markov model to estimate the costs and health benefits over a 5-year time horizon from the intervention compared with usual care, from the perspective of the governments. Finally, an impact evaluation projected the costs for rolling out the intervention to the Australian population with Type 2 diabetes. This involved estimating the population with Type 2 diabetes who would fit the criteria for the intervention.

RESULTS

Over a period from July 2011 – July 2014, a total of 590 potential participants were screened for eligibility for entry into the trial. Of these, 166 individuals did not meet the inclusion criteria, 88 individuals declined to participate, and 179 were excluded for other reasons. A total 157 participants were randomly assigned to the intervention (n=88) and control (n=69) arms. Of the 157 randomised participants, 24 individuals (2 in the control arm and 22 in the intervention) did not commence the study. Overall, there were 63 participants in each treatment arm at baseline with data for analysis.

Process evaluation

In the intervention arm, fourteen of the participants (22%) were connected to the internet via the NBN, while the remaining participants (88%) accessed the monitoring service through ADSL fixed broadband. Over the study period, there were 1,664 interactions with participants. Most interactions were done by telephone (46% of interactions), which was commonly used for consultations, appointment arrangements, and following up minor issues with patients. Home visits accounted for 15% of interactions, and were utilised by information technology staff during the trial to troubleshoot equipment, software, and connection issues. Video consultation accounted for 17% of interactions, and was the preferred method of communication for CC nurses to administer health coaching and education. Of the videoconferences that commenced, 29% failed to ensure a connection of a quality that was reasonable to facilitate a video consultation.

Surveys were completed by 20 GPs with intervention patients (49% response rate). The majority of GPs (80%) thought their patients had benefitted from participating in the trial, and 90% indicated they would refer patients with diabetes to this type of service in the future. Comments from the GP surveys indicated that benefits for their patients included better understanding and awareness of their condition, as well as improvements in weight and diabetes control. Satisfaction with the intervention related to the positive improvements in their patients' health.

Participant interviews and the UTAUT survey highlighted a generally positive experience of the service. Outcomes of the interviews showed that participants learnt more about their Type 2 diabetes; particularly in terms of education about diet, movement and the importance of regular monitoring of their condition. An unexpected outcome for some participants was the identification of other health conditions, such as increased blood pressure, which may not have been detected through usual care practices. Participants highly valued the regular video conferences / telephone calls with the care coordination nurses, which impacted significantly on the participant experience of the intervention.

Of note, trial staff spent significant time liaising with the vendor on development and improvement to the products. A number of ongoing 'bugs' also affected the use of the equipment by participants.

Clinical outcomes evaluation

At baseline, there were no statistically significant differences in clinical measures between the intervention and control groups. At 6 months, the primary clinical outcome measure, HbA_{1c}, showed there was a clinically meaningful and statistically significant benefit from the intervention, with HbA_{1c} levels decreasing from median 8.4% (Interquartile Range (IQR): 7.8-9.0) to median 7.5% (IQR: 7.0-8.4) compared to the control group [median 8.4%; IQR: 7.8-9.0) versus 8.0%; IQR: 7.1-8.9). This difference was statistically significant ($p<0.001$). There were no other statistically significant clinical effects detected between groups over the relatively short time period of 6 months.

Quality of life (measured using the SF-12 and valued using the SF-6D algorithm to calculate quality-adjusted life years, QALYs) remained similar between baseline and 6-months (control group, $p=0.814$; intervention group, $p=0.703$). The effect of the study arm on SF-6D change was not statistically significant ($p=0.533$, $R^2=0.12$) even after the removal of influential observations.

Economic evaluation

The Markov model revealed that the cumulative expected cost over a 5-year period was $33,970 per participant in the intervention group and $43,270 in the control group, resulting in incremental cost of -$9,300 (i.e. a cost-savings). Participants in the intervention group would accumulate 3.04 QALYs during the 5-year period, while 2.98 QALYs would be accumulated in the control group, resulting in incremental QALYs of 0.05 (rounded figures). The intervention is the dominant strategy as this is cost saving with greater health benefits compared to usual care. This finding was invariant to all factors in a sensitivity analysis.

Impact Evaluation

If this service was made available Australia wide, it was estimated that 46,560 patients could use the service in year 1, increasing to 184,138 over 5 years. If the service is fully implemented, the average cost of the intervention was estimated at $5.03 per day (on an ongoing basis). Costs for providing the service would be $175 million in year 1 and increase to $338 million in year 5. However, cost-offsets from reduced GP visits, specialist visits and admissions to hospital were estimated to be $118 million in year 1 increasing to $467 million in year 5. Thus, net costs would be $57 million in year 1, thereafter reduced with cost-offsets to savings of $129 million in year 5, and overall for the first 5 years would result in cost-savings to the health system of $291 million.

CONCLUSIONS

A relatively small number of participants were enrolled in the trial, with 63 in the intervention group and 63 in the usual care (control) group. The two study groups were similar in terms of key characteristics, indicating that the randomisation was successful. Retention was high with only a 20% drop out rate at 6-months.

There was a statistically significant decrease in HbA_{1c} levels in the intervention group while the HbA_{1c} levels remained similar in the control group during the 6-month trial period. In the intervention arm, 82% of participants (51/62) were in the poor glycaemic control category (≥7.5% HbA_{1c}) at baseline, and by the end of the 6 months, the proportion dropped to 52% (30/58); while in the control arm the proportion of participants in the poor glycaemic control category actually increased, from 71% (44/62) to 73% (41/56).

Other outcome results showed that participants receiving the intervention reported a significantly better level of care on the PACIC scale at 6-months than those receiving usual care. There were no serious adverse events observed during the trial.

Regarding the use of healthcare resources, healthcare costs were generally lower in the intervention group, and the overall costs (including GP, specialist and hospital events) were

significantly lower in the intervention group (mean difference: $2,756; p=0.032) compared to the control group. This result excluded the cost of intervention ($1,875) applicable in the intervention group. Thus, the intervention was clearly cost-saving.

A limitation of the trial was the small number of participants completing a study period of 12 months, as originally planned in the protocol. External influences on the implementation of the trial resulted in the majority of participants completing a six month study period. This also resulted in a significant spike of enrolments and service initiation in late 2013 / early 2014, which put time and logistical pressures on monitoring clinicians, possibly resulting in decreased time for initial engagement in these patients. An additional limitation of the trial was the inclusion of people in categories where there may be limited cost-benefit e.g. the inclusion criteria was worded as participants requiring a HbA_{1c} result of 58 mmol/mol (7.5%) or above in the last 12 months. This resulted in 20% (18% intervention arm and 22% control arm) of participants having an HbA_{1c} of less than 58 mmol/mol (7.5%) at baseline. Nevertheless, an overall intervention effect was noted for the intervention group compared with the usual care group, even with those with the inclusion of lower HbA1c levels. Thus, the trial was overall very positive, despite the small number or participants and the relatively short follow-up period. This is an outstanding result.