ORIGINAL ARTICLE

Using Digital Health Technology to Prevent and Treat Diabetes

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Introduction

THIS ARTICLE IS OUR ANNUAL attempt to highlight the digital approaches successfully being used to improve outcomes for patients with, or at risk for, diabetes. In the past few years a new classification for these efforts has emerged, called digital therapeutics—products that use digital technology to prevent and treat medical conditions.

Digital therapeutics can be divided into three types:

Digital services aim to modify patient behaviors to improve health outcomes. Ideally, these digital therapeutics use evidence-based approaches and publish studies that show the specific therapeutic can help drive important clinical and economic outcomes.

Adjunctive digital therapeutics support the use of traditional therapies such as medications, devices, and monitors. These therapeutics can assist in improving clinical outcomes, but they do so indirectly by enhancing the effectiveness of the traditional therapeutics and typically stop short of claiming an independent therapeutic benefit.

Digital drug replacements seek to provide a clinical benefit through the digital technology itself as a replacement for a traditional treatment, and not through any other source. Because of this, digital drug replacements usually require significant scrutiny by way of clinical trial results and review by the Food and Drug Administration before they can be reimbursed in a fee-for-service health-care environment.

Of course, these categories are not set in stone. There are already hybrid digital therapeutics in which traditional therapeutics are coupled with an evidence-based digital service to create a new prevention and treatment paradigm.

It is hoped these various approaches will be proven to be impactful and will be able to create business models that allow for sustaining their impact at scale.

Key Articles Reviewed for the Article

Evaluation of a diabetes self-management program: claims analysis on comorbid illnesses, health care utilization, and cost

Turner R, Ma Q, Lorig K, Greenberg J, DeVries AJ

[Med Internet Res 2018; 20: e207](#)

Mobile Diabetes Intervention Study (MDIS) of patient engagement and impact on blood glucose

Quinn CC, Butler EC, Swasey KK, Shardell MD, Terrin MD, Barr EA, Gruber-Baldini AL

[JMIR Mhealth Uhealth 2018; 6: e31](#)

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Digital diabetes management application improves glycemic outcomes in people with type 1 and type 2 diabetes

Offringa R, Sheng T, Parks L, Clements M, Kerr D, Greenfield MS

J Diabetes Sci Technol 2018; **12**: 701–708

Web-based self-management support for people with type 2 diabetes (HeLPDiabetes) randomised controlled trial in English primary care

Murray E, Sweeting M, Dack C, Pal K, Modrow K, Hudda M, Li J, Ross J, Alkhaldi G, Barnard M, Farmer A, Michie S, Yardley L, May C, Parrott S, Stevenson F, Knox M, Patterson D

BMJ Open 2017; **7**: e016009

Cost-effectiveness of facilitated access to a self-management website

Li J, Parrott S, Sweeting M, Farmer A, Ross J, Dack C, Pal K, Yardley L, Barnard M, Hudda M, Alkhaldi G, Murray E

J Med Internet Res 2018; **20**: e201

Comparing the efficacy of a mobile phone-based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial

Mackillop L, Hirst JE, Bartlett KJ, Birks JS, Clifton L, Farmer AJ, Gibson O, Kenworthy Y, Levy JC, Loerup L, Rivero-Arias O, Ming WK, Velardo C, Tarassenko L

JMIR Mhealth Uhealth 2018; **6**: e71

Use of a connected glucose meter and certified diabetes educator coaching to decrease the likelihood of abnormal blood glucose excursions: The Livongo for Diabetes Program

Downing J, Bollyky J, Schneider J

J Med Internet Res 2017; **19**: e234

One Drop I Mobile: an evaluation of hemoglobin A1c improvement linked to app engagement

Osborn CY, van Ginkel JR, Rodbard D, Heyman M, Marrero DG, Huddleston B, Dachis J

JMIR Diabetes 2017; **2**: e21

The impact of a mobile diabetes health intervention on diabetes distress and depression among adults: secondary analysis of a cluster randomized controlled trial

Quinn C, Swasey K, Christopher J, Crabbe F, Shardell M, Terrin M, Barr E, Gruber-Baldini A

JMIR Mhealth Uhealth 2017; **5**: e183

Effectiveness of text message based, diabetes self-management support programme (SMS4BG)

Dobson R, Whittaker R, Jiang Y, Maddison R, Shepherd M, McNamara C, Cutfield R, Khanolkar M, Murphy R

BMJ 2018; **361**: k1959

Testing a smartphone app (Young with Diabetes) to improve self-management of diabetes over 12 months: randomized controlled trial

Castensøe-Seidenfaden P, Husted GR, Jensen AK, Hommel E, Olsen B, Pedersen-Bjergaard U, Kensing F, Teilmann G

JMIR Mhealth Uhealth 2018; **6**: e141

A systematic review of reviews evaluating technology-enabled diabetes self-management education and support

Greenwood DA, Gee PM, Fatkin KJ, Peebles M

J Diabetes Sci Technol 2017; **11**: 1015–1027

Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update

Sepah SC, Jiang L, Ellis RJ, McDermott K, Peters AL

[BMJ Open Diab Res Care 2017; 5: e000422](#)

A fully automated conversational artificial intelligence for weight loss: longitudinal observational study among overweight and obese adults

Stein N, Brooks K

[JMIR Diabetes 2017; 2: e28](#)

Peer-based social media features in behavior change interventions systematic review

Elaheebocus SMRA, Weal M, Morrison L, Yardley L

[J Med Internet Res 2018; 20: e20](#)

The use of Facebook in recruiting participants for health research purposes: a systematic review

Whitaker C, Stevelink S, Fear N

[J Med Internet Res 2017; 19: e290](#)

Serious games for children with chronic diseases: a systematic review

Holtz BE, Murray K, Park T

[Games Health J 2018; 7: 291–301](#)

A team-based online game improves blood glucose control in veterans with type 2 diabetes: a randomized controlled trial

Kerfoot BP, Gagnon DR, McMahon GT, Orlander JD, Kurgansky KE, Conlin PR

[Diabetes Care 2017; 40: 1218–1225](#)

“Active Team” a social and gamified app-based physical activity intervention: randomised controlled trial study protocol

Edney S, Plotnikoff R, Vandelanotte C, Olds T, De Bourdeaudhuij I, Ryan J, Maher C

[BMC Public Health 2017; 17: 859](#)

Evaluation of a diabetes self-management program: claims analysis on comorbid illnesses, health care utilization, and cost

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[J Med Internet Res 2018; 20: e207](#)

Background

Diabetes mellitus is a widespread disease, with an estimated 30.3 million Americans currently living with the disease. The U.S. Department of Health and Human Services laid out national goals through its Healthy People 2020 initiative to enhance the quality of life for individuals who either have or are in jeopardy of developing diabetes mellitus and consequently lower the individual and national economic cost of this chronic disease. Diabetes self-management educational interventions are an essential focal point of this national initiative. The goal of this investigation was to assess the effect of the Better Choices, Better Health – Diabetes (BCBH-D) self-

management program on comorbid diseases associated with diabetes mellitus, health-care utilization, and cost.

Methods

This study employed a propensity score matched two-group, pre–post design. Retrospective administrative medical and pharmacy claims data from the HealthCore Integrated Research Environment were used for outcome variables. The intervention group consisted of patients with type 2 diabetes mellitus who were recruited to a diabetes self-management program, while the control group included subjects selected from the HealthCore Integrated Research Environment who had at least two diabetes-related claims (International Classification of Diseases-Ninth Revision, ICD-9 250.xx) within 2 years before October 1, 2011 (the program launch date) but did not participate in BCBH-D. Participants in the control group were matched to cases in a 3:1 propensity score match. Outcome measures included pre- and postintervention all-cause and diabetes-related usage and costs. Cost outcomes were calculated as least-squares means. Repeated measures analyses (generalized estimating equation approach) were conducted for utilization, comorbid conditions, and costs.

Results

Program users who were identified in HealthCore Integrated Research Environment claims ($n=558$) were paired to a control group of 1669 participants. After the intervention, the self-management group experienced significant decreases in diabetes mellitus-related comorbid conditions, with a significantly lower postintervention disease burden (mean 1.6 [SD 1.6]) vs the control group (mean 2.1 [SD 1.7]; $P=0.001$). There was less postintervention all-cause use of medical services in the intervention group than in the control group, with $-40/1000$ emergency department visits vs $+70/1000$ ($P=0.004$) and -5780 outpatient visits per 1000 vs $-290/1000$ ($P=0.001$). There was a reduction of U.S. \$2207 in unadjusted aggregate all-cause medical cost in the intervention group, vs a reduction of U.S. \$338 in the control group ($P=0.001$). After using structural equation analysis to adjust for other variables, the direct impact of the BCBH-D was determined to be $-\$815$ ($P=0.049$).

Conclusions

BCBH-D program patients experienced a decrease in all-cause health-care usage and expenses, with direct monetary savings of U.S. \$815. Given the complicated nature of the diabetic patient population, further studies are required to cross-validate the results.

Comment

Note: Because two of the authors own (N.K.) or work (N.K., D.S.) for a company that markets the digital therapeutic used in this study, a conflict of interest exists and we have therefore refrained from adding any comments for this article.

Mobile Diabetes Intervention Study (MDIS) of patient engagement and impact on blood glucose

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JMIR Mhealth Uhealth 2018; 6: e31

Background

Successfully treating diabetes includes patient self-management behaviors focused on preventing or delaying complications and comorbid diseases. Based on results from large clinical trials and professional guidelines, diabetes education programs and health providers prescribe daily regimens of glucose monitoring, healthy eating, stress management, medication compliance, and physical activity. Staying consistently committed to these regimens long term is difficult. The use of mobile health to assist patients with lifestyle changes and self-management behaviors is on the rise. The effectiveness of mobile health in improving diabetes outcomes is dependent on patients engaging with the technology, learning its content, and effectively interacting with

providers. The goal of this study was to find patient engagement themes in diabetes messaging with care providers and to determine whether differences in engagement in the Mobile Diabetes Intervention Study (MDIS) caused changes in glycated hemoglobin A1c (HbA1c) levels during the course of a 1-year treatment period (1.9% decrease in the parent study).

Methods

In the primary MDIS study, 163 patients were assigned to one of three mobile intervention groups or to a routine care control group based on the cluster randomization assignment of their physicians. The control cohort had no changes from their regular care routine. Participants in all intervention groups received access to a patient portal where they could record their blood glucose levels, prescription changes, self-management data, and blood pressure. Depending on group assignment, participants received differing levels of physician access to patient information. Participants in the intervention group could decide to interact with certified diabetes educators by sending as well as receiving messages through the secure online interface. In this secondary analysis, 4109 patient messages were evaluated using qualitative techniques to identify self-care trends and determine participant engagement. Mixed methods were utilized to find the effect of patient engagement on change in HbA1c over the course of 1 year.

Results

The self-care behavior themes that elicited the highest participant engagement were glucose monitoring (75/107, 70.1%), medication management (71/107, 66.4%), and risk reduction (71/107, 66.4%). The mean number of messages sent per patient was greatest for glucose monitoring (9.2 [SD 14.0]) and healthy eating (6.9 [SD 13.2]). In comparison with sending no messages, sending any messages regarding glucose monitoring ($P=0.03$) or medication ($P=0.01$) was associated with a decrease in HbA1c of 0.62% and 0.72%, respectively. Sending any messages about healthy eating, glucose monitoring, or medication combined resulted in HbA1c falling by 0.54% vs sending no messages related to these themes ($P=0.045$).

Conclusions

This study helps validate the feasibility of diabetes interventions through mobile platforms. Future studies should work to identify the differences between patients who use mobile interventions and those who do not and to identify customized strategies to increase patient engagement.

Comments

This digital therapeutic study adds to the growing body of literature demonstrating the elements of interventions that tend to work. Interpretation of these findings is limited due to the comparison of not performing a specific activity with performing some or a lot of that activity. A behavior such as sending a message is a relatively small action. The power of small actions may only be seen when done many times. To demonstrate such an effect requires analysis of a continuous variable

and not an all-or-nothing finding. It is hoped that subsequent studies are powered to allow further understanding of this critical issue.

Digital diabetes management application improves glycemic outcomes in people with type 1 and type 2 diabetes

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J Diabetes Sci Technol 2018; **12**: 701–708

Background

Diabetes is a chronic condition that requires constant self-management. In response, myriad platforms have been created to encourage keeping track of diabetes data with the goal of improving diabetes management. This study examined the real-world advantages of using a mobile diabetes management service by people with type 1 and type 2 diabetes.

Methods

A cohort of mobile service users (n=899) and a control cohort (n=900) were formed by randomly assigning participants from a database of diabetes users. Outcomes were modeled utilizing different blended effect generalized linear models, assigning random intercepts for each participant, and modifying the distribution assumption for each result.

Results

Participants using the mobile platform monitored their blood glucose at an increased frequency (+8.8 tests per month [95% confidence interval 3.4, 14.1], $P<0.001$) and experienced fewer hyperglycemic events along with lower average glucose levels vs the control group. Additionally, mobile user could anticipate a 3.5% reduction in average blood glucose (−6.4 mg/dL [95% CI −2.0, −10.7], $P<0.001$) and a 10.7% reduction in hyperglycemia ($P<0.001$) after 2 months.

Conclusion

Participants using the mobile platform tested their blood glucose more frequently and demonstrated greater improvement in blood glucose compared with participants in the control group, who did not use the mobile platform. These results support previous study findings that digital technologies can enhance diabetes care in a real-world setting.

Comments

This study demonstrated that when patients are able to see their blood glucose levels on a mobile phone, they respond to the results and improve their glucose control. The relatively modest improvement can be expected. Patients need more than just easily accessible blood glucose levels to improve their outcomes.

Web-based self-management support for people with type 2 diabetes (HeLPDiabetes) randomised controlled trial in English primary care

Murray E¹, Sweeting M², Dack C³, Pal K¹, Modrow K¹, Hudda M⁴, Li J⁵, Ross J¹, Alkhalidi G¹, Barnard M⁶, Farmer A⁷, Michie S⁸, Yardley L^{7,9}, May C¹⁰, Parrott S⁵, Stevenson F¹, Knox M¹, Patterson D⁶

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BMJ Open 2017; **7**: e016009

Background

The purpose of this study was to determine the viability of using a web-based self-management program to improve glycemic control and reduce diabetes-related distress in patients living with type 2 diabetes.

Methods

Adults ≥18 years of age with type 2 diabetes were enrolled from participating general practices. Study subjects were assigned to one of two groups. Both groups continued to receive regular care and were randomized to one of two interventions: (1) Healthy Living for People with Diabetes (HeLP–Diabetes), an interactive, theoretically informed, web-based self-management program; or (2) A simple, text-based website containing basic information only. Primary outcomes were glycated hemoglobin (HbA1c) and diabetes-related distress, evaluated using the Problem Areas in Diabetes (PAID) scale, gathered 3 months and 12 months after randomization, with 12 months as the primary outcome point. Research nurses who were blinded to the group assignment collected clinical data. Participants also answered online self-report questionnaires. The investigation compared groups as randomized (intention to treat) using a linear mixed effects model, adjusted for baseline data with multiple imputation of missing values.

Results

Between September 2013 and December 2014, 374 subjects were randomized: 185 were assigned to the intervention group, and 189 were assigned to the control group. The last follow-up results, taken at 12 months, for HbA1c were obtained for 318 (85%) members and for PAID, for 337 members (90%). Of these responses, 291 (78%) and 321 (86%) were recorded inside the predefined time frame of 10–14 months postenrollment. HbA1c was lower for members in the intervention cohort compared with the control cohort

(mean contrast -0.24% ; 95% CI -0.44 to -0.049 ; $P=0.014$). No significant overall difference was found between groups in the average PAID score ($P=0.21$); however, predetermined subgroup investigation of members who had been diagnosed more recently with diabetes demonstrated a positive effect of the intervention in this cohort ($P=0.004$). No negative effects were observed or reported.

Conclusion

Results showed that HeLP-Diabetes caused improvement in glycemic control over a year-long period.

Comments

This randomized, controlled trial (RCT) of a digital therapeutic was a very well-done study with an innovative digital therapeutic approach to providing self-management support. Because the participants, all with type 2 diabetes, had relatively good control on entry into the study, an improvement in glucose control was hard to demonstrate. Outcomes likely could have been improved if there had been more social support between participants. The lack of HbA1c improvements in a well-done study with a reasonable intervention reminds us that to demonstrate clinical and economic impact, the study must select for patients who have poor diabetes management and/or higher than average health-care utilization and costs. See the next article for further analysis of the same study.

Cost-effectiveness of facilitated access to a self-management website

Li J¹, Parrott S¹, Sweeting M², Farmer A³, Ross J⁴, Dack C⁵, Pal K⁴, Yardley L^{3,6}, Barnard M⁷, Hudda M⁸, Alkhalidi G⁹, Murray E⁴

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J Med Internet Res 2018; **20**: e201

Background

Active self-management by individuals with type 2 diabetes improves outcomes and decreases health service costs. Existing evidence for the cost-effectiveness of digital self-management education is limited. The objective of this study was to determine the cost-effectiveness of a type 2 diabetes self-management website compared with usual care.

Methods

A cost-effectiveness analysis was conducted using data collected from a 12-month, multicenter, two-arm randomized controlled study. Adults 18 and older with type 2 diabetes and registered with 21 participating primary care centers in England were recruited. Participants were randomized to either usual care with Internet-based technology (HeLP-Diabetes), an interactive web-based self-management program, or to usual care plus a comparator website containing basic information only. The individuals' intervention costs and expanded health-care resource use were collected as well as two health-related quality of life measures: the PAID scale and EQ-5D-3L. These were used to calculate quality-adjusted life years (QALYs).

Results

Overall, 374 participants were chosen, with 185 in the intervention group and 189 in the control group. The initial analysis showed the cost-effectiveness ratios of £58 per unit improvement on PAID scale and £5550 per QALY gained by the Internet-based technology compared to the control group. The final analysis showed less cost-effectiveness and higher uncertainty with incremental cost-effectiveness ratios of \$116 per unit improvement on PAID scale and £18,500 per QALY. The cost-effectiveness acceptability curve showed an 87% probability of cost-effectiveness per QALY willingness-to-pay threshold. The analysis measured 363 users would need to use the Internet-based technology to become less costly than usual care.

Conclusion

Use of HeLP-Diabetes is cost-effective compared with usual care.

Comments

This RCT (same as the previous article) of a digital therapeutic demonstrated cost-effectiveness despite the relatively good diabetes control on entry. Imagine what the results could have been if the study subjects were sicker and costly at baseline. This intervention, with positive clinical and economic results, adds to the growing literature regarding cost-effectiveness and cost savings from digital therapeutics. The particulars of each intervention and the specifics of the participants are critical to the outcomes and to their generalizability. As more studies with a variety of digital approaches emerge and demonstrate impact, the field will be ready to make a major impact on the health and well-being of a large segment of the population—at least we hope so.

Comparing the efficacy of a mobile phone-based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial

Mackillop L^{1,2}, Hirst JE², Bartlett KJ¹, Birks JS³, Clifton L³, Farmer AJ⁴, Gibson O⁵, Kenworthy Y², Levy JC⁶, Loerup L⁵, Rivero-Arias O⁷, Ming WK⁸, Velardo C⁵, Tarassenko L⁵

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JMIR Mhealth Uhealth 2018; 6: e71

Background

Treatment of hyperglycemia in women with gestational diabetes mellitus (GDM) improves maternal and neonatal results and requires significant oversight by clinicians. Currently, this is accomplished through biweekly or monthly hospital clinic visits. There are few opportunities for interventions in the time between these appointments.

This study was done using a randomized controlled trial to evaluate if the utilization of a smartphone-based, real-time glucose management system to remotely monitor women living with GDM was as successful in controlling blood glucose as regular care practices through clinical visits.

Methods

Women with an irregular oral glucose tolerance test before 34 weeks of pregnancy were randomly assigned to either standard clinic care or standard clinic care plus smartphone-based blood glucose management (GDM-health, the intervention). The main outcome was a change in mean blood glucose in each cohort from enrollment to delivery, calculated with alterations made for the number of blood glucose tests, proportion of preprandial and postprandial readings, and baseline attributes.

Results

A total of 203 women were randomized. Blood glucose information was accessible for 98 women in the intervention cohort and 85 women in the control cohort. No significant difference was observed in rate of change of blood glucose (-0.16 mmol/L in the intervention and -0.14 mmol/L in the control per 28 days, $P=0.78$). Women in the intervention cohort reported higher overall happiness with care ($P=0.049$). Preterm birth was less common in the group who received the intervention (5/101, 5.0% vs 13/102, 12.7%; odds ratio 0.36 [95% CI 0.12 to 1.01]). Additionally, cesarean delivery was less common than vaginal delivery in the intervention cohort (27/101, 26.7% vs 47/102, 46.1%; $P=0.005$). Other glycemic, maternal, and neonatal results were comparable in the two groups. The median time from enrollment in the intervention to delivery was similar (intervention, 54 days; control, 49 days; $P=0.23$). There were significantly more blood glucose readings in the cohort who received the intervention (mean 3.80 [SD 1.80]) vs mean 2.63 [SD 1.71] readings per day in the intervention and control cohorts, respectively; $P<0.001$). No significant difference in direct health-care costs was observed between the two cohorts, with a mean cost difference of the intervention compared with control of $-\text{£}1044$ [95% CI $-\text{£}2186$ to $\text{£}99$]. There were no unforeseen negative results.

Conclusion

Despite the similarity in glycemic control and maternal and neonatal outcomes across the two cohorts, women favored the interventional model of care. Studies should delve deeper into the possible effectiveness of promoting self-management behaviors and healthier lifestyles. Remote, digital blood glucose monitoring may be a scalable, feasible intervention to address the increasing global burden of GDM.

Comments

This RCT of a digital therapeutic in women with gestational diabetes, while only showing modest results, demonstrated that a mobile cell phone-based glucose monitoring system was found by participants to be practical and relatively easy to use. It is not very surprising that the study was not able to demonstrate significant clinical results beyond engagement and blood sugar testing. Also, women received the intervention for an average of <2 months, which might have been too short of a time period to have much of an effect. To be a complete digital therapeutic requires a comprehensive intervention wrapped around the use of blood glucose monitoring. It is hoped that a larger study, with a more robust intervention, would show significant improvements in outcomes.

Use of a connected glucose meter and certified diabetes educator coaching to decrease the likelihood of abnormal blood glucose excursions: The Livongo for Diabetes Program

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J Med Internet Res 2017; 19: e234

This manuscript is also discussed in the article on Self-Monitoring of Blood Glucose, page S-4.

Background

The Livongo for Diabetes Program offers patients a two-way messaging appliance that measures and stores the individual's blood glucose for provider and patient review. It also provides unlimited blood glucose strips and access to diabetes resources, including goal setting and coaching sessions. At-risk self-insured employers, health plans, and provider organizations sponsor the program for individuals previously diagnosed with diabetes. The goal of the study was to evaluate the collected data from 4544 individuals with diabetes from October 2014 to December 2015.

Methods

Each study subject was equipped with an uploadable glucose meter. The probability of having a day with a blood glucose reading either above or below the normal range (70–180 mg/dL) in months 2 to 12 was compared with data during the first month of the program.

Results

Study subjects tested their blood glucose levels an average of 1.8 times per day. Subjects experienced an average 18.4% decrease in likelihood of having a day in which blood glucose is below the normal blood glucose range of 70 mg/dL and an average 16.4% decrease in the likelihood of having a day above the normal blood glucose range of 180 mg/dL. The biggest impact was seen in hyperglycemic individuals who were not using insulin.

Conclusions

This approach successfully decreased the likelihood of abnormal glucose readings.

Comments

This study of a digital therapeutic reported on the impact from providing patients an up-loadable glucose meter and cell-phone-based glucose display, combined with professional coaching to help the patient minimize abnormal blood sugars. Results show infrequent blood glucose testing and modest improvement in glucose values in the months on the program compared with the prior month. Further studies are needed to determine the impact of these approaches on clinical and economic outcomes.

One Drop | Mobile: an evaluation of hemoglobin A1c improvement linked to app engagement

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JMIR Diabetes 2017; 2: e21

Background

Three recently published reviews examined 19 research studies that tested the impact on HbA1c of 16 diabetes mobile applications, including 5 publicly accessible applications. Most of the reviewed studies used small sample sizes and did not associate mobile application engagement with results. This investigation looked at both a change in HbA1c in a large group of individuals utilizing the One Drop | Mobile application and the relationship between application engagement and changes in HbA1c.

Methods

The One Drop | Mobile application is intended to manually as well as automatically store, track, and share health data. Participants can set reminders to take medication, see statistics, set goals and objectives, track health outcomes, and gain insights from their data. In June 2017, we queried data on individuals with diabetes utilizing the application who had entered no fewer than two HbA1c values in the application >60 and ≤365 days apart. Multiple imputation corrected for missing data. Both unadjusted and adjusted mixed effects

repeated measures models tested mean HbA1c change by time, type of diabetes, and interaction between the two. Multiple regression models evaluated connections between utilizing the application to track meals, physical activity, blood glucose, and medication and HbA1c change.

Results

The sample (n=1288) included individuals with type 1 diabetes (T1D) (n=367) or type 2 diabetes (T2D) (n=921) 35% female, diagnosed with diabetes for a mean of 9.4 (SD 9.9) years, and tracked an average 1646.1 (SD 3621.9) self-care exercises between their first (mean 8.14% [SD 2.06%]) and second HbA1c data entry (mean 6.98% [SD 1.1%]). HbA1c results were significantly associated with participant-entered average blood glucose 90 days before the second HbA1c entry ($\rho=0.73$ to 0.75 , $P<0.001$). HbA1c decreased by an absolute 1.07% (unadjusted and adjusted $F=292.03$, $P<0.001$) from first to second HbA1c entry. There was a significant interaction between type of diabetes and HbA1c. Participants with type 2 diabetes showed a greater decrease in HbA1c over time than participants with type 1 diabetes ($F=10.54$, $P<0.001$). For participants with type 2 diabetes (n=921), HbA1c decreased by 1.27% ($F=364.50$, $P<0.001$) from first to second HbA1c entry. Additionally, recording meals was associated with a greater HbA1c decrease even after adjusting for covariates and then modifying for insulin use for participants with T2D (all $P<0.05$).

Conclusions

Over a median of 4 months of using the mobile app, individuals with T1D and T2D reported a 1.07%–1.27% absolute decrease in HbA1c. Use of the application to track self-care was associated with improvement in HbA1c. More research is required to fully explore the health advantages of publicly accessible diabetes applications, especially studies regarding the link between application engagement and short- and long-term outcomes.

Comments

This evaluation of a mobile digital therapeutic diabetes support app (for patients with T1D and T2D) demonstrates that a well-developed app can impact behaviors and improve diabetes outcomes. The significance of the study, with a relatively large sample size, is decreased given the average time between HbA1c determinations of 4 months. We suspect that this approach to providing patients with glucose management support could be more impactful if it were coupled with helping patients improve their confidence and ability to accomplish their goals.

The impact of a mobile diabetes health intervention on diabetes distress and depression among adults: secondary analysis of a cluster randomized controlled trial

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Background

Diabetes is a complicated, taxing disease that requires around-the-clock effort and monitoring by patients. The weight of self-management, including various pharmaceutical regimens, routine mindfulness exercises, and provider appointments, affects patients' life satisfaction. Diabetes distress and depression are two essential parts of emotional well-being that may have a negative impact on diabetes outcomes.

This study examined the effect of the 1-year Mobile Diabetes Intervention cluster randomized clinical trial on emotional well-being as measured by diabetes distress and depression among adults with T2D.

Methods

A group of 163 adults with poorly managed T2D were recruited from community primary care practices that were cluster randomized into either a typical care control group or an intervention group. Intervention members were given a cell phone with coaching programming including a web-based interface to talk with providers. A priori established secondary outcomes included measured by the Diabetes Distress Scale (DDS), with subscales that measure emotional tax, interpersonal distress, doctor-related distress, and regimen-related distress, as well as depression evaluated according to the Patient Health Questionnaire-9. Linear mixed models were utilized to calculate the impact of the intervention on diabetes distress levels both overall and independently by gender, and to evaluate whether the intervention influenced distress or depression. Additionally, the effect of total DDS on changes in HbA1c was examined.

Results

There were no significant treatment group results for DDS overall (baseline $P=0.07$; differences overtime $P=0.38$) or for depression ($P=0.06$ after some time). Significant decreases in total DDS were seen over the course of the year-long intervention ($P=0.01$). There was a significant decrease in regimen-related distress for all participants ($P<0.001$); however, there was no noteworthy change over time for emotional burden ($P=0.83$), interpersonal distress ($P=0.64$), or doctor-related distress ($P=0.73$). Female participants in both the typical care and intervention groups were more likely to have higher total DDS, emotional burden, doctor-related distress, and regimen-related distress, but not interpersonal distress. Additionally, females reported higher baseline depression in comparison with males ($P=0.006$). In general, depression diminished over the treatment time frame ($P=0.007$) yet stayed unaffected by group assignment ($P=0.06$) or by sex ($P=0.97$). Diabetes distress had no impact on the change in HbA1c ($P=0.91$) over the treatment time frame.

Conclusion

Despite the fact that the authors found no overall or sex-specific impact of the intervention on diabetes distress or depression, this examination makes a critical contribution to the larger understanding of mobile health interventions and their potential effects on emotional well-being. Our examination verified past findings that even with a strong correla-

tion between diabetes distress and depression, these measures are not assessing the same construct. The designers of future mobile innovations have an opportunity to personalize, contextualize, and intervene in the emotional well-being of people living with diabetes.

Comments

This study of a digital therapeutic addressed an important challenge seen with many people with diabetes: how to reduce distress and depression. While the study did not demonstrate positive results, it is nonetheless an important study. It is a real challenge to create a digital therapeutic that is effective, and it appears that one important element is the use of theory-based and proven-effective in-person interventions that are faithfully transformed for digital delivery. Determining what does not work allows developers to try other approaches.

Effectiveness of text message based, diabetes self-management support programme (SMS4BG)

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Background

The purpose of this study was to assess the success of a theory-based, personalized, text message-based, diabetes self-management support intervention (SMS4BG) in improving diabetes management in adults whose diabetes is currently not well controlled.

Methods

This experiment was designed as a two-arm, parallel randomized controlled trial with a 9-month duration with individuals who used primary and secondary health-care services in New Zealand. A total of 366 participants aged 16 years and older with poorly controlled T3D or T2D (HbA1c ≥ 65 mmol/mol or 8%) were randomized between June 2015 and November 2016 (n=183 intervention, n=183 control). Participants in the intervention group received a personalized set of text messages for up to 9 months in addition to regular care. The text messages supplied information, support, motivation, and reminders regarding diabetes self-management and lifestyle behaviors. The messages were delivered via a

tailored, automated content management system. The control group received regular care. The primary outcome was change in HbA1c from baseline to 9 months.

Results

The decrease in HbA1c at 9 months was significantly greater in the intervention cohort (mean -8.85 mmol/mol [standard deviation 14.84]) than in the control cohort (-3.96 mmol/mol [SD 17.02]; adjusted mean difference -4.23 [95% CI -7.30 to -1.15], $P=0.007$). Only 4 of the 21 secondary outcomes showed statistically significant improvements in the intervention cohort at 9 months. Significant improvements were observed for foot care behavior (adjusted mean difference 0.85 [95% CI 0.40 to 1.29], $P<0.001$); overall diabetes support (0.26 [95% CI 0.03 to 0.50], $P=0.03$); health status on the EQ-5D visual analogue scale (4.38 [95% CI 0.44 to 8.33], $P=0.03$); and perceptions of illness identity (-0.54 [95% CI -1.04 to -0.03], $P=0.04$). Participants reported high levels of satisfaction with SMS4BG, with 161 (95%) of 169 participants stating it was useful and 164 (97%) willing to recommend the program to other people living with diabetes.

Conclusion

A personalized, text message-based, self-management support program resulted in moderate improvements in glycemic control among adults with poorly controlled diabetes. While the clinical significance of these results is uncertain, the findings support further investigation into the use of SMS4BG and other text message-enabled support for this patient population.

Comments

This RCT of a digital therapeutic, using text messages for patients with diabetes, demonstrated modest positive results. It was a well-done study and demonstrated that text messaging can be an effective way to engage, educate, and motivate patients. Combining patients with T1D and T2D for analysis may mask some different impacts in the two populations. I assume the sample size was too small for such subanalysis. Perhaps the modest findings were because providing limited text messages is not powerful enough to overcome the all-too-common barriers to adopting and sustaining healthy behaviors. The SMS platform is quite promising, given its low cost and nearly ubiquitous availability. SMS is a delivery channel looking for the right interventions. When and how that secret sauce will be discovered is only a matter of time and the creativity of researchers and developers.

Testing a smartphone app (Young with Diabetes) to improve self-management of diabetes over 12 months: randomized controlled trial

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Background

Self-managing T1D in the transition from childhood through young adulthood is a challenging endeavor. Utilizing a mobile health (mHealth) app could possibly help young people better track their individual and daily needs through self-management. However, much more study and randomized controlled trials are necessary.

The objective of this study was to evaluate the mHealth app “Young with Diabetes” on the ability of young adults to self-manage their diabetes.

Methods

Participants aged 14–22 years with poor glycemic control, along with their parents, were entered into the study. They were randomly assigned to (1) a Young with Diabetes and routine health-care cohort (Young with Diabetes group) or (2) the routine care (control group). Activity on the Young with Diabetes group was closely monitored through the app’s features, including a chat room, contact with their health-care provider, reminders, tips, and T1D topics, such as carbohydrate counting. There was also a guardians’ section with similar information. Evaluated outcomes included HbA1c and three self-reported psychometric scales: Health Care Climate Questionnaire; Perceived Competence in Diabetes Scale; and Problem Areas in Diabetes care survey. Data were collected on enrollment and at 2, 7, and 12 months postenrollment.

Results

Overall, 151 participants were randomized to the Young with Diabetes ($n=76$) control ($n=75$) groups, and 49 guardians consented to participate. After 1 year, HbA1c had significantly increased (4.1 mmol/mol; 0.4%) in the Young with Diabetes group, vs the control group ($P=.04$); this finding was not seen when contrasting mobile application users (Young with Diabetes who utilized ≥ 5 days) with nonusers. Participants engaged with the Young with Diabetes app on a mean of 10.5 days. They invested the most time talking about alcohol and finding more information about sex. Most participants and half of the guardians stated that Young with Diabetes helped them. Over 80% would recommend Young with Diabetes to others with diabetes.

Conclusion

HbA1c was not improved while patients used Young with Diabetes. Qualitative assessment is necessary to investigate the advantages and weaknesses of Young with Diabetes.

Health-care providers should engage with young people on delicate subjects, provide a space to receive support from their peers, and know guardians' needs for information on how to support their children.

Comments

This RCT of a digital therapeutic tested the impact of a smartphone app on youth and young adults with type 1 diabetes. Despite the near universal acceptance of the app, there was only modest engagement and no improvement in diabetes-related outcomes. These results reinforce the challenges of making digital therapeutics that not only engage the participant but also help the person adopt and sustain the healthy behaviors necessary to improve outcomes.

A systematic review of reviews evaluating technology-enabled diabetes self-management education and support

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J Diabetes Sci Technol 2017; **11**: 1015–1027

Background

As the prevalence of cell phones has increased, technology is more frequently used to facilitate diabetes self-management support and education. This review outlines how technology-enabled diabetes self-management education and support affects outcomes for individuals living with diabetes.

Methods

This systematic review includes high-quality review articles and meta analyses published between January 2013 and January 2017 that concentrated on the use of technology to facilitate diabetes self-management education and support.

Results

Twenty-five studies were selected to be analyzed. A large number looked at the utilization of cell phones and secure messaging, and most of the studies described physical activity, healthy eating, and metabolic monitoring as the primary self-care practices assessed. Eighteen of the 25 surveys showed significant decreases in HbA1c as an outcome measure. Four key components were found to be fundamental for improving HbA1c outcomes: communication, patient-generated health data, education, and feedback.

Conclusion

Self-management solutions facilitated by technology can significantly improve HbA1c. The interventions found to be most successful incorporated all elements of a technology-enabled self-management feedback loop: the connection of

patients living with diabetes to their health-care team through two-way communication, the analysis of patient-generated health data, individualized education, and personalized feedback. Conclusions from this review provide compelling reasons for policy-makers, payers, and organizations to consider including these solutions in the framework of diabetes self-management education and support services for population health and value-based care models. With the far-reaching availability of cell phones, digital health solutions that incorporate evidence-based, behaviorally designed interventions can enhance the scope and accessibility of diabetes self-management education and continuous support.

Comments

This paper, an analysis of the impact of digital self-management support interventions, demonstrates that technology-enabled interventions can improve outcomes. A review of reviews is an interesting way to multiply the learnings from each review. While different than a meta-analysis, which pools data, a review of reviews uses a different method to pool conclusions. Both approaches have their limitations but can provide useful information. Such is the case with this paper.

Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update

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Background

Translations of the Diabetes Prevention Program (DPP) have demonstrated favorable clinical outcomes; however, long-term results for digital interventions are limited. This study examined clinical outcomes in a digital DPP up to 3 years postenrollment as well as the relationship between program engagement and clinical outcomes.

Methods

Adult patients (age ≥ 18 years; n=220) diagnosed with prediabetes were enrolled in a single-arm, nonrandomized trial. The commercially available intervention (Omada Health Program) is a 16-week DPP-based weight loss intervention followed by an ongoing weight maintenance intervention. Changes in body weight and HbA1c were assessed annually. Relationships between program engagement during the first year and clinical outcomes across 3 years were examined.

Results

Participants were 62% women, 50.2% non-Hispanic white, and 51.7% college educated or higher. From baseline to 3

years, those participants who completed four or more lessons and nine or more lessons achieved significant sustained weight loss (-3.0% and -2.9% , respectively) and an absolute reduction in HbA1c (-0.31% and -0.33% , respectively). Logins and group participation factor were significant predictors of weight loss at 16 weeks and 1 year. Lesson completion and health behavior tracking consistency was not associated with weight loss.

Conclusion

This study demonstrates long-term reductions in body weight and HbA1c in a digital DPP and identifies patterns of program engagement that predict weight loss.

Comments

This study, from the provider of the digital DPP to the most individuals, is a welcome addition to the literature demonstrating persistent outcomes 3 years after participants started the program.

Note: Two authors (N.K. and D.S.) have a potential conflict since they own (N.K.) or work (N.K., D.S.) for a company that markets a competitive product.

A fully automated conversational artificial intelligence for weight loss: longitudinal observational study among overweight and obese adults

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JMIR Diabetes 2017; 2: e28

Background

Two-thirds of adults in the United States have prediabetes or are overweight and therefore at risk for developing type 2 diabetes. Face-to-face counseling can enable patients to make healthier decisions regarding their eating habits and lifestyle changes. The lack of medical practitioners coupled with prohibitive costs challenges bringing these programs to scale. The health-care system needs successful and affordable interventions that can get results on a broader scale. This examination explored the capacity of conversational artificial intelligence (AI) in the form of a standalone, fully automated, text-based mobile coaching service to advance weight loss and other healthy living practices identified with diabetes prevention. Additionally, this investigation measured patient receptiveness to AI coaches as another option to live medical professionals.

Methods

A longitudinal observational investigation was carried out in overweight and obese (body mass index ≥ 25) adults who utilized Health Coach AI (HCAI). HCAI incorporates aspects of cognitive behavioral therapy to facilitate weight reduction and healthy eating decisions. Weight reduction, quality of meals, physical exercise, and sleep data were gathered via

participant input. Sleep and exercise data were gathered through automatic data collection by the participants' cell phones. Participant engagement was evaluated by length and frequency of app use. A four-question in-app survey was used to evaluate the app's ease of use and acceptability.

Results

Data were analyzed for 70 participants who met engagement standards set by the Centers for Disease Control and Prevention criteria for Diabetes Prevention Program, a clinically proven weight reduction curriculum concentrated on diabetes prevention. Weight loss (standard error of the mean) was 2.38% (0.69%) of baseline weight. Average time of application use was 15 (SD 1.0) weeks, with an average of 103 sessions per user. Factors that predicted weight loss included amount of AI use, number of coaching sessions, and number of meals logged. Healthy meal consumption increased by 31% . The in-app user trust survey returned positive feedback from a 100% completion rate, with a satisfaction score of 87 out of 100 and net promoter score of 47.

Conclusions

This study demonstrated that utilization of an AI health coach is associated with weight loss outcomes similar to those seen with in-person interventions. It can likewise support behavioral changes and have high user satisfaction. AI and its possible applications in telemedicine should be further examined through clinical trials researching impacts on weight, health behaviors, and participant engagement and acceptability.

Comments

This pilot of an AI-enabled DPP digital therapeutic demonstrates that AI can be used to motivate and educate individuals who need to lose weight for health. The authors state that "AI health coaches mimic health professionals' empathetic health counseling through casual conversations using empathetic text-based communication and other interactive elements"—very cool and promising. The small sample size limits the abilities to demonstrate significant outcomes in this study. The modest weight loss is a good early result.

Note: Two authors (N.K. and D.S.) have a potential conflict since they own (N.K.) or work (N.K., D.S.) for a company that markets a competitive product.

Peer-based social media features in behavior change interventions systematic review

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J Med Internet Res 2018; 20: e20

Background

Social media features have been incorporated into digital behavior change interventions (DBCIs) in an effort to increase their impact. The objective of this research was to perform a systematic review of DBCIs, targeting behavioral risk factors that have included social media platforms as part of their intervention.

Methods

This study surveyed eight databases to identify DBCIs that included social media features and focused on tobacco smoking, diet and nutrition, physical activities, or alcohol consumption. Social media taxonomy was used to inform the development, description, and evaluation of these interventions. Two independent researchers executed the screening and review processes of the potential articles.

Results

A total of 5264 articles were screened, and 143 articles representing a total of 134 studies were selected for full review. The majority of the studies (70%) reported positive outcomes, 28% found no effects, and 2% yielded negative outcomes. Few studies focused on the correlation between the inclusion of social media features and intervention effect. The social media taxonomy was used with 36 social media features organized under seven high-level categories. Using the taxonomy and recommendations could inform future research to isolate and address the effects of social media features on DBCIs, cross-study comparisons, and evaluations.

Comments

This review attempted to define the impact of peer-based social media on patient outcomes. We included this paper because the behaviors addressed in the interventions were lifestyle related and relevant to diabetes prevention and T2D management. A positive effect was usually seen when social networks were included; however, the studies were not able to show the specific impact of the social network. That is not surprising given the complex nature of behavioral interventions and the range of approaches to social support. A helpful result from the analysis is a taxonomy of the differences seen in social networks. The approaches include identify representation, communication, peer grouping, data sharing, competition, activity data viewing, and online social networking. It is hoped that future studies will identify the specific social media provided and the unique impact of the social media strategy.

The use of Facebook in recruiting participants for health research purposes: a systematic review

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J Med Internet Res 2017; **19**: e290

Background

Social media platforms are used for communication and trading information. People can post and share videos, pictures, and websites, which can then be talked about, republished, and endorsed by other people, their friends, and organizations. Advertisements can be presented and promoted to target groups of users by demographics, for example age or gender. Recruiting for health research studies is complicated and follows specific criteria. Classic recruiting for research studies depends on flyers, daily paper advertisements, radio and television commercials, letters, e-mail messages, site postings, and verbal discussion. It is possible that these strategies are not optimal for engaging hard-to-reach demographic groups and can be sluggish and costly. Recruiting participants through social media, specifically Facebook, might be quicker and less expensive. The goal of this study was to systematically review literature pertaining to the effectiveness of utilizing Facebook in recruiting people to participate in health research studies.

Methods

A literature review on articles published in the past 12 years was conducted in the English language in March 2017. The review utilized MEDLINE, EMBASE, Web of Science, PubMed, PsycInfo, Google scholar, and a hand search of article references. The number of users, period of recruitment, cost per click or user, number of impressions, and conversation rate were extracted from the selected articles.

Results

A total of 35 studies were found (United States [n=22], Australia [n=9], Canada [n=2], Japan [n=1], and Germany [n=1]) and were evaluated utilizing the Critical Appraisal Skills Programme checklist. Most studies were targeted to adolescents or young adults (16–24 years), with the rest of the focus on narrow demographic groups (e.g., veterans). Median value findings included 264 enrolled members, a 3-month recruitment period, 3.3 million impressions, a cost per click of U.S. \$0.51, conversion rate of 4% (range 0.06–29.50), study eligibility of 61% (range 17–100), and cost per enrolled study subject of U.S. \$14.41. In general, the studies indicated they were able to effectively engage hard-to-reach populations with the caveat that most of the recruits were young, white women.

Conclusions

Evidence suggesting that Facebook can be an effective recruitment instrument continues to accumulate, and researchers should consider using it when conducting health studies. Benefits of using Facebook relative to other standard recruitment include a reduction in cost, shorter recruiting time frames, improved representation, and better participant selection in young and hard-to-reach populations. Despite these improvements, drawbacks still exist, such as the overrepresentation of Caucasian women and restrictions connected to Internet access. It is necessary for upcoming studies to consider recruiting through other popular forms of social media and focus on recruiting participants across all age groups.

Comments

This paper addresses a very important issue: how to effectively recruit participants into health programs. Most research studies start with patients who show up for health interventions. While it is important that interventions demonstrate clinical and economic outcomes, successfully scaling programs to a high percentage of a targeted population requires effectively and efficiently getting patients to sign up and show up for the intervention. We need more studies showing which social media approaches work for what segments of the population.

Serious games for children with chronic diseases: a systematic review

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Games Health J 2018; 7: 291–301

Background

The objective for this study was to determine whether serious games impact health outcomes for children under 18 years of age who are living with chronic illnesses. The effects of changes in self-efficacy, adherence, knowledge, parent involvement, and study quality were also analyzed.

Methods

Randomized controlled trials utilizing a serious game as an intervention, for users under 18 years old, to ameliorate their chronic illness were identified from EBSCO, PubMed, and Web of Science databases and included in the study. Two independent researchers extracted data including title, author, and publication year; theory; chronic illness; number and age of participants; game description; study quality; intervention time frame; statistically significant findings; and parent involvement. Any discrepancies were resolved and consensus was reached. Eighteen studies were incorporated into the review.

Results

The health conditions included in the review were cerebral palsy, diabetes, asthma, vision disorders, and developmental disorders. Health outcomes were measured, including glycemic control, lung function, hospital admissions, motor capability, and visual acuity. Psychosocial factors surveyed included self-efficacy and knowledge. Two articles included parents in the interventions, and three articles utilized a specific theory. Six investigations produced significant health outcomes, and four studies found a significant change in one psychosocial variable.

Conclusion

This investigation showcases the potential for serious games to enhance health outcomes of young people. The

inconsistent outcomes suggest that future serious game interventions should be better formulated and thoroughly tested in order to support their effect on enhancing health results.

Comments

This systematic review of the impact of serious games for youth with chronic diseases provides a good overview of how games could impact outcomes. Unfortunately, but not surprisingly, the impact of the reviewed games was minimal. We fear that these first-generation health-promoting games will require significantly more research and development before they will be proven effective. Hopefully the creators of these approaches do not become impatient given the time and resources it takes to create a successful intervention and successfully bring it to market in a profitable way.

A team-based online game improves blood glucose control in veterans with type 2 diabetes: a randomized controlled trial

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Diabetes Care 2017; 40: 1218–1225

Background

There is limited evidence regarding whether web-based games can enhance the long-term health outcomes of patients with diabetes. We researched if presenting diabetes self-management education (DSME) via team-based online games delivered through e-mail or a mobile application could result in long-term improvement in HbA1c for patients living with diabetes.

Methods

A total of 456 patients taking oral diabetes medications with HbA1c ≥ 58 mmol/mol were randomly assigned to either a DSME game (with a civics booklet) or a civics game (with a DSME booklet). The 6-month games sent two questions twice a week through e-mail or mobile app. Participants earned points based on performance, and scores were posted on leaderboards. Modest financial rewards were given to winning teams and individuals. The primary outcome measure was change in HbA1c over a year-long period.

Results

Patients in the DSME game group had significantly greater HbA1c reductions over 12 months than patients in the civics game group (-8 mmol/mol [95% CI -10 to -7])

and -5 mmol/mol [95% CI -7 to -3], respectively; $P=0.048$). HbA1c decreases were greater among patients with baseline HbA1c >75 mmol/mol (-16 mmol/mol [95% CI -21 to -12] and -9 mmol/mol [95% CI -14 to -5] for DSME and civics game patients, respectively; $P=0.031$).

Conclusions

Patients living with diabetes who were randomized to an online game delivering DSME showed continual and significant improvements in HbA1c improvements. Among patients with poorly controlled diabetes, the DSME game reduced HbA1c by a magnitude comparable to starting a new diabetes medication. Online games may be a scalable intervention to improve health outcomes for populations of geographically dispersed patients living with diabetes and other chronic diseases.

Comments

Gamification to improve health, while having great promise, has not yet reached the level proven effective. This paper, an RCT of a game-based digital therapeutic approach with a relatively large sample size, was well done and demonstrated a positive outcome. How much of the impact was secondary to the team-based approach was not analyzable from this study design, but it would have been good to know. Ideally, this will be just one of what will become many studies demonstrating impact from a variety of gamification approaches.

“Active Team” a social and gamified app-based physical activity intervention: randomised controlled trial study protocol

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BMC Public Health 2017; **17**: 859

Background

A sedentary lifestyle is one of the primary preventable causes of chronic illness and early death, yet more than half of the Australian populace is not regularly active. Online physical activity interventions, which could possibly be a solution to reaching more users at a lower cost, have been a focal point of recent research. To better understand the capability of this approach, there is a need to build interventions that support retention and engagement and maintain impacts over time. This randomized controlled trial will assess the viability of a gamified physical activity intervention that connects individuals to one another through Facebook and is delivered via a mobile app.

Methods

The study is a three-group, cluster RCT investigation with 440 sedentary Australian adults who utilize Facebook at least once a week. Participants will be enlisted in groups of three to eight with their current friends on Facebook. Participant groups will be randomly assigned to one of three conditions: (1) waitlist control condition, (2) basic experimental condition (pedometer in addition to basic application with no social and gamification features), or (3) socially enhanced experimental condition (pedometer in addition to application with social and gamification features). Participants will be assessed at enrollment and at 3 and 9 months postenrollment. The main goal is to increase the minutes of at least moderate physical activity completed daily at 3 months, measured utilizing GENEActive accelerometers (Activeinsights Ltd., UK). The secondary goals are self-reported physical activity, anxiety and depression, well-being, quality of life, social-cognitive theory constructs, and application use and engagement.

Results

Since this article was a description of a not-yet-completed study, there are no results to present.

Conclusion

The current study will include novel social and gamification elements that will be used to examine whether the included features increase the effectiveness of app-based physical activity interventions. The results will be used to guide the development and increase the efficacy of future health behavior interventions.

Comments

While we usually do not include papers that describe future studies, this paper was included to highlight the real-world approaches to using social media, gamification, and mobile apps to change behaviors (in this case physical activity). The digital therapeutic protocol is elegantly simple and will attempt to understand the impact not only on physical activity, the primary outcome, but also on participant well-being. We look forward to reading the results in a few years.

Conclusion

This year's article has 17 manuscripts, of which 12 (71%) are reports of high-quality studies about specific digital therapeutics. This represents an exciting change from our articles in prior ATTD Yearbooks. We reviewed our articles from the past 3 years and found 12 studies about specific digital therapeutics out of a total of 51 selected articles (24%) (2015 was 6/16; 2016 was 2/17; and 2017 was 3/18). With the typical publication lag from study enrollment to publication of 3–4 years, the past promise of things to come is now getting closer to reality.

Many of the included studies are partnerships between academic institutions and the companies attempting to bring them to scale. Such partnerships are often necessary to build the evidence base need to justify reimbursement from health plans, providers, and employers. Some of these interventions

will, however, be marketed direct to consumers, where the requirements for efficacy and cost savings are much less stringent.

As we highlighted in prior ATTD Yearbook articles, to be successful at scale, a program needs to not only work for those who actually show up to start the intervention; the intervention must also be coupled with effective outreach, education, and activation to get a large enough proportion of the targeted population to sign up, show up, and be ready and inclined to complete the program. Once again, there were only a few papers on what works, and with which popula-

tions, to increase showing up, participation, and completion. Time will tell which of these interventions and companies will thrive, but we are encouraged by what we see emerging in the digital therapeutics field.

Author Disclosure Statement

N.K. and D.S. work for, and have equity interest in, Canary Health, Inc, and are conflicted regarding the articles noted within the article. C.F. declares that no competing financial interests exist.