Using Digital Health Technology to Prevent and Treat Diabetes

Neal Kaufman^{1,2} and Eran Mel³

Introduction

THIS ARTICLE IS our annual attempt to highlight the key digital health-related diabetes prevention and treatment articles published in the past year (between July 1, 2018, and June 30, 2019). Continuing a trend seen over the past several years, there are increasing numbers of papers that report on research studies using a digital therapeutic specifically designed to get health and economic outcomes that matter. However, there are still very few studies with rigorous protocols and enough participants to demonstrate generalizable results. This reflects the relatively new field of digital therapeutics and the time and cost it takes to plan, implement, evaluate, write-up, and publish high quality research.

As in years past, we made a special effort to try to find papers that addressed the critical need to engage patients in effective interventions if they are going to have any impact. Four of the 19 papers this year address recruitment and engagement—better than in the past, but still far behind what is needed to inform and influence the field.

One area we wish to highlight is the explicit or implicit reference in many studies to increasing self-efficacy—one's capacity to identify actions that improve one's life and the confidence to accomplish those actions. When individuals with low self-efficacy become more confident that they can set and reach a goal they

1. Accelerate health behavior change (e.g. healthy eating, medication adherence),
2. Reduce depression, anxiety, and stress-related disorders,
3. Diminish social isolation, and
4. Improve system navigation and health program uptake.

Importantly, the impact of self-efficacy to improve life and health is a universal characteristic and not isolated to a specific national, cultural, or socio-economic group. Decades of research has demonstrated this central tenet of human identity. While each of us is unique, we have many things in common with others throughout the world. In general, people with a strong sense of self-efficacy (high confidence they can set a goal and accomplish it) view challenging problems as tasks to be mastered, develop deeper interest in the activities in which they participate, form a stronger sense of commitment to their interests and activities, and recover quickly from setbacks and disappointments. Mahatma Gandhi stated it more simply: "If I have the belief that I can do it, I shall surely acquire the capacity to do it even if I may not have it at the beginning." On the contrary, if someone has low self-efficacy, they typically avoid challenging tasks, believe that difficult tasks and situations are beyond their capabilities, focus on personal failings and negative outcomes, and quickly lose confidence in personal abilities. It is hoped that future yearbook articles will have many successful interventions in which increasing self-efficacy is the mechanism of action of the digital therapeutic.

¹Fielding School of Public Health, Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA

²Canary Health, Inc., Los Angeles, CA

³The Jesse Z. and Sara Lea Shafer Institute for Endocrinology and Diabetes, National Centre for Childhood Diabetes, Schneider's Children's Medical Center of Israel, Petah Tikva, Israel

Key Articles Reviewed for the Article

Reduced medical spending associated with increased use of a remote diabetes management program and lower mean blood glucose values

Whaley CM, Bollyky JB, Lub W, Painter S, Schneider J, Zhaod Z, He K, Johnson J, Meadows ES

J Med Econ 2019; **22**: 869–877

Effect of health information technologies on glycemic control among patients with type 2 diabetes

Yoshida Y, Boren SA, Soares J, Popescu M, Nielson SD, Simoes EJ

Curr Diab Rep 2018; **18**: 130

Tailored mobile text messaging interventions targeting type 2 diabetes self-management: a systematic review and a meta-analysis

Sahin C, Courtney KL, Naylor PJ, E Rhodes R

Digit Health 2019; **5**: 1–21

Electronic health lifestyle coaching among diabetes patients in a real-life municipality setting: observational study

Komkova A, Brandt CJ, Hansen Pedersen D, Emneus M, Sortsø C

JMIR Diabetes 2019; **4**: e12140

Evaluating the effects of mobile health intervention on weight management, glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus

Guo H, Zhang Y, Li P, Zhou P, Chen LM, Li SY

J Endocrinol Invest 2019; **42**: 709–714

Real-world assessments of mySugr mobile health app

Debong F, Mayer H, Kober J

Diabetes Technol Ther 2019; **12**: S235–S240

A web-based cognitive behavior therapy intervention to improve social and occupational functioning in adults with type 2 diabetes (the SpringboardD trial): randomized controlled trial

Clarke J, Sanatkar S, Baldwin PA, Fletcher S, Gunn J, Wilhelm K, Campbell L, Zwar N, Harris M, Lapsley H, Hadzi-Pavlovic D, Christensen H, Proudfoot J

J Med Internet Res 2019; **21**: e12246

IDF Europe's position on mobile applications in diabetes

Rose KJ, Petrut C, L'Heveder R, de Sabata S

Diabetes Res Clin Pract 2019; **149**: 39–46

Enhanced self-efficacy and behavioral changes among patients with diabetes: cloud-based mobile health platform and mobile app service

Chao DY, Lin TM, Ma WY

JMIR Diabetes 2019; **4**: e11017

A mobile phone-based program to promote healthy behaviors among adults with prediabetes who declined participation in free diabetes prevention programs: mixed-methods pilot randomized controlled trial

Griauzde D, Kullgren JT, Liestenfeltz B, Ansari T, Johnson EH, Fedewa A, Saslow LR, Richardson C, Heisler M

JMIR Mhealth Uhealth 2019; **7**: e11267

The post-trial analysis of the Indian SMS diabetes prevention study shows persistent beneficial effects of lifestyle intervention

Nanditha A, Snehalatha C, Raghavan A, Vinita R, Satheesh K, Susairaj P, Simon M, Selvam S, Ram J, Naveen Kumar AP, Godsland IF, Oliver N, Johnston DG, Ramachandran A

Diabetes Res Clin Pract 2018; **142**: 213–221

Results from a trial of an online diabetes prevention program intervention

Moin T, Damschroder LJ, AuYoung M, Maciejewski ML, Havens K, Ertl K, Vasti E, Weinreb JE, Steinle NI, Billington CJ, Hughes M, Makki F, Youles B, Holleman RG, Kim HM, Kinsinger LS, Richardson CR

Am J Prev Med 2018; **55**: 583–591

Effectiveness of an app and provider counseling for obesity treatment in primary care

Bennett GG, Steinberg D, Askew S, Levine E, Foley P, Batch BC, Svetkey LP, Bosworth HB, Puleo EM, Brewer A, DeVries A, Miranda H

Am J Prev Med 2018; **55**: 777–786

The effect of a digital behavioral weight loss intervention on adherence to the dietary approaches to stop hypertension (DASH) dietary pattern in medically vulnerable primary care patients: results from a randomized controlled trial

Steinberg D, Kay M, Burroughs J, Svetkey LP, Bennett GG

J Acad Nutr Diet 2019; **119**: 574–584

Web-based digital health interventions for weight loss and lifestyle habit changes in overweight and obese adults: systematic review and meta-analysis

Beleigoli AM, Andrade AQ, Cançado AG, Paulo MN, Diniz MFH, Ribeiro AL

J Med Internet Res 2019; **21**: e298

Recruiting to a randomized controlled trial of a web-based program for people with type 2 diabetes and depression: lessons learned at the intersection of e-mental health and primary care

Fletcher S, Clarke J, Sanatkar S, Baldwin P, Gunn J, Zwar N, Campbell L, Wilhelm K, Harris M, Lapsley H, Hadzi-Pavlovic D, Proudfoot J

J Med Internet Res 2019; **21**: e12793

Clinical trial recruitment and retention of college students with type 1 diabetes via social media: an implementation case study

Wisk LE, Nelson EB, Magane KM, Weitzman ER

J Diabetes Sci Technol 2019; **13**: 445–456

Digital recruitment and acceptance of a stepwise model to prevent chronic disease in the Danish primary care sector: cross-sectional study

Larsen LB, Sondergaard J, Thomsen JL, Halling A, Sønderlund AL, Christensen JR, Thilsing T

J Med Internet Res 2019; **21**: e11658

Recruitment of men to a multi-centre diabetes prevention trial: an evaluation of traditional and online promotional strategies

Bracken K, Hague W, Keech A, Conway A, Handelsman DJ, Grossmann M, Jesudason D, Stuckey B, Yeap BB, Inder W, Allan C, McLachlan R, Robledo KP, Wittert G

Trials 2019; **20**: 366

Reduced medical spending associated with increased use of a remote diabetes management program and lower mean blood glucose values

Whaley CM¹, Bollyky JB^{2,3}, Lub W², Painter S², Schneider J², Zhaod Z⁴, He K⁴, Johnson J⁴, Meadows ES⁴

¹RAND Corporation, Santa Monica, CA; ²Livongo Health, Mountain View, CA; ³Stanford University School of Medicine, Stanford, CA; ⁴Eli Lilly and Company, Indianapolis, IN

J Med Econ 2019; **22**: 869–877

Aims

Numerous new mobile technologies have been developed to assist in the management of chronic conditions, but there is little data on the effect of using these technologies on medical spending remains limited. With the increasing availability of digital technologies to assist in diabetes management, it is important to understand this connection. This study used medical claims and real-time blood glucose data to examine the financial impact of using a remote digital diabetes management program.

Materials and Methods

Data collected from a remote digital diabetes management program was analyzed in a retrospective analysis of multivariate difference-in-difference along with an instrumental variables regression modeling. The study population was drawn from Livongo members who were continuously enrolled in health benefits for the entire 1-year period before and after they were given access to the Livongo for Diabetes program. A phased introduction was used to recruit participants into the program. In a phased introduction, all employees with diabetes were invited to join the program. Participants included members (those who accepted the invitation, $n=2,261$) and nonmembers ($n=8,741$) who received health insurance benefits from three self-insured employers. Blood glucose (BG) values were captured remotely from members via connected BG meters and spending data were gathered from medical spending claims. Medical spending was compared between people with well-controlled (BG 154 mg/dL) and poorly controlled (BG 154 mg/dL) diabetes.

Results

Access to the Livongo for Diabetes program was associated with a 21.9% decrease in medical spending ($P<0.01$), which added up to an \$88 saving per member per month at 1 year. Members experienced a 10.7% ($P<0.01$) decrease in diabetes-related medical expenditures and a 24.6% ($P<0.01$) decrease in spending on office-based services when compared with nonmembers. Overall, participants with well-controlled BG values had 21.4% ($P<0.03$) lower medical spending.

Conclusions

Remote digital diabetes management was linked to lower medical spending at 1 year. Reductions in spending increased with active utilization. Subsequent investigations should analyze the long-term effects of the remote diabetes management program and assess the effect on participant health and well-being.

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Comments

This paper is one of the first studies to look at the financial impact of providing virtual coaching support to patients with diabetes who are also offered remote monitoring of their blood glucose. While the results are promising, the retrospective nature of the study and the many potential confounders inherent in the research design make these results promising but in no way close to definitive. Time, and additional studies with more reliable and valid designs, will tell. (Note: this study used the Livongo for Diabetes program.)

Effect of health information technologies on glycemic control among patients with type 2 diabetes

Yoshida Y^{1,2}, Boren SA¹, Soares J³, Popescu M¹, Nielson SD⁴, Simoes EJ¹

¹Department of Health Management and Informatics, School of Medicine, University of Missouri-Columbia, Columbia, MO; ²Missouri Cancer Registry and Research Center, University of Missouri-Columbia, Columbia, MO; ³Centers for Disease Control and Prevention, Division of High-Consequences Pathogens and Pathology, Prion and Public Health Office, Atlanta, GA; ⁴Mercy Medical Center, Sioux City, IA

Curr Diab Rep 2018; **18**: 130

Purpose of Review

Meta-analysis findings are presented across selected clinical trials regarding the effect of health information technologies (HITs) on glycemic control among patients with type 2 diabetes (T2D).

Recent Findings

HITs are potentially beneficial in diabetes management; however, previous studies reported varying results regarding effect size of glycated hemoglobin level (HbA1c) collected from HITs. This inconsistency is likely due to differences in sample size, observation of standard quantitative methods, and/or search criteria (e.g., type of HITs, type of diabetes, specification of patient population, randomized vs. non-randomized trials).

Summary

Systematic searches were carried out in Medline, Cumulative Index of Nursing and Allied Health Literature, and the Cochrane Library for peer-reviewed randomized control trials investigating the effect of HITs on HbA1c reduction. We also searched Google Scholar and conducted a manual search to identify additional research. Thirty-four studies (40 estimates) met the criteria and were included in the analysis. Overall, when HITs were introduced into standard diabetes treatment, HbA1c was statistically and clinically reduced. The combined HIT interventions led to a bias-adjusted HbA1c reduction of -0.56

(Hedges' $g = -0.56$ 95% CI $[-0.70, -0.43]$). This significant decrease was observed across each of the four types of HIT intervention reviewed; the most significant effects were generated by mobile phone-based approaches (Hedges' $g = -0.67$ 95% CI $[-0.90, -0.45]$). HITs can be an effective tool for glycemic control among patients with T2D. Future studies should examine long-term effects of HITs and explore factors that influence their effectiveness.

Comments

As with most reviews of independent studies, definitive conclusions regarding impact are difficult to determine. This review of 34 studies provides further support to the emerging consensus that health information technology-enabled interventions can lead to positive impact.

Tailored mobile text messaging interventions targeting type 2 diabetes self-management: a systematic review and a meta-analysis

Sahin C^{1,2,3,4}, Courtney KL^{1,2,3,4}, Naylor PJ^{1,2,3,4}, E Rhodes R^{1,2,3,4}

¹Social Dimensions of Health Program, University of Victoria, Victoria, British Columbia, Canada; ²School of Health Information Science, University of Victoria, Victoria, British Columbia, Canada; ³School of Exercise Science, Physical and Health Education, University of Victoria, Victoria, British Columbia, Canada; ⁴Behavioural Medicine Laboratory, School of Exercise Science, Physical and Health Education, University of Victoria, British Columbia, Canada

Digit Health 2019; 5: 1–21

Background

Text messaging can provide a customized, convenient, cost-effective support to assist patients in continuously tracking their medical and behavioral outcomes; however, it is not yet clear how to create and deliver messages that effectively motivate patients to modify their behavior. The objective of this study was to identify, assess, and summarize available scientific evidence on tailored text messaging interventions in the area of T2D self-management. The systematic review focused on message design and delivery features as well as tailoring strategies. The meta-analysis addressed the moderators of the effectiveness of tailored text messaging interventions.

Methods

A comprehensive search was conducted; sources of data encompassed major electronic databases, key journal searches, and reference list searching for related studies. PRISMA and Cochrane Collaboration's guidelines and recommended tools for data extraction, quality appraisal, and data analysis were followed. Data were retrieved regarding participant characteristics (age, gender, ethnicity) along with interventional and methodological characteristics (study design, setting, and length; choice of modality; comparison group; message type, format, content, frequency, timing, and delivery; use of in-

teractivity; tailoring strategies; and theories used). Outcome measures of interest included diet, physical activity, medication adherence, and HbA1c. A random effects meta-analysis was performed when possible to pool data on the effectiveness of the moderator variables and tailored text messaging interventions.

Results

Thirteen eligible trials were located for the systematic review and 11 for the meta-analysis. Most of the eligible studies were randomized controlled trials that were conducted in high-income settings, used multimodalities, and typically delivered informative, educational messages via an automated delivery system. Tailored text messaging programs produced a meaningful effect ($g = 0.54$ [95% CI 0.08–0.99] $P < 0.001$) on HbA1c values for 949 patients in all. Subgroup analyses uncovered the importance of some moderators, including message delivery (QB = 18.72, $df = 1$, $P = 0.001$), message direction (QB = 5.26, $df = 1$, $P = 0.022$), message frequency (QB = 18.72, $df = 1$, $P = 0.000$), and use of multimodalities (QB = 6.18, $df = 1$, $P = 0.013$).

Conclusions

Tailored mobile text messaging interventions can improve glycemic control in T2D patients. However, more rigorous interventions with larger samples and longer follow-ups are required to confirm these findings and explore the effects of tailored text messaging on other self-management outcomes.

Comments

This paper, a review and meta-analysis of text messaging interventions for adults with T2D, adds to the literature regarding technology-enabled behavior change interventions. Limitations of the study are that most of the studies were in higher-income individuals and that the participants starting A1c ranged from 6.5% to 8%. These values reflect relatively good glucose control, making it hard to demonstrate significant impact. The article provides a well written review of the elements of interventions and the theories on which they are built. I fear that interventions only using text messaging will not provide enough of a dose effective to change behaviors especially for those people with low self-efficacy (confidence) and low motivation to improve. I hope I am wrong. Stay tuned.

Electronic health lifestyle coaching among diabetes patients in a real-life municipality setting: observational study

Komkova A¹, Brandt CJ², Hansen Pedersen D³, Emneus M¹, Sortsø C¹

¹Institute of Applied Economics and Health Research Aps, Copenhagen, Denmark; ²Research Unit of General Practice, Department of Public Health, University of Southern Denmark, Odense, Denmark; ³The Maersk Mc-Kinney Moller Institute, University of Southern Denmark, Odense, Denmark

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Background

Internet and mobile interventions promoting healthy behaviors and lifestyle practices have garnered a great deal of attention due to their scalability and accessibility, low costs, privacy and user control, and potential for use in real-life settings. They also provide the possibility of real-time modifications and allow interactive advising. Between summer 2016 and summer 2018, a real-life electronic health (eHealth) lifestyle coaching intervention based on previous qualitative studies was implemented in eight Danish municipalities.

Objective

The purpose of this study was to assess the outcome data associated with a real-life implementation of the eHealth intervention among diabetes patients in a municipal setting. The eHealth intervention begins with an initial meeting, meant to establish a strong empathic relationship, and subsequent digital lifestyle coaching and collaboration, with support through a Web-based patient community.

Methods

An observational study was conducted to examine the effect of an eHealth intervention on self-reported weight change in 103 obese diabetes patients in a real-life municipal setting. Participants in the study took part in the eHealth intervention for range of 3 to 12 months. Weight change was reported at 6, 9, and 12 months. Effects of the intervention on weight change was estimated using regression methods.

Results

Analysis showed that the eHealth intervention led to significantly reduce weight among diabetes patients, averaging 4.3% of initial body mass, which corresponds to 4.8 kg over a mean period of 7.3 months. Individuals who participated in the intervention for more than 9 months achieved average weight reduction of 6.3% (6.8 kg).

Conclusions

This study presents evidence that a real-life eHealth lifestyle intervention had a positive effect on the lifestyles of diabetes patients in a municipal setting. Future research should focus on determining whether the effect is sustainable from a long-term perspective.

Comments

The results are not very surprising. If you enroll motivated people in a weight loss program, they lose weight. The obvious question is whether it can be sustained beyond a year and whether less motivated people can be helped. This study was unable to address these questions.

Evaluating the effects of mobile health intervention on weight management, glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus

Guo H, Zhang Y, Li P, Zhou P, Chen LM, Li SY

NHC Key Laboratory of Hormones and Development (Tianjin Medical University), Tianjin Key Laboratory of

Metabolic Diseases, Tianjin Medical University Metabolic Diseases Hospital, Tianjin Institute of Endocrinology, Tianjin, China

J Endocrinol Invest 2019; **42**: 709–714

Purpose

The effects of mobile health (mHealth) intervention on pregnancy weight management, blood glucose control, and pregnancy outcomes were explored.

Methods

The study was carried out in 124 patients with gestational diabetes mellitus. Patients were randomly divided into two groups: control ($n = 60$) and treatment ($n = 64$). Patients in the control group received standard outpatient treatment, while the treatment received online guidance from a nurse through a mobile medical mobile phone-based app as well as regular offline clinical treatment via the mHealth group. Patients were treated for an average of 13 weeks. General condition, compliance, blood glucose, glycosylated hemoglobin, weight gain, pregnancy, and neonatal outcome were monitored for patients in both groups longitudinally.

Results

The treatment (mHealth) group demonstrated higher levels of compliance ($83.3 \pm 12.5\%$ vs. $70.4 \pm 10.1\%$, $t = -6.293$, $df = 122$; $P < 0.001$), lower frequency of outpatient service (8.1 ± 1.3 vs. 11.2 ± 1.1 , $t = 14.285$, $df = 122$; $P < 0.001$), and lower HbA1c before delivery (4.7 ± 0.2 vs. 5.3 ± 0.3 , $t = 13.216$, $df = 122$; $P < 0.001$). Rates of off-target measurements, both fasting ($4.6 \pm 0.4\%$ vs. $8.3 \pm 0.6\%$, $t = 40.659$, $df = 122$; $P < 0.001$) and 2 hours post-prandial ($7.9 \pm 0.7\%$ vs. $14.7 \pm 0.8\%$, $t = 50.746$, $df = 122$; $P < 0.001$), showed higher compliance as well. The mHealth group exhibited less weight gain than did the control group (3.2 ± 0.8 vs. 4.8 ± 0.7 , $t = 11.851$, $df = 122$; $P < 0.001$).

Conclusions

Mobile health intervention management of patients with gestational diabetes mellitus improves treatment compliance and blood glucose control, and results in reduced weight gain, thereby decreasing the occurrence of complications in both pregnant women and fetuses during delivery and pregnancy.

Comments

The results from this study are promising but hard to interpret given the relatively small sample size and the confounding of results, since the mHealth group also received offline clinical treatment. While this is part of providing complete diabetes care, it makes it more difficult to tease out the impact of the mHealth component from the non-mHealth supports.

Real-world assessments of mySugr mobile health app

Debono F¹, Mayer H², Kober J²

¹hi.health, Vienna, Austria; ²mySugr GmbH, Vienna Austria

Diabetes Technol Ther 2019; **12**: S235–S240

Abstract

Mobile health (mHealth) solutions such as diabetes self-management apps improve glycated hemoglobin, particularly those that provide a feedback loop between patient and healthcare provider. mHealth apps that incorporate behaviorally designed interventions can improve patient access to diabetes self-management education and ongoing support. The mySugr mobile app was designed to support patients in their diabetes self-management. Most studies of mHealth apps were conducted under controlled conditions and did not elucidate the nuances of patient perceptions and utilization of these apps in everyday life. In this article, we discuss findings from real-world observations of changes in glycemic control and patient satisfaction associated with the use of the mySugr mHealth app.

Comments

This review, written by employees of the company which created and markets mySugr, provides a good overview of many of the patient reported outcomes so important to successful self-management. Other studies have addressed specific glucose related outcomes seen with mySugr, and this is a refreshing take on the things that matter to patients.

A web-based cognitive behavior therapy intervention to improve social and occupational functioning in adults with type 2 diabetes (the Springboard trial): randomized controlled trial

Clarke J^{1,2}, Sanatkar S^{2,3}, Baldwin PA^{1,2}, Fletcher S⁴, Gunn J⁴, Wilhelm K², Campbell L⁵, Zwar N⁶, Harris M⁷, Lapsley H², Hadzi-Pavlovic D², Christensen H¹, Proudfoot J^{1,2}

¹Black Dog Institute, Sydney, Australia; ²School of Psychiatry, University of New South Wales–Sydney, Sydney, Australia; ³The Black Dog Institute, Sydney, Australia; ⁴Department of General Practice, University of Melbourne, Melbourne, Australia; ⁵Diabetes and Metabolism Division, Garvan Institute of Medical Research, Sydney, Australia; ⁶School of Medicine, University of Wollongong, Wollongong, Australia; ⁷Centre for Primary Health Care and Equity, University of New South Wales–Sydney, Sydney, Australia

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Background

Depressive symptoms are frequently co-occurring in individuals with T2D mellitus (T2DM). Effective treatments for depression exist, but access to psychological support is typically low. Web-based cognitive behavioral therapy is accessible, nonstigmatizing, and a potentially helpful method for mitigating the substantial personal and public health impacts of comorbid T2DM and depression.

Objective

This study on the web-based cognitive behavioral therapy program myCompass assessed its effectiveness at improving social and occupational functioning in adults patients with T2DM and

mild to moderate depressive symptoms. myCompass is a fully automated, self-guided public health treatment program for common mental health problems. The treatment was also evaluated regarding its effect on depressive symptoms, diabetes-related distress, anxiety symptoms, and self-care behavior.

Methods

Participants with T2DM and mild to moderate depressive symptoms ($n=780$) were recruited online via Google and Facebook advertisements targeting adults with T2DM and via community and general practice settings. Patients self-administered online screening, consent, and self-report scales. Double-blind computerized block randomization was used to assign participants to either myCompass ($n=391$) for 8 weeks plus a 4-week tailing-off period or to an active placebo intervention ($n=379$). The primary outcome measure was the Work and Social Adjustment Scale, which participants completed at baseline and postintervention (3 months). Secondary outcome measures included the Patient Health Questionnaire-9 item, Diabetes Distress Scale, Generalized Anxiety Disorder Questionnaire-7 item, and items from the Self-Management Profile for Type 2 Diabetes.

Results

Treatment-group participants using myCompass logged in an average of six times during the study period and completed an average of 0.29 modules, while those using Healthy Lifestyles logged in an average of four times and completed an average of 1.37 modules. Mean baseline scores on several outcome measures, including the primary outcome of work and social functioning, were in near-normal range, despite the extensive recruitment process. Approximately 61.6% (473/780) of participants completed the postintervention assessment. Improvement was noted via intention-to-treat analysis in the areas of functioning, depression, anxiety, diabetes distress, and healthy eating over time in both groups. The only specific between-group effects were in blood glucose monitoring and medication adherence. Follow-up analyses suggested that the outcomes did not depend on age, morbidity, or treatment engagement.

Conclusions

At 3 months postintervention, social and occupational functioning did not improve more for myCompass users than for users of the control program, nor did depressive symptoms, diabetes-related distress, anxiety symptoms, and self-care behavior. Interpretation of these findings should take into account the near-normal mean baseline scores on several variables, as well as the self-selected study sample and sample attrition. To reduce the burden posed by T2DM, further attention should be paid to factors influencing uptake and engagement with mental health treatments by people with T2DM along with the impact of illness comorbidity on patient conceptualization and experience of mental health symptoms.

Comments

This study was well done and tried to answer a very important question of whether a digital therapeutic that focuses on improving participants' mental health is effective.

Unfortunately, the study's flaws—and all studies have them—were too great to overcome. The main problem with this study was the lack of mental health problems on entry into the study. If the population does not have a problem with the main outcome being evaluated, it is nearly impossible to demonstrate impact. I also worry about an intervention which has an average of only six logons and an average of 0.29 modules over 8 weeks. Depending on the intensity of each interaction the dose effect would be expected to be small.

fitness; device connectivity platforms; coaching/wellness; and social networking/blog. Apps should be thought of as tools to help patients self-manage their diabetes or other conditions. Apps should be contrasted with true digital therapeutics in which the program delivers an intervention to a targeted population for a specific set of outcomes. Ideally, they are based on theory and evidence regarding what works and use a specific mechanism of action which has proven effective with the target population for the desired outcomes. Given the thousands of apps available it is truly worth following the advice: "Buyer beware."

IDF Europe's position on mobile applications in diabetes

Rose KJ¹, Petrut C², L'Heveder R³, de Sabata S⁴

¹International Diabetes Foundation (IDF) Europe Board Member, Visiting Faculty EIR-Healthcare Management, INSEAD, Fontainebleau, France; ²IDF Europe Board Member, Clinical Psychologist and Psychotherapist, Cluj Napoca, Romania; ³IDF Europe Senior Advocacy and Communication Consultant, France; ⁴IDF Europe Regional Manager, Belgium

Diabetes Res Clin Pract 2019; **149**: 39–46

Abstract

In the last 10 years, advances in technology and connectivity have led to an explosion of internet-based and mobile applications (apps), which have made it easier and faster to access to information and have changed our daily lives. Currently, 60 million people live with diabetes in Europe and 32 million more at risk. For this reason, people with diabetes are a major target for software companies, who aim to help people manage this chronic condition and to prevent diabetes in at-risk individuals. The International Diabetes Federation (IDF) Europe is the voice of 70 national associations representing those with diabetes as well as health professionals in 47 European countries and a strong supporter of healthcare innovation. With the emergence of apps in the field of diabetes, considering the general uptake of a connected lifestyle, and recognizing the potential for these apps to make a difference in the lives of people living with diabetes, IDF Europe considered mobile applications in diabetes and investigated diabetes and new technology through psychology, motivation, and behavioral change in diabetes management; the healthcare professional perspective; and potential roles of diabetes-related apps, pointing to existing evidence and important ethical issues. Finally, following this examination, IDF Europe offered recommendations at the individual, healthcare professional, political, and app developer levels.

Comments

This paper focused on diabetes-related apps (applications that reside on a mobile phone) and can serve as a starting point for substantive discussions about the use of apps in diabetes prevention and control. It distinguished six different types of apps: tracking/logging; nutrition;

Enhanced self-efficacy and behavioral changes among patients with diabetes: cloud-based mobile health platform and mobile app service

Chao DY¹, Lin TM², Ma WY³

¹Healthcare Solution Center, Health Inventor of Taipei, Taipei City, Taiwan; ²Graduate Institute of Management, National Taiwan University of Science and Technology, Taipei City, Taiwan; ³Department of Metabolism, Cardinal Tien Hospital, New Taipei City, Taiwan

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Background

The prevalence of chronic disease, especially diabetes, is increasing rapidly. Self-management has become a more common approach for improving outcomes in these chronic conditions, and health promotion models have shifted toward patient-centered care and self-efficacy. Devices and mobile apps in the Internet of Things (IoT) have become vital self-management tools for gathering and analyzing personal data for better individual health outcomes. However, the exact influence of web-based interventions on self-efficacy and the related individual motivations behind patients' behavioral changes have not been determined.

Objective

The objective of this study was to gain insight into the self-efficacy of patients with newly diagnosed diabetes (type 2 diabetes mellitus) and to analyze the correlation between this and patient-centered health promotion behavior along with investigating the implications of the results for IoT and mobile health mobile apps. A cloud-based interactive healthcare management mobile app and interactive personalized management framework were developed and a platform was adopted as a service tier.

Methods

Potential participants were identified using data from the electronic health database ($n=3,128$), of whom 121 were selected after assessment based on exclusion criteria. Randomized controlled trials were employed to determine patient preferences in the health promotion program ($n=62$) and mobile self-management education ($n=28$). The transtheoretical model was used as a framework for observing self-management behavior for improving individual health, and the

theory of planned behavior was used to evaluate personal goals, execution, outcome, and personal preferences. After determining individualized health promotion interventions using mobile app, these interventions were applied to improve patients' self-management and self-efficacy.

Results

Questionnaires were administered through the mobile app for pre- and postintervention assessment. For 6 months following the trial, a dynamic questionnaire allocation method was used to follow up and monitor patient behavioral changes. Subjects at a high risk of complications related to blood pressure (systolic blood pressure ≥ 120 mm Hg) and BMI (≥ 23 kg/m²) were considered to possess high motivation to change and to achieve high scores in the self-care knowledge assessment ($n=49$ [95% CI -0.26% to -0.24% ; $P=0.052$). Clinical outcomes in the group with mobile-based intervention were slightly better than those in the control group (glycated hemoglobin mean -1.25% [95% CI 6.36 to 7.47]; $P=0.002$). In addition, 86% (42/49) of participants expanded their health knowledge through the mobile-based app along with information and communications technology. The behavior-change compliance rate was higher among female participants. The personal characteristics of steadiness and dominance also corresponded with a higher compliance rate in the dietary and wellness intervention (83%, 81/98). Most subjects (71%, 70/98) also increased their attention to healthy eating, being active, and monitoring their condition (30% 21/70; 21% 15/70; and 20% 14/70, respectively).

Conclusions

Overall compliance rate among participants was higher after the mobile app-based health intervention. Various intervention strategies based on patient characteristics, healthcare-related word-of-mouth communication, and social media may be used to increase self-efficacy and improve clinical outcomes. Further research focus on determining the most influential factors and the most effective adherence management techniques.

Comments

This paper reports the results of a digital therapeutic intervention for Chinese adults with T2D. It demonstrated that participants increased their self-efficacy and ability to self-manage their diabetes through the adoption of new health promoting behaviors. This is encouraging.

A mobile phone-based program to promote healthy behaviors among adults with prediabetes who declined participation in free diabetes prevention programs: mixed-methods pilot randomized controlled trial

Griauzde D^{1,2,3}, Kullgren JT⁴, Liestenfeltz B⁵, Ansari T⁶, Johnson EH², Fedewa A⁴, Saslow LR⁵, Richardson C^{2,3}, Heisler M^{2,3,4,6}

¹Veterans Affairs Center for Clinical Management Research, Veterans Affairs Ann Arbor Healthcare System, Ann

Arbor, MI; ²University of Michigan Medical School, Ann Arbor, MI; ³Institute for Healthcare Policy and Innovation, University of Michigan, Ann Arbor, MI; ⁴University of Michigan School of Dentistry, Ann Arbor, MI; ⁵University of Michigan School of Nursing, Ann Arbor, MI; ⁶University of Michigan School of Public Health, Ann Arbor, MI

JMIR Mhealth Uhealth 2019; 7: e11267

Background

Although evidence shows that diabetes prevention programs (DPPs) can delay or prevent progression to type 2 diabetes mellitus (T2DM), few individuals with prediabetes enroll in such programs when offered. It is possible that many individuals with prediabetes have low levels of autonomous motivation (i.e., motivation from internal sources) to prevent T2DM.

Objective

This study investigates the feasibility and acceptability of an mHealth intervention aimed at increasing autonomous motivation and healthy behaviors among adults with prediabetes who previously declined participation-free DPPs. The study also examined changes in autonomous motivation among adults offered two versions of the mHealth program compared with an information-only control group.

Methods

A 12-week, parallel, three-arm, mixed-methods pilot randomized controlled trial was conducted between May 2017 and February 2018. Participants were randomly assigned to one of three groups: the control group received information about prediabetes and strategies to prevent T2DM; the app-only group received an mHealth app focused on increasing autonomous motivation; and the app-plus group received the app plus a physical activity tracker and wireless-enabled digital scale for self-monitoring. Primary outcome measures included rates of intervention uptake (number of patients enrolled/number of patients assessed for eligibility), retention (number of participants who completed 12-week survey/number of participants), and adherence (number of device-usage days). Change in autonomous motivation (measured using the Treatment Self-Regulation Questionnaire) was the secondary outcome and was analyzed using difference-in-difference analysis. Postintervention qualitative interviews were also conducted.

Results

Overall, 28% (69/244) of eligible individuals were randomized for the trial, and 80% (55/69) of randomized participants completed the 12-week survey. The app-plus group had significantly higher retention rates than the other two study arms combined ($P=0.004$, χ^2). No significant differences were found in adherence rates between app-only and app-plus participants (43 days vs 37 days; $P=0.34$). Across all groups, mean autonomous motivation scores were relatively high at baseline (6.0 of 7.0 scale), with no statistically significant differences in follow-up scores within or between groups. Results from qualitative interviews with participants ($n=15$), revealed reasons why they enjoyed using the app (e.g.,

encouraged self-reflection) and why they did not (e.g., did not consider personal circumstances) along with strategies to improve the intervention (e.g., increased interpersonal contact).

Conclusions

Among individuals with prediabetes who did not engage in free DPPs, this mHealth intervention was feasible and acceptable. Future work should examine the effectiveness of a refined intervention on clinically relevant outcomes (e.g., weight loss) in a larger population of individuals not enrolled in DPP who exhibit low baseline autonomous motivation and should also identify any other factors associated with DPP nonenrollment. These might serve as additional potential targets for interventions.

Comments

This paper provides further suggestions that digital interventions can be effective in helping adults adopt and sustain health-promoting behaviors. In this case the population was adults with prediabetes who did not engage in a free, in-person, diabetes prevention program but did successfully participate in a short (3 month) digitally delivered program. While the results are promising, the sample size was too small and the length of time for the intervention and follow-up was too short to make any definitive conclusions.

The post-trial analysis of the Indian SMS diabetes prevention study shows persistent beneficial effects of lifestyle intervention

Nanditha A¹, Snehalatha C¹, Raghavan A¹, Vinitha R¹, Satheesh K¹, Susairaj P¹, Simon M¹, Selvam S¹, Ram J², Naveen Kumar AP³, Godsland IF⁴, Oliver N⁴, Johnston DG⁴, Ramachandran A¹

¹India Diabetes Research Foundation and Dr. A. Ramachandran's Diabetes Hospitals, Chennai, India; ²Hubert Department of Global Health, Emory Global Diabetes Research Center, Atlanta, GA; ³Visakha Steel General Hospital, Visakhapatnam, India; ⁴Faculty of Medicine, Imperial College, London, UK

Diabetes Res Clin Pract 2018; **142**: 213–221

Aims

In previous work, we have shown that mobile phone-based text messaging worked as an effective tool for delivering lifestyle changes among Asian Indian men, resulting in a 36% relative risk reduction in incident diabetes over 2 years. This study investigated the persistence of beneficial effects of lifestyle intervention on diabetes prevention persisted for 3 years after active intervention ceased.

Methods

The primary 2-year (2010–2012) randomized controlled trial compared lifestyle changes associated with the use of automated text messaging reminders in the intervention ($n = 271$) versus standard care advice ($n = 266$) at baseline. At the close

of the study period, a trained dietician dispensed additional advice regarding lifestyle modifications to both groups. Participants free of diabetes ($n = 394$) were again invited 3 years later to ascertain the sustained effect of intervention. The primary outcome was incidence of T2D.

Results

During follow-up (mean time 5 years), 346 out of 394 (87.8%) men were reviewed. In the intervention group, incidence of diabetes declined by 30%, and the gap in between-group differences over time (Kaplan-Meier analysis) declined as well. Significant improvement in dietary adherence occurred in the intervention group at the 2-year and 5-year follow-ups (trend $\chi^2 = 21.35$, $P < 0.0001$). Cox regression analysis showed a significant reduction in the fifth-year incidence of diabetes for the intervention group. High BMI index and 2-hour plasma glucose at 2 years increased the incidence of diabetes.

Conclusions

A sustained reduction in incident diabetes was observed after active lifestyle intervention ended. It is possible that this reduction is associated with patients' continuing practices of improved lifestyle.

Comments

This is the first post-trial analysis of prevention of diabetes in Asian Indians. Lifestyle modification of 2 years in high risk persons lowered the progression from prediabetes to T2D. This 2-year text message-based diabetes prevention program for adult men used frequent short messages sent through mobile phones. This analysis demonstrated a 5-year post enrollment outcome showing a 30% reduction in diabetes incidence occurred at 5 years. The results are very impressive for any population, but even more so for a lower income population. It is also exciting to see that a relatively low-cost approach—text messaging—was impactful.

Results from a trial of an online diabetes prevention program intervention

Moin T^{1,2,3}, Damschroder LJ⁴, AuYoung M⁴, Maciejewski ML^{5,6}, Havens K^{7,8}, Ertl K⁷, Vasti E¹, Weinreb JE^{1,2}, Steinle NI^{9,10}, Billington CJ^{11,12}, Hughes M⁴, Makki F⁴, Youles B⁴, Holleman RG⁴, Kim HM^{4,13}, Kinsinger LS¹⁴, Richardson CR^{13,15}

¹Department of Medicine, VA Greater Los Angeles Healthcare System, Los Angeles, CA; ²Department of Medicine, David Geffen School of Medicine, University of California, Los Angeles, CA; ³VA Health Services Research and Development, Center for Healthcare Innovation, Implementation and Policy, VA Greater Los Angeles Healthcare System, Los Angeles, CA; ⁴Ann Arbor VA Center for Clinical Management Research, Ann Arbor, MI; ⁵Department of Medicine, Durham VA Medical Center, Durham, NC; ⁶Department of Medicine, Duke University School of Medicine, Durham, NC; ⁷Clement J. Zablocki VA Medical Center, Milwaukee, WI; ⁸Department of Medicine, Medical

College of Wisconsin, Milwaukee, WI; ⁹Department of Medicine, Baltimore VA Medical Center, Baltimore, MD; ¹⁰Department of Medicine, University of Maryland School of Medicine, Baltimore, MD; ¹¹Department of Medicine, Minneapolis VA Healthcare System, Minneapolis, MN; ¹²Department of Medicine, University of Minnesota Medical Center, Minneapolis, MN; ¹³Center for Statistical Consultation and Research, University of Michigan, Ann Arbor, MI; ¹⁴VHA National Center for Health Promotion and Disease Prevention, Durham, NC; ¹⁵Department of Family Medicine, University of Michigan, Ann Arbor, MI

Am J Prev Med 2018; 55: 583–591

Introduction

Online DPPs can be scaled up and widely delivered; however, about their real-world effectiveness and how these outcomes compare with in-person DPP is relatively unknown. Here, online DPP weight loss and participation outcomes are investigated along with secondarily compared outcomes among participating patients with parallel in-person interventions.

Methods

A large nonrandomized trial was conducted, along with a supplemental comparative analysis of individuals participating in a concurrent trial of two parallel in-person programs, an in-person DPP and the Veterans Administration's standard of care weight loss program (MOVE!). Online enrollment was used to recruit obese/overweight veterans with prediabetes into an online DPP ($n=268$) between 2013 and 2014. A similar set of eligibility criteria were used to enroll in-person participants between 2012 and 2014 ($n=273$ in-person DPP, $n=114$ MOVE!) within a separate trial. The online DPP offered a virtual group format with a live e-coach, weekly modules delivered asynchronously, and wireless home scales. For in-person programs, 8–22 group-based, face-to-face sessions were offered. Data on weight change at 6 and 12 months was collected via wirelessly uploaded readings from home scales or from electronic medical records based on in-person clinic visits. Outcomes were analyzed between 2015 and 2017.

Results

From a total of 1,182 invitations, 268 (23%) participants enrolled in online DPP. Among these, 158 (56%) completed eight or more modules. Mean weight decreased at both 6 and 12 months (-4.7 kg and -4.0 kg, respectively). Supplemental analysis revealed that online DPP participants were the most likely to complete eight or more sessions/modules (87% online DPP vs 59% in-person DPP vs 55% MOVE!; $P<0.001$). Participants in both online and in-person DPP exhibited significantly more weight loss than did MOVE! participants at 6 and 12 months. No significant difference was found in weight change between the online and in-person DPP groups.

Conclusions

An intensive, multifaceted online DPP intervention had higher participation but similar weight loss compared with in-person DPP, meaning that an intensive, multifaceted online DPP in-

tervention might be as effective as in-person DPP and could extend the reach of intervention programs to at-risk individuals.

Comments

This study compared the standard CDC-recognized online Diabetes Prevention Program to an in-person program created specifically for the U.S. Veteran's Administration. While the study was not able to definitively state that outcomes from an online program are equal to those for an in-person program—that would be a difficult and expensive study—the results suggest the two approaches might be able to get about the same results. Given the challenges going to scale with in-person DPP offerings, it is encouraging to read that digital could be part of the effort to get population health impacts.

Effectiveness of an app and provider counseling for obesity treatment in primary care

Bennett GG^{1,2}, Steinberg D¹, Askew S¹, Levine E¹, Foley P¹, Batch BC^{3,4}, Svetkey LP^{4,5}, Bosworth HB⁶, Puleo EM⁷, Brewer A⁸, DeVries A⁸, Miranda H⁹

¹Duke Global Digital Health Science Center, Duke Global Health Institute, Durham, NC; ²Department of Psychology and Neuroscience, Duke University, Durham, NC; ³Department of Medicine, Division of Endocrinology, Duke University Medical Center, Durham, NC; ⁴Sarah W. Stedman Nutrition and Metabolism Center, Duke University Medical Center, Durham, NC; ⁵Department of Medicine, Division of Nephrology, Duke University Medical Center, Durham, NC; ⁶Center for Health Services Research in Primary Care, Durham Veterans Affairs Medical Center, Durham, NC; ⁷School of Public Health and Health Sciences, University of Massachusetts, Amherst, MA; ⁸Piedmont Health, Inc., Carrboro, NC; ⁹Wake County Human Services, Raleigh, NC

Am J Prev Med 2018; 55: 777–786

Introduction

Treatment for obesity is less successful in socioeconomically disadvantaged populations, particularly when that treatment is delivered via primary care. The reach of clinical obesity treatments can be extended via digital health strategies to better serve patients at highest risk.

Methods

A two-arm, effectiveness random controlled trial (RCT) of a 12-month digital weight-loss intervention embedded within a community health center system. Adult patients aged 21–65 years in the community system who had obesity and hypertension, diabetes, and hyperlipidemia were included in the study. Patients were randomly assigned to usual care ($n=175$) or to an intervention ($n=176$) that consisted of app-based self-monitoring of behavior change goals with tailored feedback, a smart scale, counseling calls from a dietician, and clinician counseling based on app-generated recommendations delivered via electronic health record. The primary outcome was weight change at 1 year. Randomization commenced on June 18, 2013, and final assessments were completed on

September 10, 2015. Data was analyzed in 2016–2017. The trial retained 92% of usual care and 96% of intervention participants at 12 months.

Results

Larger weight losses were seen in the Track intervention group versus usual care at 6 months (net effect -4.4 kg [95% CI -5.5 , -3.3]; $P < 0.001$) and 12 months (net effect -3.8 kg [95% CI -5.0 , -2.5]; $P < 0.001$). Patients in the intervention group were more likely to lose 5% or more of their baseline weight at 6 months (43% vs 6%, $P < 0.001$) and 12 months (40% vs 17%; $P < 0.001$). Intervention group patients who completed 80% or more of expected self-monitoring episodes (-3.5 kg), counseling calls (-3.0 kg), or self-weighing days (-4.4 kg) experienced significantly more weight loss than less engaged intervention participants (all $P < 0.01$).

Conclusions

A digital obesity treatment, integrated with health system resources, can lead to clinically meaningful weight-loss outcomes among socioeconomically disadvantaged primary care patients with elevated risk of cardiovascular disease.

Comments

This RCT of a digitally supported weight loss intervention in obese patients with at least one of the following chronic conditions (diabetes, hypertension, or hyperlipidemia) demonstrated greater weight loss in the experimental group. As expected, participants who were more engaged with the technology were associated with better results than those who were less engaged. While the results were statistically significant at 12 months, the long-term benefits need to be determined.

The effect of a digital behavioral weight loss intervention on adherence to the dietary approaches to stop hypertension (DASH) dietary pattern in medically vulnerable primary care patients: results from a randomized controlled trial

Steinberg D^{1,2}, Kay M^{2,3}, Burroughs J², Svetkey LP^{4,5}, Bennett GG^{2,6}

¹Duke University School of Nursing, Durham, NC; ²Duke Global Digital Health Science Center, Duke Global Health Institute, Durham, NC; ³Duke Center for Childhood Obesity Research, Durham, NC; ⁴Sarah W. Stedman Nutrition and Metabolism Center, Duke University Medical Center, Durham, NC; ⁵Department of Medicine, Division of Nephrology, Duke University Medical Center, Durham, NC; ⁶Bishop-MacDermott Professor of Psychology, Global Health and Medicine, Duke University, Durham NC

J Acad Nutr Diet 2019; **119**: 574–584

Background

Treatment for obesity typically focuses on reducing overall dietary calorie count, with only a minor focus on improving diet quality. The dietary approaches to stop hypertension

(DASH) dietary pattern is effective in management of hypertension and other chronic conditions; however, it is not clear whether behavioral weight control interventions improve compliance with the DASH system. A post hoc analysis was conducted on a behavioral weight loss intervention that did not emphasize diet quality to examine whether the intervention impacted DASH adherence in medically vulnerable patients of a community health center.

Methods

Participants ($n = 306$) were enrolled in the randomized controlled weight loss intervention Track, for patients with elevated cardiovascular risk. Usual care was compared with an intervention that included weekly self-monitoring, tailored feedback on diet and exercise goals, and dietitian and provider counseling in community health centers. Block Food Frequency Questionnaires were collected at baseline and 12 months to measure dietary intake. Participant adherence to DASH was determined using previously validated scoring indices based on recommended nutrient or food group targets. Total scores for both indices ranged from 0 to 9, with higher scores indicating greater DASH adherence.

Results

The mean age of patients in the study was 51.1 ± 8.8 years, and mean BMI was 35.9 ± 3.9 . Most were female (69%) and black (51%); 13% were Hispanic. Half (51%) of participants had an annual income $< \$25,000$, and 33% of patients in the study had both diabetes and hypertension. The mean baseline DASH nutrient score was 1.81 ± 1.42 ; 6% of subjects achieved a score of at least 4.5. Similar scores were seen for the DASH foods index. Although improvements in mean DASH nutrient score for the intervention group were small, they were significantly greater than in the control group (intervention vs control: 1.28 ± 1.5 vs 0.20 ± 1.3 ; $P < 0.001$); there was no difference in DASH food score between study arms. No significant predictors of change in DASH score were found, and no association was discovered between adherence to DASH and changes in blood pressure. In the intervention arm, improvements in DASH nutrient score were associated with greater weight loss ($r = -0.28$; $P = 0.003$).

Conclusion

The intervention was not designed to increase adoption of DASH, but the Track intervention did produce significant weight loss along with small improvements in DASH adherence. However, despite these small improvements, overall adoption of DASH was very low among the medically vulnerable patients that were enrolled in Track. To further reduce chronic disease burden, future weight loss interventions should include a focus on both caloric restriction and increasing diet quality.

Comments

This RCT adds to the increasing literature documenting the positive impact of digital weight loss programs. In addition, the study subjects demonstrated improved nutritional quality of the foods they ate. A welcome finding indeed.

Web-based digital health interventions for weight loss and lifestyle habit changes in overweight and obese adults: systematic review and meta-analysis

Beleigoli AM^{1,2,3}, Andrade AQ⁴, Cançado AG¹, Paulo MN¹, Diniz MFH¹, Ribeiro AL^{1,5}

¹Internal Medicine Department, Faculty of Medicine, Universidade Federal de Minas Gerais, Belo Horizonte, Brazil;

²Department of Medicine, University of Adelaide, Adelaide, Australia; ³Flinders Digital Health Research Centre, College of Nursing and Health Sciences, Flinders University, Adelaide, Australia;

⁴Quality Use of Medicines and Pharmacy Research Center, School of Pharmacy and Medical Sciences, University of South Australia, Adelaide, Australia;

⁵Telehealth Center, Hospital das Clínicas, Universidade Federal de Minas Gerais, Belo Horizonte, Brazil

J Med Internet Res 2019; **21**: e298

Background

Obesity is highly prevalent, its occurrence nearly doubling in the last 30 years, and carries with it serious health implications. The use of face-to-face interventions to treat obesity places a huge demand on both time and human resources, burdening individuals as well as health systems. The use of internet-based services to deliver weight loss programs presents an attractive opportunity due to the anonymity, 24-hour accessibility, scalability, and reachability associated with web-based programs.

Objective

This review examined the effectiveness of web-based digital health interventions, excluding hybrid interventions and non-web-based technologies such as text messages and short message service (SMS) versus nontechnology active or inactive (wait list) interventions on weight loss and lifestyle habit changes in subjects with overweight and obesity.

Methods

Searches were conducted on PubMed or Medline, SciELO, Lilacs, PsychNet, and Web of Science through July 2018, in addition to references of previous reviews, for randomized trials comparing web-based digital health interventions with offline interventions. Outcomes of interest included changes such as weight, BMI, waist measurement, body fat, and lifestyle habit changes in adults with overweight and obesity. Random effects meta-analysis and meta-regression were performed for mean differences (MDs) in weight. The Grades of Recommendation, Assessment, Development, and Evaluation approach was used to assign a risk of bias rating to each study and to the quality of evidence across studies.

Results

A total of 4,071 articles were retrieved, 11 of which were included in this review. Weight (MD -0.77 kg [95% CI -2.16 to 0.62]; 1,497 participants; moderate certainty evidence) and BMI (MD -0.12 kg/m² [95% CI -0.64 to 0.41]; 1,244 participants; moderate certainty evidence) changes were not different between web-based and offline interventions. Compared with offline interventions, digital interventions resulted in

larger short-term weight loss (<6 months follow-up; MD -2.13 kg [95% CI -2.71 to -1.55]; 393 participants; high certainty evidence), but this did not carry through into long-term changes (MD -0.17 kg [95% CI -2.10 to 1.76]; 1,104 participants; moderate certainty evidence). Meta-analysis could not be completed for changes in lifestyle habits. High risk of attrition bias was identified in 5 studies. The certainty of evidence was moderate for weight and BMI outcomes, primarily due to high heterogeneity, which was mainly attributable to control group differences across studies ($R^2 = 79\%$).

Conclusions

In overweight and obese adults, greater short-term weight loss was seen with web-based versus offline interventions, although the same was not true for long-term weight loss. Heterogeneity was high across studies, and high attrition rates indicate the possibility that engagement is a major difficulty with web-based interventions.

Comments

This study looking at weight loss and lifestyle changes looks at the specific impact of what are called digital therapeutics—digital interventions that substitute for medications or other treatments including in-person programs. Unfortunately, the impact from the specific interventions studied was not sustained. We remain hopeful that current and future studies will demonstrate impact as these interventions are refined and improved.

Recruiting to a randomized controlled trial of a web-based program for people with type 2 diabetes and depression: lessons learned at the intersection of e-mental health and primary care

Fletcher S¹, Clarke J^{2,3}, Sanatkar S^{2,3}, Baldwin P^{2,3}, Gunn J¹, Zwar N⁴, Campbell L⁵, Wilhelm K³, Harris M⁶, Lapsley H³, Hadzi-Pavlovic D³, Proudfoot J^{2,3}

¹Department of General Practice, University of Melbourne, Carlton, Australia; ²Black Dog Institute, Sydney, Australia; ³School of Psychiatry, University of New South Wales Sydney, Sydney, Australia; ⁴School of Medicine, University of Wollongong, Wollongong, Australia; ⁵Diabetes and Metabolism Division, Garvan Institute of Medical Research, Sydney, Australia; ⁶Centre for Primary Health Care and Equity, University of New South Wales Sydney, Sydney, Australia

J Med Internet Res 2019; **21**: e12793

Background

E-mental health (eMH) interventions are now widely available and they have the potential to revolutionize the way that healthcare is delivered. Because most healthcare is now being delivered by primary care providers, there is a great deal of potential for eMH interventions to support, or in some cases substitute, services currently delivered in person in the community setting. RCTs of eMH interventions, however, have tended to recruit patients through online methods. This makes it difficult to discern whether participants recruited online are actually representative of those who attend

primary care. This article describes the experience of recruiting participants to an eMH trial through primary care and compares the characteristics of patients recruited through primary care versus other recruitment methods.

Methods

The strategy for recruiting patients to the Springboard RCT initially focused on general practice offices in two states of Australia. A comprehensive approach was employed over 15 months to engage practice staff and support them in recruiting patients, through face-to-face site visits, contact via telephone and trial newsletters, and creation of a web-based patient registration portal. It became apparent, however, that these efforts would not yield the necessary sample size, and supplemental recruitment began through national online advertising and promotion of the study through existing networks. Analysis of variance and chi-squared tests were employed to compare baseline characteristics of participants recruited to the trial through general practice, online, and other sources.

Results

A total of 780 patients enrolled in Springboard between November 2015 and October 2017, 740 of whom provided information regarding the recruitment source. Of these, only 24 were recruited through general practice; 520 participants were recruited online, and 196 through existing networks. Key barriers to recruitment via general practice included perceived mismatch between trial design and diabetes patient population, prioritization of acute health issues, and disruptions due to events at the practice and/or community level. Study participants recruited through the three approaches differed in several demographic and clinical categories (age, gender, depressive symptoms, employment status, and diabetes distress), with online participants being distinguished from those recruited through general practice or other sources. Most differences were associated with only a small effect size, though, and are unlikely to be of clinical significance.

Conclusions

Time, labor, and cost-intensive efforts to recruit participants for an RCT through general practice were not successful in this instance, with barriers identified at several different levels. Online recruitment yielded more participants, and online recruits were broadly similar to those yielded via general practice.

Comments

This paper addresses an often critical but neglected aspect of digital intervention success: how to get participants to sign up and show up for a digitally delivered program. It documents what has become almost conventional wisdom—that in-person recruitment (e.g., in healthcare delivery settings) for a digital intervention is often very costly yet not effective. First, it expects primary care providers to be able to change their existing workflow to recruit participants into an intervention (in-person or digital). This is very hard to do, even for mission-critical changes in practice, and even more ineffective for less

critical interventions. Second, when a prospective participant enrolls through digital recruitment the enrollment process is a gentle screening documenting the individual's ability to use a digital intervention. And third, a modern digital recruitment program can personalize the frequency, language, and delivery mechanism for each prospective participant based on their preferences and performance for specific language, content, emotionality, etc.

Clinical trial recruitment and retention of college students with type 1 diabetes via social media: an implementation case study

Wisk LE^{1,2,3}, Nelson EB¹, Magane KM¹, Weitzman ER^{1,2,4}

¹Division of Adolescent/Young Adult Medicine, Boston Children's Hospital, Boston, MA; ²Department of Pediatrics, Harvard Medical School, Boston, MA; ³Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine at the University of California, Los Angeles, Los Angeles, CA; ⁴Computational Health Informatics Program, Boston Children's Hospital, Boston, MA

J Diabetes Sci Technol 2019; **13**: 445–456

Background

We sought to measure the acceptability and effectiveness of Internet-based recruitment for engaging college-students with type 1 diabetes (T1D), who comprise a particularly hard-to-reach cohort, and to describe the methods used to execute an entirely online health-related trial using off-the-shelf tools inclusive of participant safety and validity concerns.

Method

We recruited participants (ages 17–25 years) with T1D using a variety of social media platforms and other types of online outreach. Response rate and participant attributes were measured across channels using engagement metrics tracked via Google Analytics and participant survey responses. Decision rules were developed and used to identify invalid (duplicative/false) records ($n=89$), which were then compared with valid cases ($n=138$).

Results

Recruitment via Facebook yield the largest number of recruits; demographics differed by platform. Invalid records were common and were more likely among individuals recruited via Twitter or Instagram. Invalid records and valid cases differed across most demographics. Valid cases closely resembled characteristics obtained from Google Analytics and from prior data on platform user base. The rate of retention was high, with 88.4% of participants completing follow-up. No safety concerns were discovered, and participant responses indicated high acceptability for via social media as a recruitment tool for future research.

Conclusions

Recruitment of college students with T1D into a longitudinal intervention trial via social media was demonstrated to be

feasible, efficient, and acceptable. Online recruitment also provides a sample with demographics that reflect the user base from which they were drawn. Differences in characteristics across recruitment channels were observed, though, so the use of multiple platforms is recommended for optimum sample diversity. Trial implementation, engagement tracking, and retention are feasible using off-the-shelf tools on preexisting platforms.

Comments

This is a well-done paper with unsurprising results. College-age students (with T1D) use social media platforms, making them a good way to recruit participants into clinical trials, and by extension, clinical care. We need more of these type of studies with details on the characteristics of people who respond to social media recruitment and those who do not. This will have great relevance to providers of digital therapeutics as they try to get sufficient engagement to demonstrate population health impacts.

Digital recruitment and acceptance of a stepwise model to prevent chronic disease in the Danish primary care sector: cross-sectional study

Larsen LB¹, Sondergaard J¹, Thomsen JL², Halling A³, Snderlund AL¹, Christensen JR¹, Thilsing T¹

¹Research Unit of General Practice, Institute of Public Health, University of Southern Denmark, Odense, Denmark;

²Research Unit for General Practice, Department of Clinical Medicine, Aalborg University, Aalborg, Denmark; ³Department of Clinical Sciences in Malm, Centre for Primary Health Care Research, Lund University, Lund, Sweden

J Med Internet Res 2019; **21**: e11658

Background

Stepwise approaches to health checks have been advanced as an alternative to general health checks in recent years. In 2013, we set up the Early Detection and Prevention project (Tidlig Opsporing og Forebyggelse) to develop a stepwise approach directed at patients at high or moderate risk of a chronic disease. Secure personal digital mailboxes provided by the Danish public authorities were used as a novel method for recruitment. In addition to safety and security, these mailboxes offer a low-cost, quick, and easy way to reach Danish residents.

Objective

A stepwise primary care model for the prevention of chronic diseases was employed to investigate the association between the rates of acceptance of two digital invitations sent to and participants' sociodemographic determinants, medical treatment, and healthcare usage.

Methods

Two digital invitations were sent to randomly selected residents of two Danish cities who were born between 1957 and 1986. The outcome was acceptance of the two digital invi-

tations. Poisson regression was used to determine statistical associations, and the data-driven chi-square automatic interaction detection technique was used to generate a decision tree analysis to predict acceptance of the digital invitations.

Results

A total of 8,814 patients received an invitation via digital mailbox from 47 general practitioners. Of these, 40.22% (3,545/8,814) accepted the first digital invitation, and 30.19% (2,661/8,814) accepted both digital invitations. Women, older patients, patients of higher socioeconomic status, patients not diagnosed with or being treated for diabetes mellitus, chronic obstructive pulmonary disease, or cardiovascular disease were more likely to accept both invitations. Patients who had seen their general practitioner within the previous 2 years were also more likely to accept the digital invitations.

Conclusions

To our knowledge, this is the first study to report on the acceptance rates for digital invitations to participate in a stepwise model for chronic disease prevention. Additional studies of digital invitations will be required to determine whether acceptance rates seen in this study can be expected from future studies. More research is also necessary to determine whether a multimodal recruitment approach—including digital invitations to personal digital mailboxes—will be effective in reaching hard-to-reach subpopulations more effectively than digital invitations alone.

Comments

This study demonstrated that when adults receive invitations to enroll in a digital intervention via a private message (in their government sponsored digital mailbox) and a trusted source (person's general practitioner), they enroll. It is not surprising that Denmark has these digital mailboxes. While this might not be possible in many other countries, many patients have a similar system—the private patient portal from their healthcare provider or health plan. This approach is most promising and, in our experience, tends to get the highest level of engagement (i.e., a higher proportion of prospective participants open the email, click on the message, sign up for the program, and show up once the program starts).

Recruitment of men to a multi-centre diabetes prevention trial: an evaluation of traditional and online promotional strategies

Bracken K¹, Hague W¹, Keech A¹, Conway A², Handelsman DJ², Grossmann M³, Jesudason D⁴, Stuckey B⁵, Yeap BB⁶, Inder W⁷, Allan C⁸, McLachlan R⁸, Robledo KP¹, Wittert G⁹

¹NHMRC Clinical Trials Centre, University of Sydney, Sydney, New South Wales, Australia; ²Anzac Research Institute, and Andrology Department, Concord Hospital, Sydney, New South Wales, Australia; ³Department of Medicine, the University of Melbourne, and Department of Endocrinology, Austin Health, Melbourne, Victoria,

Australia; ⁴Queen Elizabeth Hospital, Adelaide, SA, Australia; ⁵Department of Endocrinology and Diabetes, Keogh Institute of Medical Research, Sir Charles Gairdner Hospital and Medical School, University of Western Australia, Perth, WA, Australia; ⁶Department of Endocrinology and Diabetes, Medical School, University of Western Australia and Fiona Stanley Hospital, Perth, WA, Australia; ⁷Princess Alexandra Hospital, Brisbane, Queensland, Australia; ⁸Department of Clinical Research, Hudson Institute of Medical Research, Melbourne, Victoria, Australia; ⁹Free-masons Foundation Centre for Men's Health, School of Medicine, University of Adelaide, Adelaide, SA, Australia

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Background

Effective interventions are required to prevent the current rapidly increasing prevalence of T2D; for this reason, there is a pressing need for research to identify interventions to effectively prevent diabetes. Clinical trials are essential, but recruitment is expensive, and can be challenging and expensive, and there are limited data addressing cost-effective and efficient recruitment techniques. This paper investigates a range of promotional strategies used to recruit men to a large T2D prevention trial and reports on the cost and effectiveness of each.

Methods

This observational study was nested within the Testosterone for the Prevention of Type 2 Diabetes study, a large, multicenter RCT of testosterone treatment for the prevention of T2D in men 50–74 years of age classified as high risk for developing diabetes. Participation in the study was promoted via mainstream media (television, newspaper, and radio); direct marketing (mass mailings), publicly displayed posters, appearances at local events; digital platforms (Facebook, Google, etc.); and online promotions by local businesses and organizations. The resulting number of participants recruited as well as the direct cost were recorded for each technique. Feedback from staff was used to estimate staff effort.

Results

A total of 19,022 men were screened, 1,007 (5%) of whom were enrolled in the study. The most effective recruitment strategies were targeted radio advertising (accounting for 42% of participants), television news coverage (20%), and mass mailouts (17%). Other strategies, including radio news, community outreach (publicly displayed posters, attendance at local events), newspaper advertising, online promotions, and Google and Facebook advertising, each contributed approximately 4%–5% of enrolled participants. Recruitment promotions cost an average of AU\$594 per randomized

participant. Mass mailings by a government health agency were the most cost-effective paid strategy, costing AU\$745 per participant. Other paid strategies were more expensive, with newspaper advertising costing AU\$1,941 per participant, followed by mail-outs by general practitioners at AU\$1,104 per participant, and radio advertising at AU\$1,081.

Conclusion

Radio advertising, television news coverage, and mass mailings by a government health agency proved to be the most effective recruitment strategies. Close monitoring of recruitment outcomes and ongoing enhancement of recruitment activities played a central role in recruitment to this RCT.

Comments

While the study isn't about digital therapeutics, we included this paper because of the paucity of papers on recruitment into interventions for adults with T2D. The most discouraging finding was the extraordinarily expensive rate for all approaches, making the knowledge gained less useful for clinical care versus research studies.

Final Remarks

While this year's article on digital health technologies that prevent or treat diabetes has some important studies, it is lacking in ground-breaking studies. The field is too new and there are too few researchers with the ability to perform the needed research. Our overall take on the digital therapeutic industry is that it is currently very challenging to create profitable business models based on digital health technologies. Nonetheless, adoption of these approaches is slowly progressing throughout the healthcare delivery ecosystem including health plans, healthcare providers, and employers. It is hoped that partnerships between academia and the expanding digital therapeutics ecosystem will lead not only to innovative approaches, but to effective interventions for the tens of millions of patients with diabetes and other chronic conditions who can benefit from these interventions. The time is near when these interventions will be routine and included in all healthcare programs. At least we hope so.

Author Disclosure Statement

N.K. works for, and has equity interest in, Canary Health, which offers a digital self-management support program and a digital diabetes prevention program. None of the included articles is in direct conflict. E.M. has nothing to disclose.