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Diabetes LIVE (Learning in Virtual Environments): Testing the Efficacy of Self-Management Training and Support in Virtual Environments (RCT Protocol)

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Abstract

Background—Ongoing self-management improves outcomes for those with type 2 diabetes (T2D); however, there are many barriers to patients receiving assistance in this from the healthcare system and peers. Findings from our pilot study showed that a virtual diabetes community on the Internet with real-time interaction among peers with T2D—and with healthcare professionals—is feasible and has the potential to influence clinical and psychosocial outcomes.

Objective—The purpose of this paper is to present the protocol for the Diabetes Learning in Virtual Environments (LIVE) trial.

Protocol—Diabetes LIVE is a two-group, randomized, controlled trial to compare effects of a virtual environment (VE) and traditional website on diet and physical activity. Our secondary aims will determine the effects on: metabolic outcomes; effects of level of engagement and social network formation in LIVE on behavioral outcomes; potential mediating effects of changes in

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self-efficacy; diabetes knowledge, diabetes-related distress, and social support on behavior change and metabolic outcomes. We will enroll 300 subjects at two sites (Duke/Raleigh-Durham and NYU/New York) who have T2D and do not have serious complications or comorbidities. Those randomly assigned to the intervention group have access to the LIVE site where they can find information, synchronous classes with diabetes educators, and peer support to enhance self-management. Those in the control group have access to the same informational and educational content in a traditional asynchronous web format. Measures of self-management, clinical outcomes, and psychosocial outcomes are assessed at baseline, 3, 6, 12 and 18 months.

Discussion—Should LIVE prove effective in improved self-management of diabetes, similar interventions could be applied to other prevalent chronic diseases. Innovative programs such as LIVE have potential for improving healthcare access in an easily disseminated alternative model of care that potentially improves the reach of self-management training and support.

Keywords

e-health; randomized controlled trial; self-management; type 2 diabetes mellitus; virtual reality

Diabetes is a critical, public health problem amenable to self-management and improved metabolic control. Diabetes self-management training (DSMT), ongoing self-management support by peers and professionals, and strategies for coping with the demands of chronic illness are among the evidence-based strategies for effective diabetes self-management (Funnell & Anderson, 2003; Norris, Engelgau, & Narayan, 2001). Yet, according to claims data for DSMT from 2009–2011, only 6.8% of patients with newly diagnosed diabetes participated in DSMT within 12 months of diagnosis (Li et al., 2014). This demonstrates the need to provide more accessible DSMT, ongoing self-management support, and frequent educational content “refreshers” (Peyrot et al., 2005; Resnick, Janney, Buis, & Richardson, 2010).

Widespread Internet access is bringing the potential of advanced web technologies to all, despite geography and sociodemographic factors (Kaufman, 2010). e-Health programs can link patients to support from peers, particularly others with the same chronic disease, and to providers who can facilitate access to evidence-based information (Kaufman, 2010). Internet interventions for type 2 diabetes (T2D) management have resulted in increased support (Barrera, Glasgow, McKay, Boles, & Feil, 2002; Jackson, Bolen, Brancati, Batts-Turner, & Gary, 2006; Resnick et al., 2010), self-efficacy (Glasgow et al., 2012), patient activation (Lorig et al., 2010), and knowledge (Boren, Gunlock, Krishna, & Kramer, 2006; Jackson et al., 2006; Ramadas, Quek, Chan, & Oldenburg, 2011; Song et al., 2009); decreased health-related distress (Lorig et al., 2010; Williams, Lynch, & Glasgow, 2007) and decreased depressive symptoms (Williams et al., 2007); improvements in glycemic control (Boren et al., 2006; Jackson et al., 2006; Lorig et al., 2010; Or & Tao, 2014; Ramadas et al., 2011; Song et al., 2009) and self-management behaviors (Boren et al., 2006; Glasgow et al., 2012; Lorig et al., 2010; Song et al., 2009); and more efficient use of primary care services (Jackson et al., 2006), with decreased hospitalizations and emergency department visits (G. Welch & Shayne, 2006). The best DSMT Internet programs provide relevant content, engaging interactive elements, personalized learning experiences and self-assessment tools for monitoring and feedback (Kaufman, 2010; Nijland, van Gemert-Pijnen, Kelders,

Brandenburg, & Seydel, 2011; Ramadas et al., 2011). Internet interventions, such as virtual environments (VE), make it possible to access synchronous and asynchronous diabetes education, skill-building activities, and peer/professional support, opening doors to DSMT for many who face barriers (e.g., location, time) attending traditional clinic-based programs.

Virtual environments are real time, computer-generated 3D representations on the Internet where a person interacts with others as an avatar (digital representation of a human) and experiences really being present in the environment due to sensory experiences (Schroeder, 2008). Individuals can interact with other avatars through voice or text chat, and navigate from one location to another. Most health sites within VEs disseminate information and offer support groups. However, there are few simulation scenarios through which people can begin to change behaviors that are transferrable to real life, and few examine the efficacy of this form of intervention (Johnson et al., 2014; Ruggiero et al., 2014). A VE adds functionality for social support and education beyond that of a traditional website format, including synchronous avatar presence and voice communication; placement of educational resources in 'community locations' such as the grocery store; and synchronous diabetes education classes.

In our pilot study (Second Life Impacts Diabetes Education & Self-Management [SLIDES]), we built an interactive VE for DSMT that participants reported to be highly useful and usable (Johnson et al., 2014; Vorderstrasse, Shaw, Blascovich, & Johnson, 2014). After six months of participation in the site—by 20 pilot participants—findings showed statistically significant changes in self-efficacy, social support, and foot care; and trends toward improvement in diet, weight loss, and metabolic control (Johnson et al., 2014). Based on these promising findings, the current protocol was developed on a stable, sustainable platform (UnReal Engine 3, Epic Games) that allows for gaming, to test the efficacy of a VE (Diabetes LIVE) as compared to a traditional website format for DSMT.

Protocol

The framework for our VE development in LIVE is based in social cognitive theory, social-ecological support, and computer mediated communications (Vorderstrasse et al., 2014). This theoretical framework is described fully in relation to our SLIDES and LIVE intervention components elsewhere (Vorderstrasse et al., 2014). The primary aim of this trial is to determine the effects of providing DSMT in a VE on diet and physical activity behavior change in adults with T2D compared to a traditional website format. Diet and physical activity are assessed by self-report, validated surveys and activity data is augmented by wireless pedometer (Fitbit®) data. These data will capture changes in minutes of moderate activity and steps per week. Dietary variables, including fat, fiber, and vegetable and fruit intake, will be assessed. Our secondary aims are to: (a) determine the effects on metabolic outcomes (HbA1c, lipid levels, blood pressure, body mass index [BMI]); (b) assess whether level of engagement and social network formation in LIVE differentially impacts behavioral outcomes; and (c) examine the potential mediating effects of changes in self-efficacy, diabetes knowledge, diabetes-related distress, and social support on behavioral and metabolic outcomes.

Design

A multisite, randomized, controlled trial with a longitudinal repeated measures design is being used to evaluate the efficacy of LIVE in terms of health behaviors, psychosocial outcomes or mediators, and metabolic outcomes in adults with T2D over 12 months. We will also explore the sustainability of intervention effects at 18 months. Eligible participants who provide informed consent are randomized to the intervention group (LIVE) or the control group (website) for 12 months. Both are given a Fitbit for physical activity monitoring. Participation requirements include signing in to the assigned site twice weekly for the first three months, followed by discretionary use for the remaining nine months. Follow-up measures are collected at 3, 6, 12, and 18 months for both groups. This frequency and timing is intended to capture the often intraindividual, interindividual and group variability that is likely to occur over time in behavioral outcomes in a nonlinear manner, and to assess clinical outcomes at standard assessment intervals (i.e., every 6 to 12 months) without becoming logistically burdensome for participants (Collins, 2006). We will also be able to determine changes over time during and after the intervention, as modified by relevant covariates, including amount and duration of active participation. This study was approved by the Duke Institutional Review Board (IRB; Protocol 00043325) and New York University (NYU) IRB (i14-00897).

Participants and Recruitment

Participants are being recruited at various clinics and through advertisements in the greater metropolitan areas of Durham/Raleigh, NC, and New York City. Social media and digital classified ad sites are also being used. Our target population is adults with type 2 diabetes without regard to duration of disease given that support and ongoing education are necessary throughout the trajectory of this chronic condition. Multisite participation enhances recruitment, sample diversity (race/ethnicity), and evaluation of the intervention across geographic regions.

Eligible participants are those with a diagnosis of T2D who: (a) are > 21 years old; (b) are able to read and understand English; (c) have access to a personal computer running Windows with broadband Internet connection in a private location (home) and are able to download the required software; (d) are accessible by telephone; (e) have no pre-existing medical conditions or severe diabetes related complications that would interfere with study participation (i.e., renal failure, Stage III hypertension [BP > 180/110], severe orthopedic conditions or joint replacement scheduled within 6 months, paralysis, bleeding disorders, cancer, or receipt of anti-coagulant medications [warfarin]); and (f) are able to travel to a clinical lab for blood work. In order to determine characteristics of those who decline participation and potential reach of the intervention, we are asking screened participants to respond to basic demographic questions (e.g., gender, race/ethnicity, and age) and reasons for declining. Based on our pilot recruitment, those able to be approached or contacted did respond to this request for information. See Figure 1 for recruitment procedures and study flow.

Treatment Conditions

LIVE intervention—The LIVE community was built based on the SLIDES site in collaboration with programmers, graphic designers, and the study team. Classes, resources, and the infrastructure within LIVE incorporate self-management skills and behaviors, as well as personal, cultural, and organizational influences on those behaviors (Table 1). Locations in the VE (e.g., grocery store, pharmacy) offer various ways for participants to utilize informational resources, interact with others, role play to receive feedback on health behaviors, and be awarded for achievements (Table 1). In this interactive community, participants communicate via voice chat, but occasionally use text chat. Diabetes educators facilitate the scheduled classes twice weekly. Participants also communicate via text with peers or educators through a forum. Participants are advised to consult their healthcare provider regarding any medical advice; this disclaimer is found in the site. Question and scenario-based games are offered in the site to utilize the fun quotient and promote further knowledge development. Gamification, such as point scoring (to buy virtual clothes for participant avatars) and competition with others, is being used to engage the participants. Top users of the games, Fitbit, and activity in the site are also posted on leaderboards by their alias study names throughout the site.

Control—Participants randomized to the control group are given access to a password-protected, secure website. The website contains the same educational content (Table 1) found within LIVE for the following: exercise, food items, restaurant menus, and pharmacy and bookstore items. DSMT class content delivered in the LIVE site is provided as recorded modules in the control website. Participants interact with peers and the educators via text in the forum.

Orientation to Treatment Conditions

All participants receive training with the study coordinator when they are given access (i.e., username/password) to either the control website or LIVE site at enrollment. Written instructional materials are also provided. Participants are given headsets with microphone to allow for synchronous voice communication or listening to recorded materials. Avatars for intervention group participants are developed by the study staff and customized by participants. Participants are assigned an alias surname and choose an alias first name for use in the study site including the forums. Three days after the baseline appointment, a follow-up call is placed to participants to address questions about the study procedures and provide a re-orientation to the sites by telephone.

Prevention of Attrition and Decline in Participation

Experience with our pilot intervention (SLIDES), as well as prior Internet intervention studies, indicates that participation begins to drop off at 30 days (Glasgow et al., 2011). We are addressing this by keeping the LIVE community and website dynamic with updated materials monthly and new games every week. Our incorporation of forums in the sites enhances ongoing participation through reciprocity and co-creation, which gives people a sense of ownership (Porter, 2008). Games and gamification are enhancing learning, but also motivating participants to log in regularly.

Those who fail to log in to the assigned site for seven days or longer are sent an email by the study coordinator to encourage reconnection. If there is still no response within seven days, the coordinator calls the participant. Since this is intent to treat analysis, participants will continue to be contacted with updates and for follow-up data collection, unless they formally withdraw. Given the 10% attrition experienced in our short-term pilot study, and the estimates for longitudinal studies, we are assuming approximately 20% attrition in this study.

Data Collection

At baseline, 3, 6, 12, and 18 months, survey measures are collected and recorded using an online survey link in REDCap (2015; 1 UL1 RR024128-01) (see Table 2). At baseline, six, 12, and 18 months, a study visit is scheduled to obtain weight, BP, and waist circumference, and provide a requisition to a Clinical Laboratory Improvement Amendment (CLIA)-certified laboratory for a lipid panel and HbA1c. Measurement validity and fidelity is ensured by study staff training, protocol manuals for clinical measures, central participant survey completion in REDCap (2015), central laboratory analysis of metabolic outcomes, and collection of process data from the intervention and control sites. Participants who complete all visits and measures receive \$100 and the Fitbit as compensation for their time.

Measures

We are collecting tracking and process data (number of logins, time spent in the sites, and interaction with objects) (Blascovich & Bailenson, 2011), diet and physical activity data, metabolic control, as well as mediators of usability and acceptability (social influence, presence, and copresence), and potential psychosocial mediators of intervention effects on metabolic control (Murray, Burns, Tai, Lai, & Nazareth, 2005). Table 2 shows the details of the measures and their validity and reliability.

Sample Size, Power, and Effect Size

Our target enrollment of 300 participants, 150 in each group, accounts for attrition. Approximately half of the participants will be enrolled at each site (Duke and NYU). A stratified, randomization schema is being employed by each site using randomly generated assignments for each site programmed by the study statistician. The random group assignment is hidden in the database programming until the subject is enrolled, but no blinding occurs from the point of assignment. Sample size calculations were based on power to reject the null hypothesis for the primary aim, which states that the trajectories of dietary behavior or physical activity are equivalent for the LIVE and control participants across the 52 weeks following randomization. Our test statistic is the z -test for the parameter in the random effects model associated with the time by treatment interaction. The probability of rejecting this hypothesis in favor of the alternative (the trajectories of the two groups are different) depends upon sample size, effect size, and the type I error rate—which we set to .0167. Bonferroni correction for the multiple outcomes explain this conservative type I error rate. We calculated power using the variance covariance matrix of fixed effects (Diggle, Heagerty, Liang, & Zeger, 2013) for a variety of sample and effect sizes. A moderate effect size was selected based on our pilot data and the literature in behavioral diabetes

interventions, and in order to look for clinical significance which would involve achieving at least a moderate effect. Assuming a 20% attrition rate, we will have 240 participants for the primary analysis. With this sample size, we have an 80% probability of rejecting the null hypothesis with effect sizes of .44 or greater.

Data Analysis Plan

The goal of our primary analysis is to quantify the differences between the LIVE and control groups in trajectories of dietary behaviors (fat intake, fruit and vegetable intake), and physical activity over 52 weeks. We will fit a random effects model (Diggle et al., 2013; Levy & Wakim, 2005) to the data with a parameter representing group difference in trajectories over time. The null hypothesis that treatment group trajectories are identical for the two treatment groups will be tested via a z-test. The random effects model can handle missing data that may result from attrition. Also, the principle of intention-to-treat analysis will be followed by retaining participants in their originally assigned groups. To determine if metabolic outcomes (HbA1c, lipids, BP, BMI, waist circumference) improve significantly—with a higher rate and sustainability of improvement in the intervention group—we will use a similar model as in the primary aim with these metabolic dependent variables.

To determine if participants with higher levels of engagement and social network formation demonstrate greater improvement in diet and physical activity, we will examine differences in trajectories of dietary behaviors or physical activity between groups of participants who are low or high on measures of engagement. Analyses exploring whether increased self-efficacy, diabetes knowledge, and social support are significant mediators of improvements in dietary and physical activity behaviors, and metabolic outcomes will only be conducted on the outcomes that show significant treatment group differences at 12 months. We will test mediational effects using bootstrap methods (MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002; Preacher & Hayes, 2008).

Discussion

The findings from this study will be among the first steps in determining the efficacy of VEs for diabetes self-management education, and can inform future research on the translation of DSMT interventions into an alternative model of care over the Internet. Although we intend to recruit and reach a broad diverse population with T2D, the sample characteristics will also add to the state of the science in terms of the population reached or interested in this type of Internet-based intervention and potential generalizability. Should LIVE show efficacy in improving self-management of diabetes or metabolic control, similar interventions could be applied to other chronic diseases. This study will also extend the state of the science in terms of measurement of participant engagement in Internet interventions and the resulting effects on behavioral outcomes. This will assist in further work to evaluate the mechanisms of effect of this VE should the RCT reveal its efficacy. Such information could also be useful in personalizing recommendations for appropriate interventions in those with T2D. Finally, use of the Fitbit to track participant physical activity will augment the self-report survey data by providing a form of direct measurement of self-management behavioral outcomes.

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References

- American Association of Diabetes Educators (AADE). AADE 7 self-care behaviors. *Diabetes Educator*. 2008; 34:445–449. [PubMed: 18535317]
- American Diabetes Association. Standards of medical care in diabetes—2009. *Diabetes Care*. 2009; 32:S13–S61. [PubMed: 19118286]
- Bailenson J, Swinth K, Hoyt C, Persky S, Dimov A, Blascovich J. The independent and interactive effects of embodied-agent appearance and behavior on self-report, cognitive, and behavioral markers of copresence in immersive virtual environments. *Presence*. 2005; 14:379–393.
- Barrera M Jr, Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes self-management. *American Journal of Community Psychology*. 2002; 30:637–654. [PubMed: 12188054]
- Blascovich, J.; Bailenson, J. *Infinite reality: Avatars, eternal life, new worlds and the dawn of the virtual revolution*. New York, NY: HarperCollins; 2011.
- Boren, SA.; Gunlock, TL.; Krishna, S.; Kramer, TC. Computer-aided diabetes education: A synthesis of randomized controlled trials. *AMIA Annual Symposium Proceedings*; Paper presented at the AMIA Annual Symposium; Washington, DC.. 2006 Nov. p. 51-55.
- Collins LM. Analysis of longitudinal data: The integration of theoretical model, temporal design, and statistical model. *Annual Review of Psychology*. 2006; 57:505–528.
- D'Eramo-Melkus GA, Wylie-Rosett J, Hagan JA. Metabolic impact of education in NIDDM. *Diabetes Care*. 1992; 15:864–869. [PubMed: 1516506]
- Dannecker, KL.; Petro, SA.; Melanson, EL.; Browning, RC. Accuracy of Fitbit activity monitor to predict energy expenditure with and without classification of activities [Poster]. *Medicine & Science in Sports & Exercise*; Presented at the Annual Meeting & 1st World Congress on Exercise is Medicine; Denver, CO. 2011. p. 62
- Davis FD. Perceived usefulness, perceived ease of use, user acceptance of information technology. *MIS Quarterly*. 1989; 13:319–339.
- Diggle, P.; Heagerty, P.; Liang, K-Y.; Zeger, S. *Analysis of longitudinal data*. 2nd ed.. Oxford, UK: Oxford University Press; 2013.
- Funnell MM, Anderson RM. Changing office practice and health care systems to facilitate diabetes self-management. *Current Diabetes Reports*. 2003; 3:127–133. [PubMed: 12728638]
- Glasgow RE, Christiansen SM, Kurz D, King DK, Woolley T, Faber AJ, Dickman J. Engagement in a diabetes self-management website: Usage patterns and generalizability of program use. *Journal of Medical Internet Research*. 2011; 13:e9. [PubMed: 21371992]
- Glasgow RE, Kurz D, King D, Dickman JM, Faber AJ, Halterman E, Ritzwoller D. Twelve-month outcomes of an Internet-based diabetes self-management support program. *Patient Education and Counseling*. 2012; 87:81–92. [PubMed: 21924576]
- Jackson CL, Bolen S, Brancati FL, Batts-Turner ML, Gary TL. A systematic review of interactive computer-assisted technology in diabetes care: Interactive information technology in diabetes care. *Journal of General Internal Medicine*. 2006; 21:105–110. [PubMed: 16390512]
- Johnson C, Feinglos M, Pereira K, Hassell N, Blascovich J, Nicollerat J, Vorderstrasse A. Feasibility and preliminary effects of a virtual environment for adults with type 2 diabetes: Pilot study. *JMIR Research Protocols*. 2014; 3:e23. [PubMed: 24713420]
- Kaufman N. Internet and information technology use in treatment of diabetes. *International Journal of Clinical Practice*. 2010; 64:41–46. [PubMed: 20377663]
- Levy, JA.; Wakim, P. The selection of population average versus subject specific models for analyzing longitudinal data in trials of treatments for drug addiction; Paper presented at the Annual Meeting of the Society for Clinical Trials; Arlington, VA.. 2005 May.

- Li R, Shrestha SS, Lipman R, Burrows NR, Kolb LE, Rutledge S. Diabetes self-management education and training among privately insured persons with newly diagnosed diabetes—United States, 2011–2012. *MMWR: Morbidity and Mortality Weekly Report*. 2014; 63:1045–1049.
- Lorig K, Ritter PL, Laurent DD, Plant K, Green M, Jernigan VBB, Case S. Online diabetes self-management program: A randomized study. *Diabetes Care*. 2010; 33:1275–1281. [PubMed: 20299481]
- MacKinnon DP, Lockwood CM, Hoffman JM, West SG, Sheets V. A comparison of methods to test mediation and other intervening variable effects. *Psychological Methods*. 2002; 7:83–104. [PubMed: 11928892]
- McCaul KD, Glasgow RE, Schafer LC. Diabetes regimen behaviors: Predicting adherence. *Medical Care*. 1987; 25:868–881. [PubMed: 3320598]
- Murray E, Burns J, Tai SS, Lai R, Nazareth I. Interactive health communication applications for people with chronic disease. *Cochrane Database of Systematic Reviews*. 2005; 4
- Newlin K, Melkus GD, Chyun D, Jefferson V. The relationship of spirituality and health outcomes in Black women with type 2 diabetes. *Ethnicity & Disease*. 2003; 13:61–68. [PubMed: 12723014]
- Nijland N, van Gemert-Pijnen JE, Kelders SM, Brandenburg BJ, Seydel ER. Factors influencing the use of a web-based application for supporting the self-care of patients with type 2 diabetes: A longitudinal study. *Journal of Medical Internet Research*. 2011; 13:e71. [PubMed: 21959968]
- Norris SL, Engelgau MM, Narayan KV. Effectiveness of self-management training in type 2 diabetes: A systematic review of randomized controlled trials. *Diabetes Care*. 2001; 24:561–587. [PubMed: 11289485]
- Or CK, Tao D. Does the use of consumer health information technology improve outcomes in the patient self-management of diabetes? A meta-analysis and narrative review of randomized controlled trials. *International Journal of Medical Informatics*. 2014; 83:320–329. [PubMed: 24534118]
- Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: Results of the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) Study. *Diabetic Medicine*. 2005; 22:1379–1385. [PubMed: 16176200]
- Porter, J. *Designing for the social web*. Berkeley, CA: New Riders; 2008.
- Preacher KJ, Hayes AF. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediation models. *Behavior Research Methods*. 2008; 40:879–891. [PubMed: 18697684]
- Ramadas A, Quek KF, Chan CKY, Oldenburg B. Web-based interventions for the management of type 2 diabetes mellitus: A systematic review of recent evidence. *International Journal of Medical Informatics*. 2011; 80:389–405. [PubMed: 21481632]
- Research electronic data capture. 2015 Retrieved from <http://project-redcap.org/>.
- Resnick PJ, Janney AW, Buis LR, Richardson CR. Adding an online community to an Internet-mediated walking program. Part 2: Strategies for encouraging community participation. *Journal of Medical Internet Research*. 2010; 12:e72. [PubMed: 21169161]
- Ruggiero L, Moadsiri A, Quinn LT, Riley BB, Danielson KK, Monahan C, Gerber BS. Diabetes island: Preliminary impact of a virtual world self-care educational intervention for African Americans with type 2 diabetes. *JMIR Serious Games*. 2014; 2:e10. [PubMed: 25584346]
- Schroeder R. Defining virtual worlds and virtual environments. *Journal of Virtual Worlds Research*. 2008;1.
- Skelly AH, Marshall JR, Haughney BP, Davis PJ, Dunford RG. Self-efficacy and confidence in outcomes as determinants of self-care practices in inner city African-American women with non-insulin-dependent diabetes. *Diabetes Educator*. 1995; 21:38–46. [PubMed: 7835203]
- Song M, Choe MA, Kim KS, Yi MS, Lee I, Kim J, Shim YS. An evaluation of web-based education as an alternative to group lectures for diabetes self-management. *Nursing & Health Sciences*. 2009; 11:277–284. [PubMed: 19689636]
- Taylor-Piliae RE, Fair JM, Haskell WL, Varady AN, Iribarren C, Hlatky MA, Fortmann SP. Validation of the Stanford Brief Activity Survey: Examining psychological factors and physical

activity levels in older adults. *Journal of Physical Activity & Health*. 2010; 7:87–94. [PubMed: 20231759]

Thompson FE, Midthune D, Subar AF, Kahle LL, Schatzkin A, Kipnis V. Performance of a short tool to assess dietary intakes of fruits and vegetables, percentage energy from fat and fibre. *Public Health Nutrition*. 2004; 7:1097–1105. [PubMed: 15548349]

Thompson FE, Midthune D, Subar AF, Kipnis V, Kahle LL, Schatzkin A. Development and evaluation of a short instrument to estimate usual dietary intake of percentage energy from fat. *Journal of the American Dietetic Association*. 2007; 107:760–767. [PubMed: 17467371]

Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care*. 2000; 23:943–950. [PubMed: 10895844]

United States Department of Agriculture. 2011. Retrieved from <http://ndb.nal.usda.gov/>

Vorderstrasse A, Shaw RJ, Blascovich J, Johnson CM. A theoretical framework for a virtual diabetes self-management community intervention. *Western Journal of Nursing Research*. 2014; 36:1222–1237. [PubMed: 24451083]

Welch G, Shayne R. Interactive behavioral technologies and diabetes self-management support: Recent research findings from clinical trials. *Current Diabetes Reports*. 2006; 6:130–136. [PubMed: 16542624]

Welch G, Weinger K, Anderson B, Polonsky WH. Responsiveness of the Problem Areas In Diabetes (PAID) questionnaire. *Diabetic Medicine*. 2003; 20:69–72. [PubMed: 12519323]

Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale: An evaluation of its clinical utility. *Diabetes Care*. 1997; 20:760–766. [PubMed: 9135939]

Williams GC, Lynch M, Glasgow RE. Computer-assisted intervention improves patient-centered diabetes care by increasing autonomy support. *Health Psychology*. 2007; 26:728–734. [PubMed: 18020845]

Witmer BG, Singer MJ. Measuring presence in virtual environments: A presence questionnaire. *Presence*. 1998; 7:225–240.

FIGURE 1.
Study schema.

TABLE 1

LIVE Intervention Components for Diabetes Self-Management

Component	Operationalized	Provides	Need addressed	Attributes
Classroom sessions	<ul style="list-style-type: none"> Large classroom with seating, podium and screen in the front of the room Ability to create session in any district of the VE Video recordings from classes posted for later review 	<ul style="list-style-type: none"> Weekly synchronous scheduled 1-hour DSMT classes facilitated by NP, CDE, or health professional based on ADA/AADE curricular standards (AADE, 2008) covering seven core topics, as well as advanced topics and current issues discussions. Participants may attend any weekly session (offered at 2–3 different times weekly) 	<ul style="list-style-type: none"> DSMT (knowledge) Social support (informational, emotional, esteem, network support) 	<ul style="list-style-type: none"> Interactive Accessible Immediate feedback
Gym	<ul style="list-style-type: none"> Exercise videos and tips or information linked to the equipment for participants 	<ul style="list-style-type: none"> Menu of exercise routines (e.g., aerobics, Tai Chi) that participants mimic at home 	<ul style="list-style-type: none"> Physical activity 	<ul style="list-style-type: none"> Accessible No cost Interactive instruction
Large chain grocery store and convenience store	<ul style="list-style-type: none"> Modelled after chain grocery store and convenience store with interactive feedback regarding foods chosen by participants 	<ul style="list-style-type: none"> Nutritional information content from USDA Nutrient Database (2011) augmented with professional feedback (portion size, preparation, suggestions for alternative foods) Application of dietary education to simulated real life choices and behaviors 	<ul style="list-style-type: none"> Diet (education and application) 	<ul style="list-style-type: none"> Knowledge and skill application Modeling and practice of behaviors Interactivity and feedback
Restaurant	<ul style="list-style-type: none"> Virtual duplicate of national chain or regional 	<ul style="list-style-type: none"> Application of dietary education to simulated real 	<ul style="list-style-type: none"> Diet (education and application) 	<ul style="list-style-type: none"> Knowledge and skill application Modeling and practice of behaviors

Component	Operationalized	Provides	Need addressed	Attributes
	restaurants (Chinese, Italian, Mexican, Southern foods) with interactive menu selections	<ul style="list-style-type: none"> • Nutritional information content including nutrition content, portion size and alternative choices 	life choices and behaviors	<ul style="list-style-type: none"> • Interactivity and feedback
Bookstore	<ul style="list-style-type: none"> • Store containing books and links to print or internet resources for diabetes management 	<ul style="list-style-type: none"> • Links to free resources or to sites to purchase resources that are endorsed by experts 	<ul style="list-style-type: none"> • Informational and tangible support resources 	<ul style="list-style-type: none"> • Resource accessibility • Cultural and personal relevance
Pharmacy	<ul style="list-style-type: none"> • Store containing pharmacy items (glucometers, test strips, medications, blood pressure cuffs) 	<ul style="list-style-type: none"> • Information (scripted and links) regarding diabetes related medications; medical equipment; personal care 	<ul style="list-style-type: none"> • Informational and tangible support resources 	<ul style="list-style-type: none"> • Resource accessibility
Clothing store	<ul style="list-style-type: none"> • Store containing clothing, shoes, accessories for avatars 	<ul style="list-style-type: none"> • Free or 'points-based purchase' clothing, shoes, and accessories for avatars 	<ul style="list-style-type: none"> • Tangible resources and support 	<ul style="list-style-type: none"> • Resource accessibility
Forums	<ul style="list-style-type: none"> • Forum (laptop linked to forum) for users to co-create general diabetes related messages 	<ul style="list-style-type: none"> • Asynchronous mode of communication with peers, educators and study team 	<ul style="list-style-type: none"> • Informational and social support 	<ul style="list-style-type: none"> • Interactive • Information and resource accessibility
Messages/signs in site	<ul style="list-style-type: none"> • Health promotion messages around the site 	<ul style="list-style-type: none"> • On-line health promotion messages in every location 	<ul style="list-style-type: none"> • Cues to action • Reinforcement of healthy behaviors 	<ul style="list-style-type: none"> • Diabetes knowledge • Motivation and cue to action for behavior change
Games	<ul style="list-style-type: none"> • Scavenger hunts • Quizzes/trivia • Word games • Item identification 	<ul style="list-style-type: none"> • Designed for social interaction and individual learning/challenge 	<ul style="list-style-type: none"> • Engagement in VE • Social support 	<ul style="list-style-type: none"> • Social influence • Rewarding positive behaviors/learning

Component	Operationalized	Provides	Need addressed	Attributes
	<ul style="list-style-type: none">• Quests/ scenarios			

Note. AADE = American Association of Diabetes Educators; ADA = American Diabetes Association; CDE = certified diabetes educator; DSMT = Diabetes Self-Management Training; NP = nurse practitioner; USDA = United States Department of Agriculture (2011); VE = virtual environment.

TABLE 2

Variables and Measurement

Variable	Description/measure	Procedure
Physical activity	<ul style="list-style-type: none"> Fitbit data (minutes of moderate physical activity per week; number of daily steps). Good reliability and validity reported (especially if activity types are recorded) (Dannecker, Petro, Melanson, & Browning, 2011). <i>Stanford Brief Activities Scale</i> (SBAS) assesses work and leisure PA; sub-items assess degree of activity. The SBAS has demonstrated test-retest reliability ($r = .62$) and construct validity (significant inverse correlations with stress, anxiety, depression and direct correlations with mental and physical well-being) (Taylor-Piliae et al., 2010). SDSCA sub-scale for physical activity (2 items) below 	Fitbit Online survey Baseline, 3, 6, 12, 18 months
Dietary intake	<ul style="list-style-type: none"> SDSCA scale for diet (3 items) below <i>Multifactor Screener</i> (assesses intake of fruits and vegetables, percentage of energy from fat, and fiber). Respondents report frequency of food consumption in 16 categories; correlations with estimated true intake range from $r = .5$ to $r = .8$ (Thompson et al., 2004; Thompson et al., 2007). 	Online survey Baseline, 3, 6, 12, 18 months
Self-management behaviors	<ul style="list-style-type: none"> <i>Summary of Diabetes Self-Care Activities</i> (SDSCA), uses 11 items to assess frequency of health behaviors over the last week (diet, exercise, blood sugar testing, foot care, smoking); scores have acceptable alpha (mean = .47), and moderate test-retest correlations (mean $r = .40$) (Toobert, Hampson, & Glasgow, 2000). 	Online survey Baseline, 3, 6, 12, 18 months
Demographics	<ul style="list-style-type: none"> Demographic data (race/ethnicity, marital status, income (categorical), educational attainment, employment, age, sex, and duration of disease). 	Online survey Baseline
Metabolic indicators	<ul style="list-style-type: none"> Metabolic control measured using HbA1c, indicating average glucose levels over prior three months (ADA, 2009). Serum lipid levels (LDL, HDL, total cholesterol, triglycerides) measured at CLIA-certified central laboratory (Quest Labs/Labcorp). Accuracy and reliability of lab measures is improved by utilizing a central laboratory for sample analysis (Quest Labs/Labcorp), which have dedicated Quality Assurance units. BP, BMI (calculated from height and weight), waist circumference measured by study staff per protocol. 	Study visit Baseline, 6, 12, 18 months
Diabetes knowledge	<ul style="list-style-type: none"> <i>Diabetes Knowledge Scale</i>, a 21-item multiple choice questionnaire with an alpha of .86 (D'Eramo-Melkus, Wylie-Rosett, & Hagan, 1992). 	Online survey Baseline, 3, 6, 12, 18 months
Self-efficacy	<ul style="list-style-type: none"> <i>Outcomes Expectancies Questionnaire</i>, a 20-item Likert-type scale questionnaire with a range of 0–100, measures confidence in ability to perform diabetes self-management behaviors; has reported alpha of .92 in women with T2D (Skelly, Marshall, Haughney, Davis, & Dunford, 1995); developed for use in general diabetes population (McCaul, Glasgow, & Schafer, 1987). 	Online survey Baseline, 3, 6, 12, 18 months
Diabetes-related emotional distress	<ul style="list-style-type: none"> <i>Problem Areas in Diabetes</i> (PAID) scale; 25 items using a 6-point Likert scale; higher scores indicate higher levels of distress. Alpha of .93 and .95 (Newlin, Melkus, Chyun, & Jefferson, 2003; G. Welch, Weinger, Anderson, & Polonsky, 2003; G. W. Welch, Jacobson, & Polonsky, 1997). 	Online survey Baseline, 3, 6, 12, 18 months
Perceived support for diabetes management	<ul style="list-style-type: none"> <i>Diabetes Support Scale</i>, a 12-item survey developed specifically for assessment of social support in a diabetes Internet intervention with reported alpha of .90 to .93, sensitivity to intervention effects, 	Online survey Baseline, 3, 6, 12, 18 months

Variable	Description/measure	Procedure
	and construct validity when compared to the Interpersonal Support Evaluation List (ISEL) and Chronic Illness Support Survey (CISS) ($r = .26-.45$) (Barrera et al., 2002).	
Perceived usefulness	<ul style="list-style-type: none"> Perceived usefulness of the intervention assessed based on scale developed by Davis, et al., with 6 items using a verbal 7-point Likert scale (1 = <i>extremely likely</i> to 7 = <i>extremely unlikely</i>) (Davis, 1989). Cronbach's alpha was .98. Questions were modified to fit outcomes related to diabetes management. 	Online survey 3 & 6 months
Perceived ease of use	<ul style="list-style-type: none"> Perceived ease of use assessed based on scale developed by Davis et al. (1989); six items using a verbal seven-point Likert-type scale (1 = <i>extremely likely</i> to 7 = <i>extremely unlikely</i>). Cronbach's alpha was .94. Questions were modified to fit outcomes related to diabetes management. 	Online survey 3 & 6 months
Presence ^a	<ul style="list-style-type: none"> <i>Presence Questionnaire</i> (the feeling of being present in the virtual environment) (Witmer & Singer, 1998); 32-items on a 7-point scale with anchors based on the question stem. Cronbach's alpha was .81. 	Online survey 3, 6, 12 months
Co-presence ^a	<ul style="list-style-type: none"> Co-presence (the sense of being with other virtual humans); based on Bailenson et al. (2005); 10-item scale measures co-presence, embarrassment and likability; Cronbach's alpha for subscales was .71-.72. 	Online 3, 6, 12 months
Process data ^a	<ul style="list-style-type: none"> Number of log-ins and time spent in LIVE in minutes. Locations visited in LIVE and objects manipulated and all movement in the site monitored continuously. Voice and text data recorded continuously while in the site. Number of log-ins in online DSMT program (control) and time spent in minutes. All interactions with information categories and forums captured. 	Continuous data flow from VE and control site
Social influence ^a	<ul style="list-style-type: none"> Through direct observation and heat maps to track the movements of virtual humans on x-y-z coordinates, we will document how virtual humans interact with other virtual humans, or bots and objects in the environment, yielding ethnographic and mapping data. Evaluation of voice and text data. 	Continuous data collection from LIVE

Note. ADA = American Diabetes Association; BMI = body mass index; BP = blood pressure; DSMT = Diabetes Self-Management Training; HbA1c = hemoglobin A1c; HDL = high density lipoprotein; LDL = low density lipoprotein; LIVE = Learning in Virtual Environments; PA = physical activity

^aLIVE participants only.