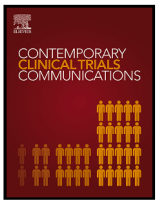
Contemporary Clinical Trials Communications 25 (2022) 100878

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: http://www.elsevier.com/locate/conctc



Design of a randomized controlled trial of digital health and community health worker support for diabetes management among low-income patients

Rory Harte [a, b, *], Lindsey Norton [a, b], Christina Whitehouse [c], Ilona Lorincz [d], Denerale Jones [b], Norma Gerald [b], Irene Estrada [b], Carolyn Sabini [a, b], Nandita Mitra [e], Judith A. Long [a, f, g], Joseph Cappella [h], Karen Glanz [i], Kevin G. Volpp [j], Shreya Kangovi [a, b, f]

[a] Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
[b] Penn Center for Community Health Workers, Penn Medicine, Philadelphia, PA, USA
[c] Villanova University M. Louise Fitzpatrick College of Nursing, Villanova, PA, USA
[d] Hospital of the University of Pennsylvania, Philadelphia, PA, USA
[e] Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
[f] Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, USA
[g] Center for Health Equity Research and Promotion, Corporal Michael J. Crescenz VA Medical Center, Philadelphia, PA, USA
[h] Annenberg School for Communication, University of Pennsylvania, Philadelphia, PA, USA
[i] Perelman School of Medicine and School of Nursing, University of Pennsylvania, Philadelphia, PA, USA
[j] Penn Center for Health Incentives and Behavioral Economics, Departments of Medical Ethics and Health Policy and Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA

ARTICLE INFO

Keywords:
Diabetes
Self-monitoring of blood glucose
Digital health
Community health worker

ABSTRACT

Background: Insulin-dependent diabetes is a challenging disease to manage and involves complex behaviors, such as self-monitoring of blood glucose. This can be especially challenging in the face of socioeconomic barriers and in the wake of the COVID-19 pandemic. Digital health self-monitoring interventions and community health worker support are promising and complementary best practices for improving diabetes-related health behaviors and outcomes. Yet, these strategies have not been tested in combination. This protocol paper describes the rationale and design of a trial that measures the combined effect of digital health and community health worker support on glucose self-monitoring and glycosylated hemoglobin.

Methods: The study population was uninsured or publicly insured; lived in high-poverty, urban neighborhoods; and had poorly controlled diabetes mellitus with insulin dependence. The study consisted of three arms: usual diabetes care; digital health self-monitoring; or combined digital health and community health worker support. The primary outcome was adherence to blood glucose self-monitoring. The exploratory outcome was change in glycosylated hemoglobin.

Conclusion: The design of this trial was grounded in social justice and community engagement. The study protocols were designed in collaboration with frontline community health workers, the study aim was explicit about furthering knowledge useful for advancing health equity, and the population was focused on low-income people. This trial will advance knowledge of whether combining digital health and community health worker interventions can improve glucose self-monitoring and diabetes-related outcomes in a high-risk population.

1. Introduction

Diabetes is a public health problem that disproportionately affects low-income people [1]. Diabetes is challenging to manage and involves complex behaviors [2]; for instance daily self-monitoring of blood glucose for individuals who require insulin [3–6]. Two different types of interventions have strong evidence for promoting health behaviors and improving outcomes among individuals with diabetes: digital health interventions (DHI) [7–9] and community health worker (CHW) support [10–14].

* Corresponding author. Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA.
E-mail address: harter@amc.edu (R. Harte).

https://doi.org/10.1016/j.conctc.2021.100878
Received 16 December 2020; Received in revised form 14 September 2021; Accepted 4 December 2021
Available online 9 December 2021

DHI strategies use computers, wearables, mobile phones and other devices to promote self-management behaviors like glucose self-monitoring [15]. By raising individual awareness of blood glucose and providing ongoing feedback, DHI can support patients' efforts to improve healthy behavior and clinician abilities to provide support [16]. DHI have been shown to reduce HbA1c [7–9]. As the technology behind DHI advances, so too does the behavioral science [17]. A promising approach is to augment adherence through behavioral economic engagement strategies such as lottery-based financial incentives [18–22].

Yet, DHI have limitations, especially for low-income populations. Recent meta-analyses show low uptake [23,24] which is driven partly by the digital divide. Commonly, DHI relies on participants connecting their smartphone to biometric devices to allow for instantaneous data transmission to an online platform [7]. Unfortunately, 29% of lower-income people do not have a smartphone and 44% don't have home broadband [25,26]. Many DHI studies have excluded low-income people, but some have provided effective intervention through basic SMS messaging [27]. DHI have high levels of attrition [23,24]. In a recent study [18], the rate of adherence to daily glucose self-monitoring was only 60% over a 6-month period compared with 30% in the control group, even with lottery-based financial incentives. One possible reason for attrition is that DHI does not address underlying barriers that drive high sugars in the first place, i.e. limited access to healthy foods and high medication costs. Patients may find it self-defeating to monitor elevated sugars without support to address these barriers [17,23].

CHWs, trusted individuals who share life experience with the people they serve, can influence attitudes [10], shift social norms [28], bolster self-efficacy [29,30] and address socioeconomic barriers by facilitating linkages to resources and services. Several CHW interventions have improved outcomes for low-income individuals with diabetes [10–14]. Individualized Management for Patient-Centered Targets (IMPaCT) is a standardized CHW intervention that was tested in three randomized clinical trials, including over 400 patients with diabetes [31–33], which demonstrated improved outcomes including glycemic control and reductions in total hospital days [34]. CHW interventions have limitations, including being resource intensive and thus not as scalable as digital approaches. CHWs are not clinicians and cannot medically manage abnormal blood sugars in real-time. Some patients can become ashamed and discouraged by failed attempts at health behavior change and disengage from their CHW [35].

It seems logical to combine digital health and financial incentives with CHW support because these interventions have complementary effects on behavior change pathways (Fig. 1). To our knowledge, these strategies have not been combined and tested. We describe a randomized trial that combines digital health with financial incentives and CHW support to help low-income individuals with diabetes increase rates of daily self-monitoring of blood glucose and improve glycemic control.

Digital interventions affect attitude, knowledge, and reinforcement. They provide knowledge of blood glucose levels and this awareness can shift a patient's attitude about the importance of self-monitoring. Well-designed financial incentives can reinforce self-monitoring behavior to increase the likelihood of habit formation.

CHW interventions affect attitude, self-efficacy, perceived norms, barriers, and discouragement. They can influence attitudes through strategies like motivational interviewing [10], shift social norms through positive modeling [28], and bolster self-efficacy through action-planning and problem-solving. CHWs can also directly address socioeconomic barriers to healthy behaviors [29,30]. CHWs may also use strategies like positive affect induction and attribution retraining to help individuals cope with barriers and failures without becoming discouraged.

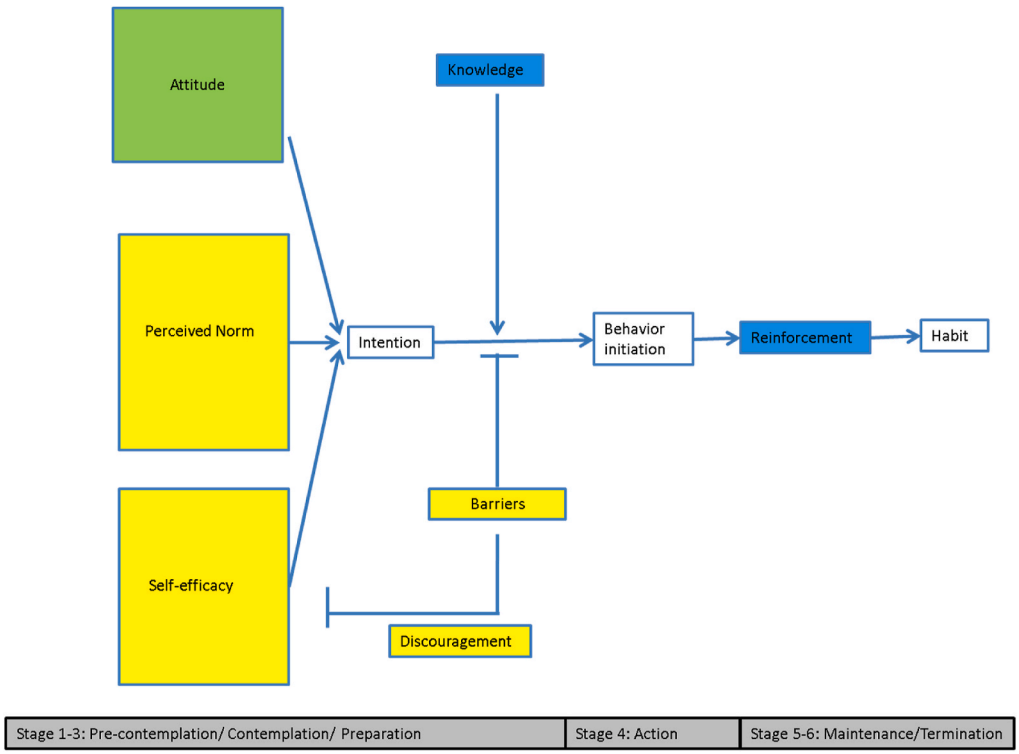


Fig. 1. This is a conceptual framework that lays out factors which affect health behaviors such as self-monitoring of blood glucose. The framework draws elements from the Reasoned Action Approach [76,77], the Health Belief Model [78,79] Goal-setting theory [80] and the Transtheoretical Model (Stages of Change) [81,82]. An individual's intention to initiate a behavior is influenced by his attitudes, social norms, and self-efficacy. Once an individual intends to initiate a behavior, he may be thwarted by external barriers or lack of knowledge. If he overcomes these factors and manages to initiate a behavior, he will still require reinforcement to turn the behavior into a habit. If he does not overcome a setback or failure, he may be discouraged and have decreased self-efficacy.

2. Methods

2.1. Design, overview and hypotheses

This study is a type 1 effectiveness-implementation [36] trial that combines a single-blind randomized controlled trial with qualitative process interviews. The primary aim of this type of trial is to determine the effectiveness of a clinical intervention, with the secondary aim of better understanding the context, facilitators and barriers to implementation [36]. Participants in the study were uninsured or publicly insured; lived in high-poverty, urban neighborhoods; and had poorly controlled diabetes mellitus with insulin dependence. At the time of enrollment, all participants set a diabetes management goal. Participants who did not have their own glucometer and supplies were offered these. Participants were then randomized to one of three arms: 1) usual care, 2) digital health, 3) combined digital health/CHW support. Those assigned to usual care were asked to check their sugars daily, but not required to report these to the study team. Participants assigned to the digital health arm were asked to check their blood glucose daily and text them to the study team; pre-established medically dangerous glucose values were routed to a study clinician who provided clinical management. As a financial incentive for glucose self-monitoring, participants were entered into a lottery where they could win money for every day that they reported their sugars. Participants assigned to the combined digital health and CHW arm received the same glucose self-monitoring instructions and lottery incentives. In addition, they met with a CHW for approximately 30 minutes on the day of enrollment and received coaching on strategies for coping with obstacles and failed attempts at health behavior change. If, over the course of the study period, these participants had elevated blood glucose readings and/or a low adherence rate to self-monitoring they received intensive support from a CHW for the remainder of the study period. This support consisted of weekly check-ins (in-person or telephone) and advocacy, social support, resource connection, health system navigation and health coaching based on the individual patient's needs and preferences.

We hypothesized that patients who received the combined digital health and CHW intervention would have higher adherence to daily blood glucose self-monitoring compared to patients in the usual care arm. Our secondary hypothesis was that patients receiving the combined intervention would have a higher rate of adherence to daily glucose self-monitoring compared to those who just received the digital health intervention. Our exploratory hypothesis was that patients receiving the combined intervention would have greater improvements in glycosylated hemoglobin (HbA1c) than either the usual care or digital health arms.

The study team, aims, participants and protocols were all deliberate about a community-engaged and social justice framework. The study team includes frontline CHWs, the aims are explicit about advancing knowledge useful for advancing health equity, the population is focused on disadvantaged people and all protocols were designed in collaboration with the CHWs who delivered the intervention. This work is supported by a grant from the Commonwealth Fund and K23 grant (5K23HL128837-04). This trial is registered (Clinicaltrials.gov Identifier: NCT03939793) and approved by the Institutional Review Board of the University of Pennsylvania.

2.2. Setting and participants

Study enrollment was conducted between May 22nd, 2019 and December 19th, 2019 at an urban academic adult endocrinology clinic. Eligible patients: 1) were diagnosed with diabetes mellitus based on ICD-10-CM codes from the year prior to study enrollment; 2) had an HbA1c equal to or greater than 9% within the previous six months; 3) were insulin dependent and thus advised to perform daily glucose self-monitoring; 4) were uninsured or publicly insured; 5) were residents of 16 high-poverty zip codes in Philadelphia; 6) had access to a basic cell phone with unlimited text message capabilities or agree to associated fees with sending and receiving text messages; 7) were 18 years of age or older; 8) were able to speak and read comfortably in English. Patients are excluded if they: 1) had a continuous glucose monitor at the time of study enrollment; 2) were already working with a CHW; 3) were in another study that involved blood glucose self-monitoring; 4) lacked capacity to provide informed consent.

2.3. Procedures and randomization

Study procedures are shown in Fig. 2. Many study procedures were conducted using the Penn Way to Health and REDCap platforms. Way to Health is an automated information technology platform based at the University of Pennsylvania that integrates biometric devices, clinical trial randomization, financial system fulfillment, and secure data capture for research purposes [37]. REDCap is a web application for building and managing online surveys and databases [38].

2.3.1. Enrollment and consent

The following data elements from the electronic medical record system were used to identify patients: ICD-10-CM codes for diabetes mellitus, insurance, zip code, HbA1c and insulin use. Trained research assistants received automated lists of eligible patients on a weekly basis. Research assistants called patients on the list to explain the study and gauge their interest in participating. Interested patients were invited to come to a diabetes clinic to enroll into the study. When patients arrived for their study visit, a research assistant obtained written informed consent. The study supplemented patient's routine diabetes care and providers were aware of enrollment.

2.3.2. Goal-setting, baseline assessment and randomization

After obtaining written consent, research assistants used a script and low-literacy visual aid (Fig. 3) to help patients set a realistic HbA1c goal for the six-month study period. Research assistants collected baseline clinical, psychosocial, demographic, and psychometric data. Patients were randomized using the Way to Health platform with permuted variable block sizes with a concealed sequence to assign participants to one of three arms with 1:1:1 randomization. Research assistants (who were not involved with outcomes assessment) notified participants of the study assignment. If participants did not have their own glucometer and supplies or if their glucometer was not compatible with Glooko [39] (a diabetes data management platform used by the study team) they were provided with a One-touch Verio Flex glucometer, and a 24-week supply of test strips and lancets. Research assistants then walked patients to an onsite laboratory for serum HbA1c.

2.3.3. Follow-up assessments and incentives

In-person follow-up assessments were scheduled at 3 and 6 months, and participants were asked to bring in their glucometers for data extraction. The 3-month follow-up assessment consisted of a brief survey to assess adverse medical events and data extraction from patients' glucometers using the Glooko system. The 6-month follow-up assessment consisted of a patient-reported outcomes survey, data extraction from patients' glucometers and a serum HbA1c. HbA1c data was extracted from electronic medical record if available within approximately 4 weeks of the assessment date, for patients who did not complete the 6-month follow-up. Upon completion of the study, we invited 10 participants in the combined intervention arm to participate in an optional qualitative interview, purposively selecting individuals who had been escalated to receive intensive CHW support.

Participants received a $50 pre-paid study debit card at the completion of their baseline visit. Upon completion of the 3-month follow-up visit, $50 was uploaded to patients' study debit cards. Upon completion of the 6-month follow-up visit, $100 was uploaded to patients' study

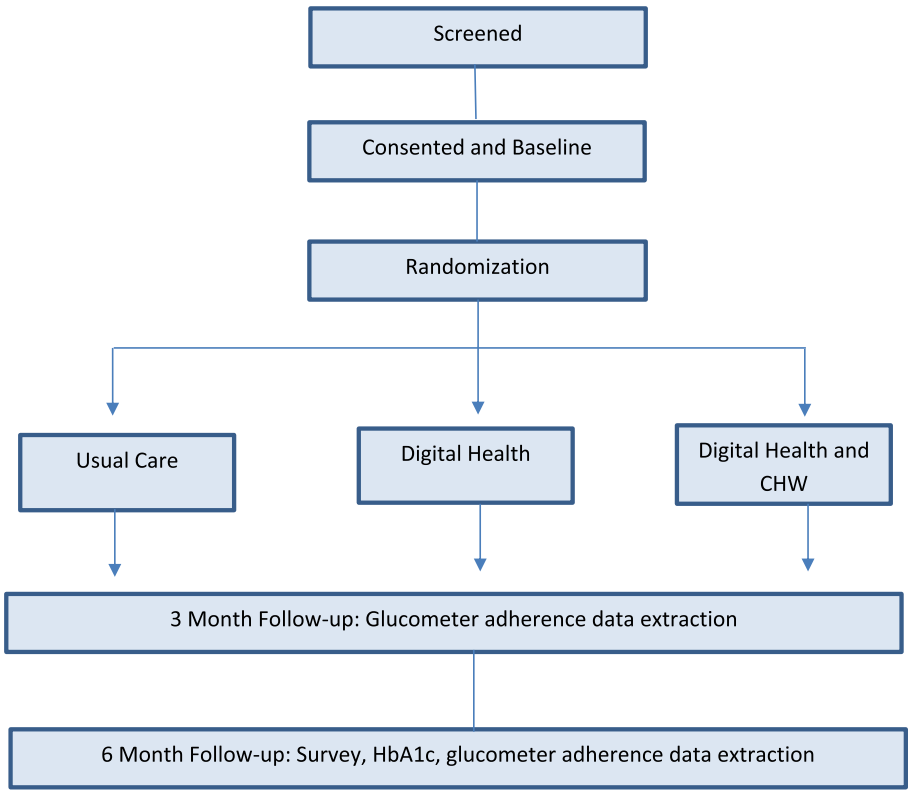


Fig. 2. Study procedures.

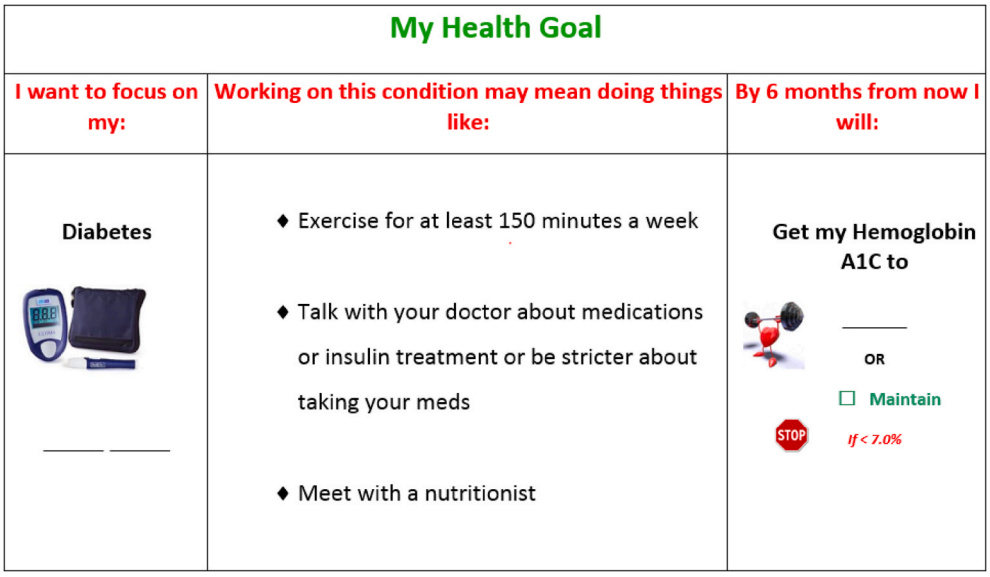


Fig. 3. This style of low-literacy visual aid has been used throughout IMPaCT CHW interventions, to assist patients in setting concrete, achievable, measurable health management goals. Research assistants used the above tool to set glycosylated hemoglobin value goals with all study patients at enrollment.

debit cards. Patients who participated in the optional qualitative interview received an additional $20.

2.4. Interventions

2.4.1. Usual care

Patients in this arm were asked to use their glucometer to check their blood glucose on a daily basis and to continue with their usual diabetes care during the study period.

2.4.2. Digital health

Patients in the digital health arm were asked to check their blood glucose on a daily basis and text the value every day to a phone number linked to the WTH platform. WTH responded to patients via automated text messages (Table 1). Throughout the study period whenever a participant sent a text to WTH with their blood glucose reading, WTH responded with a brief acknowledgement text thanking them. If participants texted in a blood glucose value that was pre-established as medically dangerous (<60, >400) they received an automated text encouraging them to follow-up with their provider. These values were also routed directly to the study clinician who called each patient within

Table 1
These are examples of automated text messages sent to patients participating in the lottery through the Way to Health platform.

Examples of automated text messages sent to patients participating in the lottery:
Hi, [participant first name]! Welcome to the Engage study! Starting tomorrow, you should check your blood sugar every day and text it to this number. When we get your text, we'll enter you into a daily lottery to win money. Good luck!
Great job! Keep texting us your blood sugar every day!
Awesome! Thanks for texting in your blood sugar reading.
$50 winner!!! Your lottery number X was chosen! You won today's lottery because you texted us your blood sugar yesterday. Congratulations!
Unfortunately, your lottery number X was not chosen today. Keep texting us your sugars every day for a chance to win the daily lottery! Good luck!
Your lottery number X was chosen today. You would have won $5, but you did not text us your blood sugar reading, so we cannot give the money to you. Text us your sugars every day in order to be eligible for the daily lottery!
You did not text us your blood sugar reading yesterday, so you cannot win today's lottery. Text us your sugars every day for a chance to win the daily lottery.

24 h to provide clinical management and coordinate care with the patients' provider.

In order to promote early motivation and habit formation, for the first 6 weeks of the study period, participants in the digital health arm were eligible to participate in a lottery for every day they texted in their blood glucose values. We used an approach that was modeled off a previous study of digital health with lottery incentives that used infrequent large payoffs and more frequent small payoffs that averaged a modest expected value of US$1.40 per day [18]. The design of the lottery and messaging was based off the behavioral economic principles of probability inflation, people overestimate the probability that they will win something, and loss aversion, people are motivated by avoiding losing something [40–42]. At enrollment, patients chose a lottery number between 00 and 99. Each day, WTH randomly generated a winning two-digit lottery number. Patients had a 1 in 100 chance of winning a $50 reward with an exact match to the winning number. They also had an 18 in 100 chance of winning a $5 reward with a one-digit match. During the 6-week lottery period, WTH sent the usual acknowledgements for any blood glucose values patients texted in. In addition, to create a sense of loss aversion, WTH also sent a text message to any patients that did not send in their blood glucose values; these explained that patients were ineligible --in some cases despite their lottery number being picked-- to collect the lottery winnings because they had not sent in their blood glucose reading. After 6 weeks, participants were notified that the lottery had ended, but that they were still encouraged to text in their daily blood glucose values.

2.4.3. Combined digital health and CHW support

On the day of study enrollment, research assistants notified an on-site CHW of any participants assigned to the combined arm. CHWs met participants and used a semi-structured interview guide to introduce themselves and provide brief coaching using behavioral strategies that increase resilience to setbacks and failure [43–48]: positive affect induction and attribution retraining. Positive affect induction uses self-affirmation and "random acts of kindness" to improve emotional resilience after failure [43,44,49–56]. Attribution retraining teaches individuals to interpret failure, not as a character flaw, but rather due to concrete and controllable causes [45–48,57–59].

During the initial meeting, the CHW and participant, together, watched a video that was developed specifically for this study. The video [83] was narrated by a CHW with diabetes, who explained her struggle to manage her diabetes and subsequent shift in thinking to attribute her failures in health behavior change from vague, uncontrollable factors to concrete, modifiable ones. Afterwards, the CHW and participant discussed the video. Then, the CHW encouraged the participant to use an "inspiration worksheet" to list positive affirmations about themselves by reflecting on "some small things that make you feel good" and "moments that you're proud of." Finally, CHWs worked with participants to complete a "problem solving worksheet," in which participants listed challenges they might encounter to improving control of their diabetes and then the CHW helped them to generate a plan to manage those challenges.

After this initial meeting, CHWs explained to patients that they might work with them in the future if they were not able to self-monitor their sugars regularly or if they have elevated blood glucose readings.

Patients in the combined arm were also enrolled into the digital health intervention using the same protocol as described for the digital health alone arm. However, if during the first 12 weeks of the study period, participants had elevated blood glucose readings (>300 mg/dL) and/or a low adherence rate to self-monitoring (did not text in their blood glucose values) for >30% of days over any 2 week period, they were 'escalated' to receive support from their CHW (Fig. 4).

CHWs contacted patients within 1–2 days of escalation and, when possible, conducted a home visit. CHWs used an in-depth semi-structured interview guide to develop a connection with patients and probe for socioeconomic and behavioral barriers to improved health, such as housing instability, food insecurity, drug or alcohol use, trauma, or inability to afford medications. CHWs discussed with patients the 6-month diabetes management goal that all patients set at enrollment. Patients and CHWs revisited the "problem solving worksheet" together to identify challenges that interfered with diabetes management and to form short-term goals and action plans to address problems. The CHWs provided hands-on, tailored support for the rest of the study period to help patients achieve their goals. When possible, CHWs communicated with patients at least once a week, including monthly face-to-face interactions. At each encounter, CHWs normalized failure and used positive affect induction and attribution retraining to help patients to cope with failure. They revisited patients' positive affirmations, provided a small gift intended to increase patients' sense of worth, and replayed and discussed the attribution retraining video prompting patients to reflect on their challenges and shift their thinking pattern. CHWs guided patients toward strategies for learning from failure instead of shutting down. Two CHWs participated in the study and

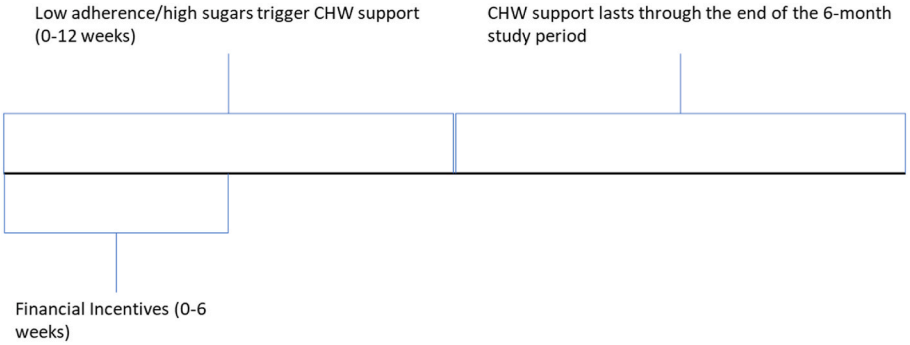


Fig. 4. Timing of elements of the combined intervention. Lottery-based financial incentives are offered for the first 6 weeks. Low adherence or elevated blood glucose readings in the first 12 weeks triggers the initiation of CHW support, which will continue through the end of the 6-month study period.

had been trained using the standardized IMPaCT model [33]. They each had a maximum caseload of 25 patients.

2.5. Measures

2.5.1. Baseline measure

At baseline, research assistants collected demographic and psychometric data and obtained a serum HbA1c. It included the following validated psychosocial surveys: SF-12 [60], Adverse Childhood Experiences [61], Single-Item Drug Screen [62], Single-Item Alcohol Screen [63], Single-Item Health Literacy Screen [64], the Perceived Stress Scale [65], Enriched Social Support Inventory [66], Patient Activation Measure [67], Behavioral Inhibition and Activation Scale (BISBAS) [68], Coping Orientation to Problems Experienced (COPE) [69], Response to Failure Scale [70], five-item scale assessing future planning extracted from the Midlife Development Inventory [71], questions assessing how people feel about monitoring a personal goal [72], Locus of Control Scale [73], and the Life Orientation Test [74].

2.5.2. Outcome measures

The pre-specified primary outcome was adherence to blood glucose self-monitoring as measured by the total number of days that the glucometer was used divided by the total number of days in the 6-month study period. The primary outcome was measured by extracting self-monitoring data directly from participant glucometers. The exploratory outcome was change in HbA1c from baseline to the 6-month follow-up assessment.

2.5.3. Process measures and qualitative interviews

Process measures included CHW documentation of patient encounters and detailed patient action plans. In addition, an un-blinded community-based researcher trained in qualitative methods conducted in-depth, qualitative interviews to elicit open-ended feedback from a sample of participants about their experiences in the study. The interviewer used a semi-structured interview guide that was based on the study conceptual framework (Fig. 1) which covered participants' attitudes, beliefs, norms and self-efficacy for glucose self-monitoring. The guide probed for barriers and salience of self-monitoring particularly in the face of challenges and setbacks. The guide also elicited participants' perspectives on the digital health and CHW interventions' effects on reinforcing the habit of self-monitoring as well as addressing any internal or extrinsic barriers to self-monitoring or glucose control. Participants were asked to provide feedback on the interventions including areas for improvement. Interviews were recorded and transcribed.

2.6. Power calculations and statistical analysis

Sample sizes were based on detecting a difference in adherence rate to self-monitoring of blood glucose between the combined arm and the usual care arm (primary hypothesis.)

Based on a similar 24-week trial [18], we assume that the adherence rate in the usual care arm will be 40% and the rate in the combined arm will be 80%. In the prior trial [18], the adherence rate in the usual care arm was 47%; however, this trial had a lower risk population (higher income and lower baseline glycosylated hemoglobin), and a longer financial incentive period. In this same trial, the adherence rate for the digital health arm was 70%; therefore, the estimate of 80% adherence in the combined arm seems reasonable. Using a two-sample comparison of proportions (usual care versus combined), we will require a sample size of 28 patients per arm to detect these differences with 80% power, assuming a Type I error rate of 0.05. Given the challenges faced by this patient population, it is important to account for loss to follow-up, which we assume based on prior trials to be 20% [31,33]. Therefore, we estimate that we will have to enroll 34 patients in each arm to end up with our minimal sample size. Our planned enrollment of 50 patients in each arm will easily allow us to meet this threshold.

Our pre-specified primary, secondary and exploratory hypotheses will be analyzed with an intent-to-treat analysis based on random assignment, using a modified Poisson regression model to compare adherence rates and a linear regression model to obtain the between-arm difference in change in HbA1c. Models may be adjusted for strong predictors to increase efficiency. For exploratory purposes, we will perform a per protocol analysis focusing on the subgroup of patients in the combined intervention who actually received CHW support, as compared to the patients in the digital health alone arm who would have received support based on low adherence or elevated glucose readings. We will also explore predictors of adherence and change in HbA1c across all three arms.

2.6.1. Qualitative analysis

Qualitative data will be analyzed using a modified grounded theory approach [75]. Ten interviews will be audio recorded, transcribed, and entered into QSR NVivo, a qualitative data analysis program for coding. We will develop a coding structure that includes major themes that emerge from the interviews. Coding will be performed by two independent research team members. Interrater reliability scores will be used to assess the degree of agreement between the coders. Any discrepancies will be discussed and resolved by consensus.

2.6.2. Missing data

Missing HbA1c results were extracted from the electronic medical record for those lost to follow-up. We tracked all missing values and assessed the pattern of missing data and whether the missing data was non-ignorable. If appropriate, we may consider statistical methods such as multiple imputation.

2.6.3. COVID modifications

The COVID-19 pandemic occurred at a point when 106 participants had completed their 3-month in person follow-up assessments, but only 51 had completed their 6-month visits. To ensure participant and staff safety all remaining in person study visits were suspended and converted to telephonic visits. The following IRB approved modifications were made to the study protocol: the primary endpoint was shifted from 6-month self-monitoring adherence to 3 month adherence; outcome surveys were conducted telephonically; laboratory orders for serum A1cs were placed in the electronic medical record so that if patients were getting other clinically necessary labs, they could also have A1cs drawn without additional study-related visits. All patients received the full balance of their incentives regardless of whether they completed in-person follow-up appointments.

3. Discussion

Diabetes has long been a burden for black, brown and lower-income people, in part because it requires health behaviors that are often challenging in the face of socioeconomic barriers [2]. This trial will advance knowledge of whether combining best practices can improve diabetes-related behavior and outcomes.

The design of this trial can offer three insights for researchers and diabetes intervention developers. First, the study team, purpose, population, and protocols are grounded in social justice and community engagement. This resulted in important adaptations; for instance, the digital health component of the intervention only required participants to have a basic cell phone with SMS messaging, this made the intervention more accessible to low-income populations. Second, the CHW intervention operationalizes behavioral strategies -- attribution retraining and positive affect induction— into practical tools and videos that CHWs can use to help patients cope with frequent setbacks and failure on the path to behavior change. Third, this trial took place in the midst of the

COVID-19 pandemic; our adaptations allowed us to successfully complete the study without jeopardizing the study team, participants or the community.

This study does have limitations. Our primary outcome was adherence to glucose-self monitoring which is a critical behavioral outcome but not one that is as clinically relevant as HbA1c, our secondary outcome. The trial may be underpowered to detect differences in self-monitoring of blood glucose between the two active intervention arms and differences in HbA1c between arms. However, this study is powered to assess the primary hypothesis that patients who received the combined digital health and CHW intervention will have higher adherence to daily self-monitoring of blood glucose compared to patients in the usual care arm. This study is powered for the primary outcome which is an extremely meaningful one: substantial data supports the fact that glucose self-monitoring improves outcomes among insulin-dependent diabetics. If this study demonstrates improvements in this outcome compared with the usual standard of care in a high-risk population, this will have far-reaching effects.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] National Diabetes Statistics Report, Estimates of Diabetes and its Burden in the United States, vol. 2020, CDC, 2020.

[2] A.F. Brown, S.L. Ettner, J. Piette, et al., Socioeconomic position and health among persons with diabetes mellitus: a conceptual framework and review of the literature, Epidemiol. Rev. 26 (2004) 63–77.

[3] A.J. Karter, L.M. Ackerson, J.A. Darbinian, et al., Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry, Am. J. Med. 111 (1) (Jul 2001) 1–9.

[4] D.M. Nathan, C. McKitrick, M. Larkin, R. Schaffran, D.E. Singer, Glycemic control in diabetes mellitus: have changes in therapy made a difference? Am. J. Med. 100 (2) (1996) 157–163, Feb.

[5] American Diabetes Association, Test of glycemia in diabetes (position statement), Diabetes Care 21 (Suppl. 1) (1998) S69–S71.

[6] S.K. Garg, I.B. Hirsch, Self-monitoring of blood glucose, Diabetes Technol. Therapeut. 21 (S1) (2019 Feb) S4–S12, https://doi.org/10.1089/dia.2019.2501, PMID: 30785324.

[7] R. Shan, S. Sarkar, S.S. Martin, Digital health technology and mobile devices for the management of diabetes mellitus: state of the art, Diabetologia 62 (6) (2019 Jun) 877–887, https://doi.org/10.1007/s00125-019-4864-7, Epub 2019 Apr 8. PMID: 30963188.

[8] D.A. Greenwood, P.M. Gee, K.J. Fatkin, M. Peeples, A systematic review of reviews evaluating technology-enabled diabetes self-management education and support, J. Diabetes Sci. Technol. 11 (5) (2017 Sep) 1015–1027, https://doi.org/10.1177/1932296817713506, Epub 2017 May 31. PMID: 28560898; PMCID: PMC5951000.

[9] X. Liang, Q. Wang, X. Yang, J. Cao, J. Chen, X. Mo, J. Huang, L. Wang, D. Gu, Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis, Diabet. Med. 28 (4) (2011 Apr) 455–463, https://doi.org/10.1111/j.1464-5491.2010.03180.x, PMID: 21392066.

[10] J.A. Long, E.C. Jahnle, D.M. Richardson, G. Loewenstein, K.G. Volpp, Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial, Ann. Intern. Med. 156 (6) (2012) 416–424, Mar 20.

[11] W. Palmas, D. March, S. Darakjy, S.E. Findley, J. Teresi, O. Carrasquillo, J.A. Luchsinger, Community health worker interventions to improve glycemic control in people with diabetes: a systematic review and meta-analysis, J. Gen. Intern. Med. 30 (7) (2015 Jul) 1004–1012, https://doi.org/10.1007/s11606-015-3247-0, Epub 2015 Mar 4. PMID: 25735938; PMCID: PMC4471021.

[12] J. Lujan, S.K. Ostwald, M. Ortiz, Promotora diabetes intervention for Mexican Americans, Diabetes Educat. 33 (4) (2007) 660–670, Jul-Aug.

[13] Heisler M, Vijan S, Makki F, Piette JD. Diabetes control with reciprocal peer support versus nurse care management: a randomized trial. Ann. Intern. Med.. Oct 19 2010;153(8):507-515.

[14] H. Alaofè, I. Asaolu, J. Ehiri, H. Moretz, C. Asuzu, M. Balogun, O. Abosede, J. Ehiri, Community health workers in diabetes prevention and management in developing countries, Ann Glob Health 83 (3–4) (2017 May-Aug) 661–675, https://doi.org/10.1016/j.aogh.2017.10.009, Epub 2017 Nov 22. PMID: 29221543.

[15] D. Kerr, F. King, D.C. Klonoff, Digital health interventions for diabetes: everything to gain and nothing to lose, Diabetes Spectr. 32 (3) (2019 Aug) 226–230, https://doi.org/10.2337/ds18-0085, PMID: 31462878; PMCID: PMC6695261.

[16] D.A. Asch, R.W. Muller, K.G. Volpp, Automated hovering in health care–watching over the 5000h, N. Engl. J. Med. 367 (2012) 1–3.

[17] S. Kangovi, D.A. Asch, Behavioral phenotyping in health promotion: embracing or avoiding failure, J. Am. Med. Assoc. 319 (20) (May 22 2018) 2075–2076.

[18] A.P. Sen, T.B. Sewell, E.B. Riley, et al., Financial incentives for home-based health monitoring: a randomized controlled trial, J. Gen. Intern. Med. 29 (5) (2014) 770–777, May.

[19] M.S. Patel, K.G. Volpp, R. Rosin, et al., A randomized, controlled trial of lottery-based financial incentives to increase physical activity among overweight and obese adults, Am. J. Health Promot. 32 (7) (2018) 1568–1575, Sep.

[20] M.S. Patel, E.J. Benjamin, K.G. Volpp, et al., Effect of a game-based intervention designed to enhance social incentives to increase physical activity among families: the BE FIT randomized clinical trial, JAMA Intern. Med. 177 (11) (Nov 1 2017) 1586–1593.

[21] J.T. Kullgren, A.B. Troxel, G. Loewenstein, et al., A randomized controlled trial of employer matching of employees' monetary contributions to deposit contracts to promote weight loss, Am. J. Health Promot. 30 (6) (2016) 441–452, Jul.

[22] D.A. Asch, A.B. Troxel, W.F. Stewart, et al., Effect of financial incentives to physicians, patients, or both on lipid levels: a randomized clinical trial, JAMA 314 (18) (2015) 1926–1935, Nov 10.

[23] K. Pal, C. Dack, J. Ross, et al., Digital health interventions for adults with type 2 diabetes: qualitative study of patient perspectives on diabetes self-management education and support, J. Med. Internet Res. 20 (2) (2018) e40, Jan 29.

[24] G. Alkhaldi, F.L. Hamilton, R. Lau, R. Webster, S. Michie, E. Murray, The effectiveness of prompts to promote engagement with digital interventions: a systematic review, J. Med. Internet Res. 18 (1) (2016) e6, Jan 8.

[25] Mobile Fact Sheet, Pew Research Center, 2019.

[26] M. Anderson, M. Kumar, Digital Divide Persists Even as Lower-Income Americans Make Gains in Tech Adoption, Pew Research Center, May 2019.

[27] C.Y. Osborn, S.A. Mulvaney, Development and feasibility of a text messaging and interactive voice response intervention for low-income, diverse adults with type 2 diabetes mellitus, J Diabetes Sci. Technol. 7 (3) (2013 May 1) 612–622, https://doi.org/10.1177/193229681300700305, PMID: 23759393; PMCID: PMC3869128.

[28] S. Kangovi, D. Grande, T. Carter, et al., The use of participatory action research to design a patient-centered CHW care transitions intervention, Health Care 2 (2) (Jul 2014) 136–144.

[29] J.V. Wood, Theory and research concerning social comparisons of personal attributes, Psychol. Bull. 106 (2) (1989) 231–248, Sep.

[30] J.M. Simoni, J.C. Franks, K. Lehavot, S.S. Yard, Peer interventions to promote health: conceptual considerations, Am. J. Orthopsychiatry 81 (3) (2011) 351–359, Jul.

[31] S. Kangovi, N. Mitra, D. Grande, H. Huo, R.A. Smith, J.A. Long, CHW support for disadvantaged patients with multiple chronic diseases: a randomized clinical trial, Am. J. Publ. Health (Aug 17 2017) e1–e8.

[32] S. Kangovi, N. Mitra, D. Grande, et al., Patient-centered CHW intervention to improve posthospital outcomes: a randomized clinical trial, JAMA Intern. Med 174 (4) (2014) 535–543, Apr.

[33] S. Kangovi, N. Mitra, L. Norton, R. Harte, X. Zhao, T. Carter, D. Grande, J.A. Long, Effect of CHW support on clinical outcomes of low-income patients across primary care facilities: a randomized clinical trial, JAMA Intern. Med. 178 (2018) 1635–1643.

[34] A. Vasan, J.W. Morgan, N. Mitra, C. Xu, J.A. Long, D.A. Asch, S. Kangovi, Effects of a standardized community health worker intervention on hospitalization among disadvantaged patients with multiple chronic conditions: a pooled analysis of three clinical trials, Health Serv. Res. 55 (Suppl 2) (2020 Oct) 894–901, https://doi.org/10.1111/1475-6773.13321, Epub 2020 Jul 8. PMID: 32643163.

[35] M. Edlind, N. Mitra, D. Grande, et al., Why effective interventions do not work for all patients: exploring variation in response to a chronic disease management intervention, Med. Care. 56 (8) (2018) 719–726, Aug.

[36] G.M. Curran, M. Bauer, B. Mittman, J.M. Pyne, C. Stetler, Effectiveness-implementation combined designs: combining elements of clinical effectiveness and implementation research to enhance public health impact, Med. Care 50 (3) (2012) 217–226.

[37] D.A. Asch, K.G. Volpp, On the Way to health, LDI Issue Brief 17 (9) (2012 Jul-Aug) 1–4.

[38] REDCap, Vanderbilt, www.project-redcap.org/.

[39] Glooko, 2020, www.glooko.com..

[40] M. Zeelenberg, R. Pieters, Consequences of regret aversion in real life: the case of the Dutch postcode lottery, Organ. Behav. Hum. Decis. Process. 93 (2) (2004) 155–168, https://doi.org/10.1016/j.obhdp.2003.10.001.

[41] M.S. Patel, D.A. Asch, R. Rosin, D.S. Small, S.L. Bellamy, J. Heuer, S. Sproat, C. Hyson, N. Haff, S.M. Lee, L. Wesby, K. Hoffer, D. Shuttleworth, D.H. Taylor, V. Hilbert, J. Zhu, L. Yang, X. Wang, K.G. Volpp, Framing financial incentives to increase physical activity among overweight and obese adults: a randomized, controlled trial, Ann. Intern. Med. 164 (6) (2016 Mar 15) 385–394, https://doi.org/10.7326/M15-1635, Epub 2016 Feb 16. PMID: 26881417; PMCID: PMC6029433.

[42] V. Cotton, M.S. Patel, Gamification use and design in popular health and fitness mobile applications, Am. J. Health Promot. 33 (3) (2019 Mar) 448–451, https://doi.org/10.1177/0890117118790394, Epub 2018 Jul 26. PMID: 30049225; PMCID: PMC6348030.

[43] J.C. Peterson, M.E. Charlson, Z. Hoffman, et al., A randomized controlled trial of positive-affect induction to promote physical activity after percutaneous coronary intervention, Arch Intern. Med. 172 (4) (2012) 329–336, Feb 27.

[44] G.O. Ogedegbe, C. Boutin-Foster, M.T. Wells, et al., A randomized controlled trial of positive-affect intervention and medication adherence in hypertensive African Americans, Arch Intern. Med. 172 (4) (2012) 322–326, Feb 27.

[45] S.E. Jackson, P.M. Rowe, N.C. Hall, L.M. Daniels, Getting the job: attributional retraining and the employment interview, J Appl Soc Psychol. 39 (4) (2009) 973–998, Apr.
[46] R. Ilies, T.A. Judge, D.T. Wagner, The influence of cognitive and affective reactions to feedback on subsequent goals role of behavioral inhibition/activation, Eur. Psychol. 15 (2) (2010) 121–131.
[47] N.C. Hall, R.P. Perry, T. Goetz, J.C. Ruthig, R.H. Stupnisky, N.E. Newall, Attributional retraining and elaborative learning: improving academic development through writing-based interventions, Learn. Indiv Differ 17 (3) (2007) 280–290.
[48] J.P. Holschuh, S.L. Nist, S. Olejnik, Attributions to failure: the effects of effort, ability and learning strategy use on perceptions of future goals and emotional responses, Read. Psychol. 22 (2001) 153–173.
[49] A. Erez, A.M. Isen, The influence of positive affect on the components of expectancy motivation, J Appl Psychol. Dec 87 (6) (2002) 1055–1067.
[50] M.E. Charlson, C. Boutin-Foster, C.A. Mancuso, et al., Randomized controlled trials of positive affect and self-affirmation to facilitate healthy behaviors in patients with cardiopulmonary diseases: rationale, trial design, and methods, Contemp Clin. Trials. 28 (6) (2007) 748–762, Nov.
[51] C.A. Mancuso, T.N. Choi, H. Westermann, et al., Increasing physical activity in patients with asthma through positive affect and self-affirmation: a randomized trial, Arch Intern. Med. 172 (4) (2012) 337–343, Feb 27.
[52] S.D. Pressman, S. Cohen, Does positive affect influence health? Psychol. Bull. 131 (6) (2005) 925–971, Nov.
[53] M.E. Charlson, M.T. Wells, J.C. Peterson, et al., Mediators and moderators of behavior change in patients with chronic cardiopulmonary disease: the impact of positive affect and self-affirmation, Transl. Behav. Med. 4 (1) (2014) 7–17, Mar.
[54] L. Bolier, M. Haverman, G.J. Westerhof, H. Riper, F. Smit, E. Bohlmeijer, Positive psychology interventions: a meta-analysis of randomized controlled studies, BMC Publ. Health (Feb 8 2013) 13.
[55] C.M. Steele, S.J. Spencer, M. Lynch, Self-image resilience and dissonance - the role of affirmational resources, J. Pers. Soc. Psychol. 64 (6) (1993) 885–896, Jun.
[56] M.J. Weiner, Emotionality and attribution: an instance of the control of the response to private events by external stimuli, J. Gen. Psychol. 86 (2d Half) (1972) 207–216, Apr.
[57] B. Weiner, Attribution theory and attributional therapy: some theoretical observations and suggestions, Br. J. Clin. Psychol. 27 (Pt 1) (1988) 99–104, Feb.
[58] N.C. Hall, R.P. Perry, J.G. Chipperfield, R.A. Clifton, T.L. Haynes, Enhancing primary and secondary control in achievement settings through writing-based attributional retraining, J. Soc. Clin. Psychol. 25 (4) (2006) 361–391, Apr.
[59] G. den Boer DK K, H.J. Hospers, F.M. Gerards, V. Stretcher, Health education strategies for attributional retraining and self-efficacy improvement, Health Educ. Res. 6 (2) (1991) 239–248.
[60] M.E. Maruish, M. Kosinski, A Guide to the Development of Certified Short Form Interpretation and Reporting Capabilities, Quality Metric Inc, Lincoln, RI, 2009.
[61] V.J.M.D. Felitti, FACP, R.F.M.D. Anda, et al., Relationship of childhood abuse and household dysfunction to Many of the leading causes of death in adults: the adverse childhood experiences (ACE) study, Am. J. Prev. Med. 14 (4) (1998) 245–258, https://doi.org/10.1016/S0749-3797(98)00017-8.
[62] P.C. Smith, S.M. Schmidt, D. Allensworth-Davies, R. Saitz, A single-question screening test for drug use in primary care, Arch. Intern. Med. 170 (13) (2010) 1155–1160, https://doi.org/10.1001/archinternmed.2010.140.
[63] P.C. Smith, S.M. Schmidt, D. Allensworth-Davies, R. Saitz, Primary care validation of a single-question alcohol screening test [published correction appears in J Gen Intern Med. 2010 Apr;25(4):375], J. Gen. Intern. Med. 24 (7) (2009) 783–788, https://doi.org/10.1007/s11606-009-0928-6.
[64] N.S. Morris, C.D. MacLean, L.D. Chew, B. Littenberg, The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability, BMC Fam. Pract. 7 (2006) 21.
[65] S. Cohen, Perceived Stress Scale, Mind Garden, Palo Alto, CA, 1994.
[66] P.H. Mitchell, L. Powell, J. Blumenthal, et al., A short social support measure for patients recovering from myocardial infarction: the ENRICHD Social Support Inventory, J Cardiopulm Rehabil 23 (6) (2003) 398–403.
[67] J.H. Hibbard, J. Stockard, E.R. Mahoney, M. Tusler, Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers, Health Serv. Res. 39 (4 pt 1) (2004) 1005–1026.
[68] C.S. Carver, T.L. White, Behavioral inhibition, behavioral activation, and affective responses to impending reward and punishment: the BIS/BAS Scales, J. Pers. Soc. Psychol. 67 (2) (1994) 319–333, https://doi.org/10.1037/0022-3514.67.2.319.
[69] C.S. Carver, M.F. Scheier, J.K. Weintraub, Assessing coping strategies: a theoretically based approach, J. Pers. Soc. Psychol. 56 (1989) 267–283.
[70] Y. Zemack-Rugar, C. Canan, D. Brinberg, The 'Response-to-failure' scale: predicting behavior following initial self-control failure, J. Market. Res. 49 (6) (2012) 996–1014, https://doi.org/10.1509/jmr.10.0510.
[71] M.E. Lachman, S.L. Weaver, The Midlife Development Inventory (MIDI) Personality Scales: Scale Construction and Scoring. Technical Report, MA Brandeis University, Waltham, 1997, https://doi.org/10.1177/1359105306066610.
[72] B.P. Chang, T.L. Webb, Y. Benn, Why do people act like the proverbial Ostrich? Investigating the reasons that people provide for not monitoring their goal progress, Front. Psychol. 8 (2017) 152, https://doi.org/10.3389/fpsyg.2017.00152, Published 2017 Feb 8.
[73] J.B. Rotter, Generalized expectancies for internal versus external control of reinforcement, Psychol. Monogr.: Gen. Appl. 80 (1) (1966) 1.
[74] Michael F. Scheier, Charles S. Carver, Michael W. Bridges, Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test, J. Pers. Soc. Psychol. 67 (6) (1994) 1063–1078, https://doi.org/10.1037/0022-3514.67.6.1063.
[75] K. Charmaz, Premises, principles, and practices in qualitative research: revisiting the foundations, Qual. Health Res. 14 (7) (2004) 976–993.
[76] M. Fishbein, I. Ajzen, Predicting and Changing Behavior: the Reasoned Action Approach, Psychology Press, New York, 2010.
[77] Fishbein M. Factors influencing behavior and behavior change. Final Report. Paper Presented at: Theorists Workshop1992; Bethesda, MD.
[78] Karen Glanz, et al., Health Behavior: Theory, Research, and Practice, fifth ed., John Wiley & Sons, 2015.
[79] N.K. Janz, M.H. Becker, The Health Belief Model: a decade later. Health education quarterly, Spring 11 (1) (1984) 1–47.
[80] Edwin A. Locke, Gary P. Latham, New Developments in Goal Setting and Task Performance, Routledge, 2018.
[81] J.O. Prochaska, C.C. DiClemente, J.C. Norcross, In search of how people change. Applications to addictive behaviors, Am. Psychol. 47 (9) (1992) 1102–1114, Sep.
[82] B. Rimer, K. Glanz, Theory at a glance, in: National Institutes of Health NCI, September 2005, p. 25.
[83] https://chw.upenn.edu/engage-video/.