Occupational Therapy Intervention Improves Glycemic Control and Quality of Life Among Young Adults With Diabetes: the Resilient, Empowered, Active Living With Diabetes (REAL Diabetes) Randomized Controlled Trial

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OBJECTIVE

To assess the efficacy of a manualized occupational therapy (OT) intervention (Resilient, Empowered, Active Living with Diabetes [REAL Diabetes]) to improve glycemic control and psychosocial well-being among ethnically diverse young adults with low socioeconomic status (SES) who have type 1 or type 2 diabetes.

RESEARCH DESIGN AND METHODS

Eighty-one young adults (age 22.6 ± 3.5 years; hemoglobin A1c [HbA1c] = 10.8%/95 mmol/mol ± 1.9%/20.8 mmol/mol) were randomly assigned to the REAL Diabetes intervention group (IG) or an attention control group (CG) over 6 months. IG participants received biweekly sessions guided by a manual composed of seven content modules; CG participants received standardized educational materials and biweekly phone calls. Blinded assessors collected data at baseline and 6 months. The primary outcome was HbA1c; secondary outcomes included diabetes self-care, diabetes-related quality of life (QOL), diabetes distress, depressive symptoms, and life satisfaction. Change scores were analyzed using Wilcoxon rank sum tests.

RESULTS

Intent-to-treat analyses showed that IG participants showed significant improvement in HbA1c (−0.57%/6.2 mmol/mol vs. +0.36%/3.9 mmol/mol, P = 0.01), diabetes-related QOL (+0.7 vs. +0.15, P = 0.04), and habit strength for checking blood glucose (+3.9 vs. +1.7, P = 0.05) as compared with CG participants. There was no statistically significant effect modification by sex, ethnicity, diabetes type, recruitment site, or SES. No study-related serious adverse events were reported.

CONCLUSIONS

The REAL Diabetes intervention improved blood glucose control and diabetes-related QOL among a typically hard-to-reach population, thus providing evidence that a structured OT intervention may be beneficial in improving both clinical and psychosocial outcomes among individuals with diabetes.
Young adulthood is a developmental stage with distinct challenges related to access to care, health behaviors, and health outcomes, yet this age-group has been largely overlooked with respect to self-management interventions (1). Young adults with diabetes are particularly vulnerable for several reasons, including the transition from pediatric to adult health care settings (2), the increasing complexity of diabetes care due to a high prevalence of mental health issues (3), the onset of medical comorbidities and diabetes complications (4), and the variability of their daily routines and social and physical environments. These self-management challenges are magnified among young adults from low socioeconomic status (SES) and/or under-represented minority backgrounds, who often have limited finances and life stability (5); are disproportionately exposed to chronic stress (6); and experience more barriers to care, unsatisfactory health care encounters, and poor patient-provider relationships than more advantaged populations (5). Together, these issues pose barriers to self-management, which contribute to elevated hemoglobin A1c (HbA1c) levels and complication rates (7).

In diabetes, as with many chronic diseases, much of the potential to maintain health and prevent secondary complications stems from patients’ ability to consistently carry out self-management activities (e.g., dietary recommendations, self-monitoring, and medication adherence). These activities are often experienced as burdensome, and ongoing adherence is a challenge for many (8). In response, occupational therapy (OT) is increasingly being incorporated into intervention models for preventing and managing chronic diseases, including type 1 and type 2 diabetes (9–13). OT is a skilled health care profession that aims to maximize the ability of individuals and populations to participate in the daily life activities (occupations) they need or want to do. The core philosophical assumption of OT is that humans are occupational beings, for whom the ability to participate in desired and meaningful activities is central to health and well-being.

OT interventions center on activity analysis, which deconstructs the demands of an activity at the level of the individual (e.g., sensory, cognitive, and neuromuscular functions; motor, process, and social interaction skills; values and beliefs; and roles, habits, and routines), task (e.g., necessary tools and resources, physical space, social interaction, timing, and sequencing), and environment (physical, social, cultural, and temporal context). Occupational therapists identify barriers to the performance of a desired activity at one or more of these levels, to inform tailored interventions that facilitate task performance. For example, intervention strategies for someone who does not consistently take their insulin due to a fear of injections could include addressing pain hypersensitivity through sensory desensitization and relaxation strategies; adapting the task by using an injection port, applying an ice pack prior to injecting; and/or adapting the environment by performing the task in a calm, relaxing space (14). Although some intervention strategies used in OT are shared across disciplines, its overarching goal of promoting occupational participation and its focus on activities as the unit of analysis and intervention are unique within the diabetes care team. Thus, inclusion of OT may amplify the efficacy of diabetes treatment through enhancing performance of daily activities among individuals who struggle to carry them out consistently and correctly.

We conducted the Resilient, Empowered, Active Living with Diabetes (REAL Diabetes) study to examine the efficacy of an OT intervention to improve glycemic control and psychosocial well-being among ethnically diverse, low-SES young adults with type 1 or type 2 diabetes. We hypothesized that the REAL intervention would improve diabetes self-management, and in turn HbA1c, by enhancing participants’ habit strength for performing diabetes self-care activities; satisfaction with daily activities; and diabetes-related self-efficacy, problem-solving, and knowledge. A secondary hypothesis was that the REAL intervention would improve psychosocial well-being, as assessed via measures of diabetes-related distress and quality of life (QOL), depressive symptoms, and life satisfaction.

**RESEARCH DESIGN AND METHODS**

**Trial Design**

The REAL study methodology has been described in detail previously (15). The study was a two-arm, parallel-group, randomized, controlled trial in which participants were assigned in a 1:1 ratio to either the REAL intervention group (IG) or an attention control group (CG).

**Participants**

Participants were initially recruited in person at one pediatric and one young adult diabetes clinic; recruitment efforts were later expanded to include mass mailings to clinic patients and social media advertisements. Trained graduate student assessors completed enrollment procedures and collected data at participants’ homes or community settings chosen by participants; participants received $25 at baseline and $50 at follow-up testing. Eligibility criteria were assessed via self-report, medical chart review, and point-of-care HbA1c testing and included the following: age 18–30 years old, diagnosis of type 1 or type 2 diabetes for ≥1 year, HbA1c ≥8.0%, low SES (as defined below), ability to communicate in English or Spanish, willingness to participate in study activities, and living in Los Angeles County. For two reasons, we felt it was appropriate to include individuals with both type 1 and type 2 diabetes. First, our previous work with this population demonstrated that the rapid progression and limited treatment options available for youth-onset type 2 diabetes meant that many had similar self-management challenges as those with type 1 diabetes (e.g., insulin therapy and frequent self-monitoring of blood glucose [ SMBG]). Second, the intervention manual was designed to be sufficiently flexible to address a range of self-management activities. Participants were excluded if they were pregnant or planned to become pregnant within the next 6 months, had a disability limiting life expectancy or functional participation in major life activities, had participated in a self-management intervention beyond usual care within the past year, or had participated in previous studies related to development of the REAL intervention.

Initial SES criteria were for participants to either be eligible for a means-tested social program such as MediCal (California’s Medicaid program) or have a self-reported household income ≤133% of the federal poverty level. Midway through recruitment, SES inclusion criteria were expanded to include participants whose self-reported household income was ≤250% of the federal poverty level or for whom, per self-report, neither parent...
had attained a bachelor’s degree or
equivalent.

Interventions
The REAL intervention is a manualized,
individually tailored intervention, com-
posed of seven content modules that are
flexibly administered in accordance
with participants’ intervention goals (16).
Two licensed occupational ther-
apists with training in motivational inter-
viewing and diabetes self-management
education delivered the intervention on
an individual basis in participants’ homes
and community settings over 6 months.
Therapists were asked to provide a mini-
um of 10 h of treatment to each partic-
itant but had
remained in MDA for up to 16 h for individuals
with more complex care needs who con-
tinued to make progress toward their
goals. Sessions were conducted primarily
on an individual basis, although some ses-
sions engaged family members in therapist-
facilitated family education, discussion, and
problem-solving to address social support
challenges identified by participants. An
endocrinologist and a licensed clinical social
worker were available for as-needed con-
sultations with the therapists regarding
medical and social issues outside the scope
of the intervention.

The REAL intervention is an adaptation
of the Lifestyle Redesign OT intervention
framework (17), which applies activity
analysis to the health management tasks
associated with preventing and managing
chronic conditions. Lifestyle Redesign
emphasizes client autonomy, narra-
tive reasoning, and establishing health-
promoting daily habits and routines. The
content modules include the following: 1) as-
essment and goal setting, 2) living with
diabetes (basic self-management knowl-
edge and skills), 3) access and advocacy
(accessing health care and self-advocacy
in health care and community settings), 4)
activity and health (establishing and
maintaining health-promoting habits and
routines), 5) social support (receiving
desired support from family and friends
and connecting to the diabetes commu-
nity), 6) emotional well-being (managing
stress and coping with diabetes-related
burnout), and 7) long-term health (re-
flecting on progress and planning for
the future). After an initial evaluation
(module 1), therapists individually tai-
lored the intervention by using content
from the remaining modules that was
relevant to clients’ individual goals, which
were informed by a variety of factors, in-
cluding their readiness to change, diabe-
tes treatment regimen, and personal
preferences. The manual was conceptual-
ized as a “menu” of possible treatment
goals and activities, organized themati-
cally by module, rather than a fixed cur-
riculum that every participant should
complete. Among participants who re-
ceived the intervention (n = 39), engage-
ment in each module was as follows:
module 1, 100%; module 2, 92%; module
3, 79%; module 4, 90%; module 5, 69%;
module 6, 56%; and module 7, 62%. Mo-
tivational interviewing was used as a com-
munication strategy with clients who
expressed ambivalence regarding behav-
ior change. Intervention fidelity was
maintained through three strategies.
First, therapists documented intervention
dose, timing, and treatment activities in
notes completed after each session. Sec-
ond, ~10% of sessions were observed
by a second therapist trained in the inter-
vention protocol, who completed a fidelity
checklist and shared feedback with the
treating therapist. Third, all team mem-
ers trained in the intervention met
weekly to facilitate problem-solving and
prevent intervention drift.

An attention (rather than usual care)
control condition was used to enhance
retention by having more frequent con-
tact with CG participants, and control for
the Hawthorne effect of study participa-
tion. It included an initial home visit and
11 follow-up phone calls. At the home
visit, a staff member delivered a standard-
ized set of educational materials pub-
lished by the National Diabetes Education
Program and MyPlate.gov. Subsequently, a
trained staff member called the participant
biweekly and engaged in a scripted phone
conversation to ask if the participant
had read and had any questions about
the materials.

Outcomes
All outcomes were prespecified and as-
essed at baseline and 6 months. The pri-
mary outcome was HbA1c, measured with
the Axis-Shield Afinion point-of-care
analyzer (18). For participants without a
point-of-care assay (due to equipment
malfunction or loss to follow-up), HbA1c
values taken within ±6 weeks of the test-
ing date were extracted from medical
records when available. Secondary out-
comes and process variables were also
assessed. Secondary outcomes included
diabetes self-care (Summary of Diabetes
Self-Care Activities [SDSCA]) (19); diabetes-
related QOL (Audit of Diabetes-Dependent
QOL [ADDQOL], Cronbach α = 0.85) (20);
diabetes distress (Problem Areas in Dia-
betes-Short Form [PAID-SF], Cronbach α =
0.83–0.86) (21); depressive symptoms
(Patient Health Questionnaire-8 [PHQ-8],
Cronbach α = 0.86–0.89) (22); and life
satisfaction (Satisfaction with Life Scale
[SWLS], Cronbach α = 0.87) (23). Process
variables included diabetes self-efficacy
(Diabetes Empowerment Scale-Short
Form, Cronbach α = 0.85) (24); diabetes
knowledge (Diabetes Knowledge Question-
naire [DKQ], Cronbach α = 0.78) (25); dia-
betes-related problem-solving (Diabetes
Problem-Solving Inventory [DPSI],
Cronbach α = 0.77) (26); habit
strength for SMBG and taking insulin
or diabetes-related medications (Self-
Report Behavioral Automaticity Index
[SRAI], Cronbach α = 0.88) (27); and
activity participation (Participation Ob-
jective, Participation Subjective [POPS],
Cronbach α = 0.43 for objective participa-
tion, 0.70 for subjective participation) (28).

We analyzed two constructs from the
Summary of Diabetes Self-Care Activities:
frequency of SMBG (using the single item
“On how many of the last 7 days did you
test your blood sugar the number of
times recommended by your health care
provider?”) and medication adherence
(using an average of the following items,
as appropriate: “On how many of the last
7 days did you take your recommended
insulin injection/number of diabetes
pills?”). For all other instruments, sum-
mary scores were calculated according
to published guidelines. All instruments
were available in English and Spanish,
previously validated among young adults,
and appropriate for both type 1 and
type 2 diabetes. At baseline, participants
provided demographic information, and
medical charts were reviewed to obtain
clinical and health care utilization data.
All self-report instruments were admi-
nistered by trained bilingual research
assistants.

Sample Size
The study was powered on an intent-to-
treat analysis of mean change in HbA1c at
follow-up compared with baseline. A
sample size of 80 was sufficient to afford
90% power to detect a between-group
difference of 0.8% in HbA1c, assuming a
pooled SD of 1%, two-sided α of 0.05, and 15% attrition. The study was not fully powered to examine secondary outcomes, process variables, and effect modification; such analyses were conducted on an exploratory basis to inform intervention refinements and power calculations for future studies.

Randomization
A randomization list was electronically generated and securely maintained by the study’s statistician. Randomization was stratified by diabetes type using random block sizes. Randomization assignment was completed by the primary investigator or a PhD research assistant using the study’s Research Electronic Data Capture (REDCap) data management system (29).

Blinding
Data collectors were blinded to participants’ group assignment at baseline and follow-up testing. Additionally, the study’s interveners were blinded to the specific assessments used to collect outcome data.

Statistical Methods
All analyses were completed on an intent-to-treat basis, including all participants for whom data were available in their original assigned groups. We compared baseline values for demographic and outcome variables to see if those with and without follow-up values were equivalent at baseline. Change scores for each participant were calculated by subtracting baseline values from follow-up values. Wilcoxon rank sum tests were used to compare changes in outcome measures between the IG and the CG. Effect sizes were calculated as Cohen d values.

We explored effect modification of treatment effect on HbA1c by sex, ethnicity, recruitment site, diabetes type, and SES with separate regression models for each potential effect modifier. SES variables (Hollingshead Index and census tract data on neighborhood income and percentage below poverty) were dichotomized as below versus above median. Change in HbA1c rank was the dependent variable, and treatment group, the potential effect modifier, and an interaction term for treatment group and effect modifier were the independent variables. We investigated the association of amount of treatment with change in HbA1c and diabetes-related QOL within the IG with Spearman correlation. All data were analyzed using SAS for Windows, version 9.4 (SAS Institute, Cary, NC). All P values are two sided.

RESULTS
Recruitment
Participants were recruited between October 2014 and December 2015. Follow-up testing was completed between April 2015 and July 2016. The trial ended after follow-up testing was completed for all participants and HbA1c data were extracted from all available medical charts for participants who were lost to follow-up.

Participant flow is outlined in Fig. 1. Overall, of 81 randomized participants, 77 (95%) received their allocated intervention, 71 (88%) completed the follow-up assessment battery, and 75 (93%) had follow-up HbA1c data. Participants with and without follow-up assessment for the primary outcome did not significantly differ at baseline by any demographic or outcome variables. Among IG participants (n = 41), 39 (95%) attended at least 1 treatment session, 24 (59%) completed ≥10 sessions, and average treatment dose was 8.7 ± 5.2 sessions. Among CG participants (n = 40), 38 (95%) completed at least one visit/phone call, and the average number of visits/calls was 8.4 ± 3.9. We found significant differences in treatment dose by sex among IG but not CG participants, with IG women completing fewer sessions than IG men (6.6 vs. 11.9, P = 0.002), whereas CG women and men completed a similar number of sessions (8.6 vs. 7.7, P = 0.54). No other baseline demographic variables were related to treatment dose.

Baseline Data
Participants’ baseline characteristics are presented in Table 1. Overall, participants

#Figure 1—Study flow diagram.
were 22.6 ± 3.5 years old, 63% female, 78% Hispanic, and 75% had type 1 diabetes. Participants’ average HbA1c was 10.8 ± 1.9% (95 ± 20.8 mmol/mol). Data are presented for the sample as a whole and for IG and CG participants. The only significant difference between IG and CG participants was a stronger family history of diabetes among CG participants (92 vs. 68%, \( P = 0.01 \)).

### Table 1—Baseline demographic, clinical, and psychosocial characteristics of REAL study participants

| Demographic       | Total, \( n = 81 \) | IG, \( n = 41 \) | CG, \( n = 40 \) |
|-------------------|----------------------|-----------------|-----------------|
| Age (years)       | 22.6 ± 3.5           | 23.3 ± 3.6      | 21.9 ± 3.3      |
| Sex (% female)    | 51 (63)              | 22 (54)         | 29 (72)         |
| Generation*       |                      |                 |                 |
| 0                 | 21 (26)              | 10 (24)         | 11 (28)         |
| 1                 | 35 (43)              | 20 (49)         | 15 (38)         |
| 2                 | 25 (31)              | 11 (27)         | 14 (35)         |
| Race/ethnicity    |                      |                 |                 |
| White             | 8 (10)               | 3 (7)           | 5 (12)          |
| Hispanic/Latino   | 8 (10)               | 3 (7)           | 5 (12)          |
| Black             | 63 (78)              | 35 (85)         | 28 (70)         |
| Other             | 2 (2)                | 0               | 2 (5)           |
| Hollingshead Index (\( n = 67 \)) | 29.6 ± 13.1 | 27.3 ± 11.9 | 32.5 ± 14.1 |
| Neighborhood income (SK)* | 43.8 ± 16 | 42.6 ± 16.0 | 45.0 ± 16.0 |
| Neighborhood % below federal poverty level† | 23.8 ± 11.3 | 23.9 ± 11.0 | 23.8 ± 11.8 |

#### Clinical

| Diabetes type     | Total, \( n = 81 \) | IG, \( n = 41 \) | CG, \( n = 40 \) |
|-------------------|----------------------|-----------------|-----------------|
| Type 1 diabetes   | 61 (75)              | 31 (76)         | 30 (75)         |
| Type 2 diabetes   | 20 (25)              | 10 (24)         | 10 (25)         |
| Diabetes duration | 9.7 ± 5.8            | 10.0 ± 5.9      | 9.4 ± 5.8       |
| Family history of diabetes | 65 (80) | 28 (68) | 37 (92) |

| Treatment regimen | Total, \( n = 81 \) | IG, \( n = 41 \) | CG, \( n = 40 \) |
|-------------------|----------------------|-----------------|-----------------|
| None              | 3 (4)                | 2 (5)           | 1 (2)           |
| Oral medication and/or noninsulin injectable only | 4 (5) | 3 (7) | 1 (2) |
| Insulin only      | 63 (78)              | 31 (76)         | 32 (80)         |
| (Oral medication and/or noninsulin injectable) + insulin | 11 (14) | 5 (12) | 6 (15) |
| Among those on insulin Fixed regimen | 28 (38) | 12 (33) | 16 (42) |
| Intensive regimen: injections/pen | 35 (43) | 20 (49) | 15 (39) |
| Intensive regimen: insulin pump | 9 (11) | 5 (12) | 4 (11) |
| Unknown           | 2 (2)                | 1 (2)           | 3 (8)           |
| Health care utilization (12 months prior to baseline) Number of routine diabetes visits (\( n = 77 \)) | 3.2 ± 1.8 | 3.0 ± 1.9 | 3.5 ± 1.8 |
| ≥2 visits with HbA1c, taken ≥3 months apart (\( n = 77 \)) | 49 (64) | 24 (60) | 25 (68) |
| Proportion of participants reporting ≥1 diabetes-related hospitalization | 19 (23) | 9 (22) | 10 (25) |

#### Psychosocial

| Substance abuse (CAGE-AID; range 0–4) | 0.5 ± 1.0 | 0.6 ± 1.0 | 0.5 ± 1.0 |
| Stressful life events (range 0–24)   | 5.0 ± 3.6 | 4.8 ± 3.6 | 5.1 ± 3.5 |

Data are mean ± SD or n (%). CAGE-AID, Cut down, Annoyed, Guilty, Eye-opener-Adapted to Include Drugs. *0 = participant born outside U.S.; 1 = participant but neither parent born in U.S.; 2 = at least one parent born in the U.S. †Using 2010 census tract data.

Main Outcomes

Changes in primary and secondary outcomes, and process variables, are presented in Table 2. For the primary outcome (change in HbA1c), data were available for 75 participants. Of these, 62 had Afinion HbA1c measurements at both baseline and follow-up, 7 had Afinion measurement at baseline and medical chart data at follow-up, and 6 had medical chart data at baseline and Afinion measurement at follow-up. We completed analyses among the 62 participants with study-administered Afinion HbA1c measurements and among participants with HbA1c measurements from any source, with similar findings. We found a significant improvement in HbA1c among IG participants as compared with CG participants (−0.57%/6.2 mmol/mol vs. +0.36%/3.9 mmol/mol, \( P = 0.01 \)).

For analysis of secondary outcomes and process variables, data were available for 71 participants. IG participants had significant improvements in diabetes-related QOL as compared with CG participants (change in ADDQOL +0.7 vs. +0.15, \( P = 0.04 \)). Furthermore, IG participants had greater improvement in habit strength for SMBG than CG participants (change in SRBAI +3.9 vs. +1.7, \( P = 0.05 \)). No other between-group differences were statistically significant. With the exception of problem-solving, there were greater improvements in the IG as compared with the CG for all secondary outcomes and process variables; effect sizes for nonsignificant outcomes ranged from negligible (0.02) to medium (0.27).

Secondary Analyses

We examined whether there were differential intervention effects on HbA1c and diabetes-related QOL among key population subgroups: sex, ethnicity (Latino/non-Latino), diabetes type, recruitment strategy (in person vs. mailings/social media), and SES (30). These analyses did not suggest any effect modification by sex, ethnicity, diabetes type, or recruitment site (all \( P \) values >0.20). With respect to SES, the Hollingshead Index score approached significance as an effect modifier for change in HbA1c (\( P = 0.08 \)).

Although the intervention did not have differential effects according to diabetes type, in that IG participants with both type 1 and type 2 diabetes had better HbA1c relative to their CG counterparts, there was a difference in the HbA1c trajectories of participants with type 1 diabetes as compared with those with type 2 diabetes. As shown in Fig. 2, IG participants with type 1 diabetes had a decrease in HbA1c (−0.84%/9.2 mmol/mol),
| Table 2—Changes in primary and secondary outcomes and process variables |
|----------------|------------------|--------------------|----------------|
|                | Overall          | Intervention      | Control        | Between-group difference | Effect size (95% CI)† |
| Primary outcome | Baseline n = 81  | Baseline n = 41   | Follow-up n = 38 | Change n = 38 | Baseline n = 40 | Follow-up n = 37 | Change n = 37 | P value* |
| HbA1c           | 10.8 (1.9)       | 11.0 (2.0)        | 10.5 (2.4)      | −0.6 (1.7)    | 10.5 (1.7)      | 10.8 (2.2)      | 0.4 (1.6)      | 0.9      | 0.01 | −0.5 (−0.9, −0.1) |
| Secondary outcomes | Diabetes-related QOL (ADDQOL; range −9 to +1) | −2.6 (1.7) | −2.4 (1.8) | −1.8 (1.7) | 0.7 (1.1) | −2.8 (1.7) | −2.5 (1.6) | 0.2 (1.5) | 0.5 | 0.04 | 0.3 (−0.1, 0.7) |
|                | Glucose monitoring (days/week) | 3.3 (2.7) | 3.1 (2.7) | 4.0 (2.6) | 0.6 (3.2) | 3.5 (2.7) | 3.6 (2.5) | −0.1 (2.7) | 0.7 | 0.37 | 0.3 (−0.2, 0.8) |
|                | Medication adherence (days/week) | 5.9 (1.8) | 5.7 (2.2) | 6.3 (1.2) | 0.3 (1.8) | 6.0 (1.3) | 6.2 (1.5) | 0.1 (1.4) | 0.2 | 0.93 | 0.1 (−0.3, 0.5) |
|                | Diabetes distress (PAID-SF; range 0–20) | 9.6 (5.7) | 9.7 (5.2) | 7.4 (6.0) | −2.6 (4.3) | 9.4 (6.2) | 7.5 (4.9) | −1.7 (4.6) | 0.8 | 0.26 | −0.1 (−0.5, 0.2) |
|                | Life satisfaction (SWLS; range 5–35) | 20.5 (6.8) | 20.3 (6.1) | 23.0 (5.9) | 2.6 (5.2) | 20.7 (7.4) | 22.2 (7.3) | 1.4 (4.4) | 1.2 | 0.21 | 0.2 (−0.2, 0.5) |
|                | Depressive symptoms (PHQ-8; range 0–27) | 6.9 (5.0) | 6.6 (5.3) | 5.4 (5.0) | −0.9 (4.1) | 7.2 (4.7) | 6.9 (5.6) | −0.0 (4.5) | 0.9 | 0.42 | −0.2 (−0.6, 0.2) |
| Process variables | Baseline n = 41  | Baseline n = 35   | Follow-up n = 35 | Change n = 35 | Baseline n = 40 | Follow-up n = 37 | Change n = 37 |           |     |
| Diabetes knowledge (DKQ; range 0–24) | 18.1 (3.2) | 18.2 (3.0) | 18.9 (2.4) | 0.6 (1.9)    | 17.9 (3.5)      | 18.2 (3.4)      | 0.2 (1.6)      | 0.3      | 0.50 | 0.1 (−0.2, 0.4) |
| Problem-solving (DPSI; range 1–5) | 3.6 (0.6) | 3.6 (0.8) | 3.7 (0.6) | 0.1 (0.6)    | 3.6 (0.5)      | 3.9 (0.5)      | 0.3 (0.5)      | 0.2      | 0.10 | −0.3 (−0.7, 0.1) |
| Diabetes self-efficacy (DES-SF; range 1–5) | 3.9 (0.7) | 3.9 (0.7) | 4.1 (0.8) | 0.2 (0.9)    | 3.9 (0.7)      | 3.9 (1.0)      | 0.0 (0.9)      | 0.2      | 0.27 | 0.2 (−0.4, 0.9) |
| Habit strength | Glucose monitoring (SRBAI; range 4–28) | 15.0 (6.9) | 13.9 (6.7) | 18.3 (6.2) | 3.9 (5.0)    | 16.2 (6.9)      | 18.1 (6.8)      | 1.6 (5.1)      | 2.3 | 0.05 | 0.3 (−0.2, −0.7) |
|                | Medication adherence (SRBAI; range 4–28) | 19.0 (6.3) | 17.9 (7.0) | 20.6 (6.2) | 2.1 (6.0)    | 19.6 (5.7)      | 20.9 (5.6)      | 1.0 (6.8)      | 1.2 | 0.32 | 0.2 (−0.3, 0.7) |
| Participation  | Objective (POPS; range: weighted z scores −3 to 3) | −0.0 (0.2) | −0.0 (0.3) | −0.0 (0.3) | 0.0 (0.3)    | −0.1 (0.2)      | −0.1 (0.2)      | −0.0 (0.2)      | 0.0 | 0.56 | 0.1 (−0.3, 0.5) |
|                | Subjective (POPS; range: −4 to +4) | −0.0 (0.1) | −0.1 (1.0) | 0.2 (1.0) | 0.3 (1.1)    | −0.1 (0.8)      | 0.3 (0.6)      | 0.3 (0.7)      | 0.0 | 0.95 | −0.0 (−0.6, 0.5) |

*Wilcoxon rank sum test for change difference between treatment groups. We provide Cohen d effect sizes as a well-recognized measure of the strength of intervention effects. It should be noted, however, that these effect sizes are based on the assumption of a normally distributed variable and are not necessarily fully consistent with the nonparametric Wilcoxon method that was used to calculate P values.
whereas CG participants with type 1 diabetes had essentially no change in HbA1c (−0.03%/0.3 mmol/mol). In contrast, IG participants with type 2 diabetes had a modest increase in HbA1c (0.2%/2.2 mmol/mol), whereas CG participants with type 2 diabetes had a large increase in HbA1c (1.58%/17.3 mmol/mol).

We investigated the extent to which, within the IG, changes in HbA1c and diabetes-related QOL were associated with demographic characteristics or with intervention dose. With respect to demographic characteristics, we found that census tract–level SES, but not individual-level SES, was associated with change in HbA1c. Specifically, median neighborhood income and a lower proportion of residents below the poverty level were associated with change in HbA1c (r = −0.46, P = 0.002 and r = 0.42, P = 0.03, respectively). However, Hollingshead Index scores were not associated with change in HbA1c (r = −0.06, P value = 0.71). With respect to intervention dose, findings were in the expected direction but were not statistically significant, with a stronger association between dose and change in diabetes-related QOL (r = 0.31, P = 0.07) than between dose and change in HbA1c (r = −0.08, P = 0.62).

**Intervention Implementation**

Fidelity monitoring and process evaluation data indicated that therapists had 96% adherence to the intervention’s key components and that participants were satisfied with the intervention. All serious adverse events reported to study personnel were evaluated by an independent medical monitor to determine whether they were study related. Eleven events were reported in total, five among CG participants and six among IG participants, of which none were determined to be study related. Of the 11 events, 7 were diabetes-related hospitalizations (for gastroparesis, diabetic ketoacidosis, or severe hyperglycemia) and 4 were hospitalizations for unrelated medical conditions.

**CONCLUSIONS**

In the REAL Diabetes Study, a manualized, individually tailored diabetes management intervention delivered by occupational therapists improved both HbA1c and diabetes-related QOL among low-SES, ethnically diverse young adults with diabetes. Although OT interventions to support chronic disease management have shown promise in previous studies, methodological limitations such as small sample sizes and lack of randomization have limited the strength of this evidence (9–13). This study provides additional evidence of the potential for OT to improve clinical and psychosocial outcomes among individuals with diabetes.

Meta-analyses of behavioral interventions to support diabetes self-management have demonstrated modest improvements in HbA1c among adults with type 1 diabetes (−0.44%/4.8 mmol/mol vs. active control) (31) and type 2 diabetes (−0.35%/3.8 mmol/mol) (32), but not improved QOL. Among transition and self-management interventions for young adults with diabetes specifically, improvements in HbA1c, ranging from 0.3% to 0.7% (3.3–7.7 mmol/mol) have been reported (33–36); two of these studies also reported improved psychosocial well-being (34,35).

Thus, the impact of the REAL intervention on HbA1c and QOL is in line with the modest but clinically significant benefits of other behavioral interventions for diabetes self-management.

The REAL study’s enrollment and treatment adherence rates are also comparable to those in other behavioral interventions in this population, supporting the feasibility and acceptability of the REAL intervention. Enrollment rates ranging from 20% (37) to 66% (38) of eligible participants have been reported in previous diabetes management interventions, in line with our 53% enrollment rate. Treatment adherence (averaging 8.7 of 10 planned sessions; 59% completed ≥10 sessions) is also in line with that reported in previous research, such as the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study lifestyle intervention, which reported 60% overall adherence to planned sessions (39) and a young adult support group in which 80% of participants attended three of five sessions and 53% attended four of five sessions (35). Although our enrollment and adherence rates are in line with similar interventions conducted among young adults with diabetes, higher rates (indicating greater acceptability and potential for reach) would be desirable. The significant sex difference in treatment dose within the IG also suggests that the REAL intervention may require further refinements to facilitate greater treatment adherence among women. To work toward this goal, we plan to use telehealth as a delivery modality, which has demonstrated strong acceptability and potential for reach among this population (40), and greater stakeholder engagement (e.g., an advisory committee of young adults with diabetes) to enhance enrollment and treatment adherence.

Although this study lacked sufficient statistical power to rigorously evaluate the mechanisms underlying the REAL intervention’s effects, we did assess process variables hypothesized to influence intervention outcomes. Of these, we found that habit strength for SMBG significantly improved. Developing habits and routines is a central focus of OT interventions in chronic disease management and is a key mechanism by which health behaviors are sustained over time (41). Thus, we are encouraged that the intervention had a positive effect on habit strength and will seek to further enhance
its focus on developing healthy habits. Furthermore, self-efficacy and habit strength for taking medications had effect sizes of 0.24 and 0.18, which, although modest, may indicate that they played a role in the intervention’s effects. In contrast, problem-solving had a small to moderate effect size (0.30) in favor of the CG and was the only variable for which greater improvements were observed in the CG as compared with the IG. Further research is needed to determine whether this was a chance finding or if the REAL intervention undermines the development of problem-solving skills and requires refinements to address this limitation.

Overall, we did not observe evidence of effect modification related to demographic characteristics, although such analyses were underpowered and should be interpreted with caution. However, we did find that both individual-level and neighborhood-level SES may be related to changes in HbA1c, which is plausible and consistent with previous research (42). Individual-level SES was the only variable to approach statistical significance as an effect modifier for HbA1c ($P = 0.08$). This suggests the possibility that although the intervention targeted a low-SES population overall, it may have been more effective for those at the higher end of the included SES range. Additionally, within the IG, there was a correlation between neighborhood-level SES and change in HbA1c. This finding is consistent with research indicating that aspects of the physical and social environment in low-SES communities, such as the limited availability of healthy food outlets and recreational facilities and poor access to health care, often pose barriers to well-being for residents of these communities (42). Collectively, these results suggest that the intervention may benefit from further refinements to better support very low-SES populations.

Another finding that merits further investigation is the different response to the intervention observed among participants with type 1 diabetes versus type 2 diabetes. IG participants with type 1 diabetes had a 0.84% (8.7 mmol/mol) reduction in HbA1c, well above the threshold of 0.5% (5.5 mmol/mol) that is considered clinically significant. However, IG participants with type 2 diabetes had a slight deterioration in HbA1c at follow-up, although substantially less than CG participants with type 2 diabetes. Given the small number of participants with type 2 diabetes overall, this finding has a high level of uncertainty. It is consistent, however, with literature indicating that youth-onset type 2 diabetes is particularly aggressive compared with other forms of diabetes (4,43). This is perhaps especially true for participants in our study, given our inclusion criteria of HbA1c $\geq$8%. Indeed, no participants attained the recommended target HbA1c $\leq$7.0% (53 mmol/mol); it is likely that ongoing intervention at multiple levels, addressing individual, family, environmental, and health system barriers to health and well-being, would be necessary to enable this high-risk population to achieve glycemic targets.

The design and implementation of the REAL study were bolstered by several strengths that enhance confidence in its findings. First, we successfully recruited a population typically conceived of as “hard to reach” (ethnically diverse young adults with low SES). A sizeable proportion of participants were recruited from community settings rather than from specialized medical centers, strengthening the generalizability of the results. Furthermore, a high level of retention decreases the likelihood that the findings were influenced by attrition bias. Finally, aspects of the study design, including randomization, blinding of data collectors, and fidelity monitoring of the intervention, further enhance the validity of the findings.

Despite these strengths, the study has several limitations. First, the study’s sample size was relatively small and lacked statistical power to examine mediation or effect modification. Furthermore, the sample was not representative of young adults with diabetes as a whole, as it represents a higher-risk group than is typical of the population overall. Finally, the study did not incorporate long-term follow-up; given that intervention effects often attenuate during a no-treatment follow-up period, future research should investigate the maintenance of improvements that were observed in this study.

In conclusion, this study provides evidence that the REAL intervention improves both blood glucose control and diabetes-related QOL among ethnically diverse, low-SES young adults with diabetes. Larger-scale translational studies evaluating this approach among various populations in real-world settings should be conducted to assess the potential impact of including OTs on diabetes care teams. Given the increasing prevalence of diabetes, workforce shortages among front-line diabetes care providers, and the shift toward multidisciplinary team-based approaches to chronic care management, OTs may merit consideration as an untapped resource to address the growing burden of diabetes in the U.S.

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References
1. Hendricks M, Monaghan M, Soutor S, Chen R, Holmes CS. A profile of self-care behaviors in emerging adults with type 1 diabetes. Diabetes Educ 2013;39:195–203
2. Peters A, Laffel L. American Diabetes Association Transitions Working Group. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American Diabetes Association, with representation by the American College of Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, The Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society). Diabetes Care 2011;34:2477–2485
3. Johnson B, Elliott J, Scott A, Heller S, Eiser C. Medical and psychological outcomes for young
adults with type 1 diabetes: no improvement despite recent advances in diabetes care. Diabet Med 2014;31:227–231.

4. Dabelea D, Stafford JM, Mayer-Davis EJ, et al.; SEARCH for Diabetes in Youth Research Group. Association of type 1 diabetes vs type 2 diabetes diagnosed during childhood and adolescence with complications during teenage years and young adulthood. JAMA 2017;317:825–835.

5. Kibbey KJ, Speight J, Wong JL, Smith LA, Teede HJ. Diabetes care provision: barriers, enablers and service needs of young adults with type 1 diabetes from a region of social disadvantage. Diabet Med 2013;30:878–884.

6. Peyrot M, McMurry JF Jr., Kruger DF. A biopsychosocial model of glycemic control in diabetes: stress, coping and regimen adherence. J Health Soc Behav 1999;40:141–158.

7. Lado JJ, Lipman TH. Racial and ethnic disparities in the incidence, treatment, and outcomes of youth with type 1 diabetes. Endocrinoïd Metab Clin North Am 2016;45:453–461.

8. González JS, Tanenbaum ML, Commissariat PV. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabete Care 2000;23:943–950.

9. Haltiwanger EP. Effect of a group adherence intervention for Mexican-American older adults with type 2 diabetes. Am J Occup Ther 2016;70(6):551–555.

10. O’Toole L, Connolly D, Smith S. Impact of an occupation-based self-management programme on chronic disease management. Aust Occup Ther J 2013;60:38–50.

11. Schwartz JK, Smith RO. Intervention promoting medication adherence: a randomized, phase I, small-N study. Am J Occup Ther 2012;66(6):636–645.

12. Garvey J, Connolly D, Boland F, Smith SM. OPTIMAL, an occupational therapy led self-management support programme for people with multimorbidity in primary care: a randomized controlled trial. BMC Fam Pract 2015;16:59.

13. Uyeshiro Simon A, Collins CER. Lifestyle Redesign: the Well Elderly Study occupational therapy program. Bethesda, MD, AOTA, 2015.

14. Pyatak EA, Carandang K, Vigen C, et al. Resilient, Empowered, Active Living with Diabetes. OTJR (Thorofare, NJ) 2015;35:187–191.

15. Jackson J, Carlson M, Mandel D, Zemrek R, Clark F. Occupation in lifestyle redesign: the Well Elderly Study occupational therapy program. Am J Occup Ther 1998;52:326–336.

16. Wood JR, Kaminiski BM, Kollman C, et al. Accuracy and precision of the Axison-Shield Afini Hemoglobin A1C measurement device. J Diabetes Sci Technol 2012;6:380–386.

17. Toobert DJ, Hampson SE, Glasgow RE. The convergent and predictive validity of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. Qual Life Res 1999;8:79–91.

18. McGuire BE, Morrison TG, Hermanns N, et al. Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes scale (PAID)-5 and PAID-1. Diabetologia 2010;53:66–69.

19. Koenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The HQ-8 as a measure of current depression in the general population. J Affect Disord 2009;114:163–173.

20. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). Diabetes Care 2003;26:1641–1642.

21. Garcia AA, Villagomez ET, Brown SA, Kouzelenan K, Hanis CL. The Starr County Diabetes Education study: development of the Spanish-language diabetes knowledge questionnaire. Diabetes Care 2001;24:1641–1642.

22. Gardner B, Abraham C, Lally P, de Bruijn GJ. Association with treatment outcome in the TODAY trial: a key to successful diabetes self-management. J Health Psychol 2004;9:461–466.

23. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. J Pers Assess 1985;49:51–75.

24. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). Diabetes Care 2003;26:1641–1642.

25. Garcia AA, Villagomez ET, Brown SA, Kouzelenan K, Hanis CL. The Starr County Diabetes Education study: development of the Spanish-language diabetes knowledge questionnaire. Diabetes Care 2001;24:16–21.

26. Glasgow RE, Toobert DJ, Barrera M Jr, Strycker LA. Assessment of problem-solving: a key to successful diabetes self-management. J Behav Med 2004;27:477–490.

27. Gardner B, Abraham C, Lally P, de Bruin GJ. Towards parsimony in habit measurement: testing the convergent and predictive validity of an automaticity subscale of the Self-Report Habit Index. Int J Behav Nutr Phys Act 2012;9:102.

28. Brown M, Dijkers MPJM, Gordon WA, Ashman T, Charatz H, Cheng Z. Participation objective, participation subjective: a measure of participation combining outsider and insider perspectives. J Head Trauma Rehabil 2004;19:459–481.

29. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap): a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–381.

30. Hollinghead ADB. Four Factor Index of Social Status. New Haven, CT, Yale University, Department of Sociology, 1975.