Translating the Diabetes Prevention Program Lifestyle Intervention for Weight Loss Into Primary Care

A Randomized Trial

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Background: The Diabetes Prevention Program (DPP) lifestyle intervention reduced the incidence of type 2 diabetes mellitus (DM) among high-risk adults by 58%, with weight loss as the dominant predictor. However, it has not been adequately translated into primary care.

Methods: We evaluated 2 adapted DPP lifestyle interventions among overweight or obese adults who were recruited from 1 primary care clinic and had pre-DM and/or metabolic syndrome. Participants were randomized to (1) a coach-led group intervention (n=79), (2) a self-directed DVD intervention (n=81), or (3) usual care (n=81). During a 3-month intensive intervention phase, the DPP-based behavioral weight-loss curriculum was delivered by lifestyle coach-led small groups or home-based DVD. During the maintenance phase, participants in both interventions received lifestyle change coaching and support remotely—through secure email within an electronic health record system and the American Heart Association Heart360 website for weight and physical activity goal setting and self-monitoring. The primary outcome was change in body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) from baseline to 15 months.

Results: At baseline, participants had a mean (SD) age of 52.9 (10.6) years and a mean BMI of 32.0 (5.4); 47% were female; 78%, non-Hispanic white; and 17%, Asian/Pacific Islander. At month 15, the mean ± SE change in BMI from baseline was −2.2 ± 0.3 in the coach-led group vs −0.9 ± 0.3 in the usual care group (P < .001) and −1.6 ± 0.3 in the self-directed group vs usual care (P = .02). The percentages of participants who achieved the 7% DPP-based weight-loss goal were 37.0% (P = .003) and 35.9% (P = .004) in the coach-led and self-directed groups, respectively, vs 14.4% in the usual care group. Both interventions also achieved greater net improvements in waist circumference and fasting plasma glucose level.

Conclusion: Proven effective in a primary care setting, the 2 DPP-based lifestyle interventions are readily scalable and exportable with potential for substantial clinical and public health impact.

Trial Registration: clinicaltrials.gov Identifier: NCT00842426


A N ESTIMATED 69% OF US adults are overweight or obese, and those with modifiable cardiometabolic risk factors are a critical target group for intervention. Lifestyle modification focused on modest (5%-10%) weight loss and moderate-intensity physical activity can significantly reduce the incidence of type 2 diabetes mellitus (DM) (as much as 58% as shown in the Diabetes Prevention Program [DPP]) and cardiometabolic risk factors in high-risk individuals with benefits sustained for at least 10 years. Evidence-based guidelines therefore recommend effective lifestyle intervention for weight management and disease prevention.

See also pages 105 and 111

However, national surveys reveal a continuing failure to incorporate weight management into clinical practice. Implementation of efficacious lifestyle interventions in the real world will require adaptation to improve generalizability and sustainability while maintain-
Receiving intervention effectiveness. A meta-analysis of translation studies based on the DPP lifestyle intervention showed promising results, but most studies used a single-group design, few leveraged information technology (IT), and none had follow-up past 12 months. Two recent trials provide further evidence on the effectiveness of alternative weight management models in primary care settings.

Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE) was a 3-arm, primary care–based randomized trial designed to evaluate the effectiveness of 2 adapted DPP lifestyle interventions among overweight or obese adults with pre-DM, metabolic syndrome, or both: (1) a coach-led, face-to-face group intervention and (2) a self-directed DVD intervention. We hypothesized that, compared with usual care, each intervention would result in greater mean reduction in body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) over 15 months.

**METHODS**

The E-LITE protocol was approved by the Palo Alto Medical Foundation’s (Palo Alto, California) institutional review board and was published previously. Some outcome data have been published in abstract form. All participants gave written informed consent.

**RECRUITMENT AND PARTICIPANTS**

Participants were recruited (July 2009–June 2010) from a single primary care clinic within the Silicon Valley (Los Altos, California) that is part of a large multispecialty group practice in the San Francisco Bay Area. All data collection and intervention visits occurred at the clinic. Inclusion criteria included an age of at least 18 years, a BMI of at least 25, and the presence of pre-DM (defined by impaired fasting plasma glucose level of 100 to 125 mg/dL) or metabolic syndrome (defined by 2005 joint criteria of the American Heart Association [AHA] and National Heart, Lung, and Blood Institute). (To convert glucose to millimoles per liter, multiply by 0.0555.) Exclusion criteria included serious medical or psychiatric conditions (eg, stroke, psychotic disorder) or special life circumstances (eg, pregnancy, planned move). Of the 3439 patients approved for study contact by their primary care provider, 1057 were determined to be ineligible, 972 declined participation, 363 were unreachable, 806 were not screened because of recruitment success, and 241 were fully eligible and randomized (Figure 1).

**RANDOMIZATION AND ALLOCATION CONCEALMENT**

We applied a covariate-adaptive, Efron’s biased coin method to assure better than chance group balance across prognostic factors (age, sex, race/ethnicity, BMI, fasting blood glucose level, waist circumference, and existing patient account to access personal electronic health record [EHR] system). Participants were randomized to (1) a coach-led, group-delivered intervention (n=79), (2) a self-directed DVD intervention (n=81), or (3) usual care (n=81). While study group assignment was identifiable to participants and interventionists, blinding was otherwise maintained for data collection, outcome adjudication, and data analysis.

**OUTCOME MEASURES**

The primary outcome was change in BMI from baseline to 15 months. Trained research assistants who were unaware of participants’ group assignment performed anthropometric and blood pressure measurements using standard protocols at baseline and at 3, 6, and 15 months, except for height (measured at baseline only). At all time points except 3 months, blood samples were taken after an overnight fast. Possible adverse events were assessed by questionnaire at each follow-up visit and reviewed by a study physician per protocol.

**STATISTICAL ANALYSIS**

Between-group differences in primary and secondary outcomes were evaluated by intention-to-treat using tests of group by time interactions in repeated-measures mixed-effects linear (for continuous outcomes) or logistic models (for categorical outcomes). The fixed effects of each model consisted of the baseline value of the outcome of interest, randomization balancing factors, recruitment cohort, group, time point (3, 6, or 15 months), and group-by-time interaction. The random effects accounted for repeated measures with an unstructured co-
of the 241 randomized participants, 205 (85.1%) had study-measured weights at 3 months, 201 (83.4%) at 6 months, and 194 (80.5%) at 15 months (Figure 1). After replacing missing study weights with measurements obtained from the EHR (for 14 participants at 3 months, 18 at 6 months, and 24 at 15 months) and by self-report (for 5 participants at 6 months and 3 at 15 months), 22 participants at 3 months (9.1%), 17 (7.1%) at 6 months, and 20 (8.3%) at 15 months had no weight measurement from any source. Similarly, missing blood pressure and laboratory values were replaced with EHR-recorded values. Primary analyses used all available data, but sensitivity analyses were performed that included only participants with study-measured values. Missing data were handled directly through maximum-likelihood estimation via mixed modeling.

Our primary aim was to compare change in BMI from baseline to 15 months between each intervention and the usual care
treatment. Least-square means ± SE were obtained from the models. We verified that mixed-model–based results were not sensitive to violations of modeling assumptions with permutation and bootstrap resampling tests.23,24

Of the 241 randomized participants, 205 (85.1%) had study-measured weights at 3 months, 201 (83.4%) at 6 months, and 194 (80.5%) at 15 months (Figure 1). After replacing missing study weights with measurements obtained from the EHR (for 14 participants at 3 months, 18 at 6 months, and 24 at 15 months) and by self-report (for 5 participants at 6 months and 3 at 15 months), 22 participants at 3 months (9.1%), 17 (7.1%) at 6 months, and 20 (8.3%) at 15 months had no weight measurement from any source. Similarly, missing blood pressure and laboratory values were replaced with EHR-recorded values. Primary analyses used all available data, but sensitivity analyses were performed that included only participants with study-measured values. Missing data were handled directly through maximum-likelihood estimation via mixed modeling.

Our primary aim was to compare change in BMI from baseline to 15 months between each intervention and the usual care...
control group. Our secondary aims were to (1) perform similar comparisons for secondary outcomes, (2) compare primary and secondary outcomes between the 2 interventions, and (3) evaluate sex as a prespecified potential moderator. Clinical interest in weight-loss outcomes by sex led to an analysis of intervention effects separately in women and men despite the absence of significant group-by-sex interaction.

The targeted sample size of 80 participants in each group was designed to provide 80% power to detect a 0.5-SD difference (medium effect by Cohen’s standards25) in the primary outcome between each intervention and usual care, using t tests at 5% α (2-sided) and assuming up to a 20% loss to follow-up at 15 months. All analyses were conducted using SAS statistical software (version 9.2; SAS Institute Inc).

RESULTS

STUDY PARTICIPANTS

At baseline, participants had a mean (SD) age of 52.9 (10.6) years and a mean BMI of 32.0 (5.4) (weight, 93.8 [17.7] kg); 47% were female, 78% were non-Hispanic white, 17% were Asian/Pacific Islander, and 4.1% were Hispanic/Latino. Most participants had high educational attainment and family annual income (Table 2). Approximately 54% of participants had pre-DM, 87% had metabolic syndrome, and 41% had both conditions.

WEIGHT LOSS

At month 15, the mean ± SE change in BMI from baseline was −2.2 ± 0.3 in the coach-led intervention (P < .001 vs usual care; P = .03 vs self-directed intervention), −1.6 ± 0.3 in the self-directed intervention (P = .02 vs usual care), and −0.9 ± 0.3 in the usual care group (Table 3). Results remained unchanged in sensitivity analyses using study-measured weights only (eTable 1; http://www.jamainternalmed.com).

At month 15, the mean ± SE change in weight from baseline was −6.3 ± 0.9 kg in the coach-led intervention, −4.5 ± 0.9 kg in the self-directed intervention, −2.4 ± 0.9 kg in the usual care control group, corresponding to a weight change of −6.6%, −5.0%, and −2.6%, respectively (Table 3 and Figure 2). The percentage of participants who achieved the 7% DPP-based weight-loss goal at 15 months was 37.0% (P = .003) in the coach-led intervention and 35.9% (P = .004) in the self-directed intervention vs 14.4% in the usual care group. Findings were similar for 5% and 10% weight-loss goal cut-points (Figure 3). Complete fitted distributions of percentage of weight changes at 15 months are shown in the eFigure.

During the trial period, 15 of 81 participants in the usual care group reported joining a weight-loss program outside the study (12 used commercial programs, 2 used nutrition classes offered by the care delivery system, and 1 used a personal trainer), compared with 5 of 79 in the coach-led group (4 used personal trainers, and 1 used a commercial program) (P = .003). No participants reported undergoing pharmacological or surgical weight-loss treatment.

For women, weight loss was significantly greater in the coach-led intervention than in the usual care con-
compared with usual care controls. Improvements reached statistical significance for waist circumference and fasting plasma glucose levels in both interventions and for diastolic blood pressure and triglyceride to high-density lipoprotein cholesterol ratio in the coach-led intervention (Table 4). Total cholesterol levels increased significantly less in the self-directed intervention vs the usual care group.

### Changes in Cardiometabolic Risk Factors

Compared with usual care controls, improvements reached statistical significance for waist circumference and fasting plasma glucose levels in both interventions and for diastolic blood pressure and triglyceride to high-density lipoprotein cholesterol ratio in the coach-led intervention (Table 4). Total cholesterol levels increased significantly less in the self-directed intervention vs the usual care group.

### Intervention Participation Rates

Participants in the coach-led intervention attended a mean ± SE of 75.1% ± 25.6% (74.6% ± 26.3% among men, 75.7% ± 25.2% among women) of the 12 weekly group sessions (median number of sessions attended, 10; interquartile range [IQR], 9-11). Only 4 participants (1 man, 3 women) in the self-directed intervention did not attend the single group orientation session. Self-directed intervention participants had a median number of 31 secure email messages (IQR, 30-32) during the 15-month period, and coach-led intervention participants had 19 (IQR, 18-22) during the 12-month period after weekly classes were over.

### Adverse Events

Five serious adverse events were detected in 4 coach-led intervention participants that may have been related to the intervention: 3 fractures and 1 case of chronic subdural hematoma requiring surgery several months...
Following the participant’s syncopal episode during a group intervention session. Six other hospitalizations were reported, which were judged to be unrelated to the study (2 in the usual care group, 1 in the self-directed group, 3 in the coach-led group). One coach-led intervention participant and 1 usual care participant developed type 2 DM during the 15-month period. There were no deaths.

This primary care–based translational intervention trial demonstrated that 2 IT-supported, DPP-based lifestyle interventions both led to clinically significant reductions in body weight (measured as change in BMI), accompanied by improvements in waist circumference and fasting plasma glucose level compared with usual care over a 15-month period.

Successful adaptation of proven lifestyle interventions such as the DPP for multiple channels of delivery, all populations at risk, and primary care settings will be critical to stem the tide of obesity and lessen its disease burden. Newly published trials demonstrated the effectiveness of 2 primary care models, 1 involving in-person or remote (primarily by phone) professional weight management support and the other combining lifestyle counseling with meal replacement or weight-loss medication. The E-LITE trial makes a unique contribution to this growing literature in that its interventions integrate standardized, packaged DPP translational programs (delivered in groups or by DVD) with existing health IT. Although these intervention components and delivery channels are not new, their integration into structured interventions for use in primary care is novel.

### Table 3. Estimated Mean Change in BMI, Weight Change, and Percentage of Weight Change Over a 15-Month Period in the Intention-to-Treat Populationa

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Usual Care (n = 81)</th>
<th>Coach-Led (n = 79)</th>
<th>Self-directed (n = 81)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>32.0 (5.4)</td>
<td>32.4 (6.3)</td>
<td>31.8 (5.1)</td>
<td>NA</td>
</tr>
<tr>
<td>At 3 mo</td>
<td>31.5 (0.3)</td>
<td>29.9 (0.2)</td>
<td>30.2 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 6 mo</td>
<td>31.5 (0.3)</td>
<td>29.4 (0.3)</td>
<td>30.2 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 15 mo</td>
<td>30.9 (0.3)</td>
<td>29.6 (0.3)</td>
<td>30.2 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Change in BMI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 3 mo</td>
<td>−0.3 (0.3)</td>
<td>−1.9 (0.3)</td>
<td>−1.6 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 6 mo</td>
<td>−0.3 (0.3)</td>
<td>−2.4 (0.3)</td>
<td>−1.5 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 15 mo</td>
<td>−0.9 (0.3)</td>
<td>−2.2 (0.3)</td>
<td>−1.6 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Weight change, kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 3 mo</td>
<td>−0.7 (0.8)</td>
<td>−5.4 (0.7)</td>
<td>−4.5 (0.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 6 mo</td>
<td>−0.7 (0.9)</td>
<td>−6.6 (0.8)</td>
<td>−4.3 (0.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 15 mo</td>
<td>−2.4 (0.9)</td>
<td>−6.3 (0.9)</td>
<td>−4.9 (0.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Weight change, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 3 mo</td>
<td>−0.7 (0.8)</td>
<td>−5.8 (0.8)</td>
<td>−4.9 (0.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 6 mo</td>
<td>−0.9 (0.9)</td>
<td>−7.2 (0.9)</td>
<td>−4.7 (0.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>At 15 mo</td>
<td>−2.6 (0.9)</td>
<td>−6.6 (0.9)</td>
<td>−5.0 (0.9)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); NA, not applicable; SE, standard error.

*The data for the 3 study groups are covariate-adjusted, mixed-model–based estimates for the intention-to-treat population.

The primary comparisons between the 2 active interventions and usual care remain statistically significant (P < .05) after the Bonferroni correction was applied by multiplying the calculated P values by a factor of 2.
The maximum weight loss achieved within the coach-led intervention was substantial (6.3 kg, net loss of 3.9 kg relative to usual care) and similar in magnitude to that achieved by the DPP lifestyle intervention and other behavioral or drug-based weight-loss trials. Weight loss in the self-directed intervention was less pronounced (a net loss of 2.1 kg) but noteworthy given its low resource requirements and high potential for dissemination. In this real-world translation study, we did not restrict participants from seeking other weight-loss treatment. Nevertheless, the net intervention effects were significant even though a higher proportion of usual care participants reported attending outside weight-loss programs during the study period. The fact that usual care participants lost some weight emphasizes the robustness of findings regarding the effectiveness of the interventions.

Women seemed to respond more favorably to the coach-led intervention compared with self-directed intervention, whereas men seemed to respond comparably to both. These sex-specific findings need to be confirmed in studies adequately powered to investigate sex differences. Future research also should investigate whether empirically supported, sex-based intervention targeting strategies can improve the effectiveness of the interventions.

The present trial has several limitations. First, study participants were primarily of high socioeconomic status and from a single primary care clinic located within the Silicon Valley of the San Francisco Bay Area and within a parent health system that was one of the first in the nation to adopt a fully functional EHR system. Therefore, its findings may not be directly generalizable to other populations and settings. Second, replacement of missing weights with clinical values recorded in the EHR or self-reported weights might have introduced bias, but sensitivity analyses using only study-measured weights did not change the results. Finally, the trial lasted only for 15 months and was not designed to evaluate event-based outcomes (eg, type 2 DM incidence) or cost-effectiveness. Thus, the long-term effects and comparative cost-effectiveness of the 2 interventions await further investigation.

Independent efforts to broadly disseminate the DPP-based GLB in-person and DVD programs have been under way. In E-LITE, these programs were integrated with health IT tools that have low-additive cost but high

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**Figure 3.** Categorical weight loss at 6 and 15 months in the intention-to-treat population. Weight loss (A) less than or equal to baseline weight, (B) greater than or equal to 5% of baseline weight, (C) greater than or equal to 7% of baseline weight, and (D) greater than or equal to 10% of baseline weight.
reach to maximize translation potential and clinical and public health impact. Technology-based interventions need to be first evaluated where the technology is available, with broad dissemination following as adoption of the technology expands. Use of computers and the Internet has increased markedly in all population segments, including in lower socioeconomic groups. The AHA’s Heart360 self-management web portal is free, trustworthy, and easily accessible for patients and primary care providers. Heart360 automated mobile texting for reminders and data transmission (without requiring Web logon after account set-up) is an enhancement that became available only after initiation of intervention with all participants in our study. It substantially extends the potential reach of the system. Moreover, health care reform provisions have accelerated adoption of EHR systems. Although the cost of acquiring an EHR system is substantial, use of a system already in place for disease management requires minimal additional investment (eg, low time commitment by the lifestyle coach to communicate with participants via secure e-mail).

The E-LITE interventions respond to the need for innovative, effective methods to manage obesity in primary care settings that do not overly burden practicing primary care providers. These interventions are demonstrably beneficial, with potential for high clinical and public health impact, but they do not meet the current definitions of primary care provider (primary care clinicians only) and delivery channel (face-to-face visits only) required to receive Centers for Medicare and Medicaid Services coverage of intensive behavioral therapy for obesity in primary care. The Centers for Disease Control and Prevention also require that lifestyle interventions be delivered in person as one of the standards for recognition in its National Diabetes Prevention Program. Consideration of expanded program criteria in these national initiatives might encourage wider adoption of alternative and, potentially, more cost-effective lifestyle interventions such as the ones evaluated in this study, assuming that their effectiveness can be documented in more nationally representative populations.

**Table 4. Estimated Mean Changes From Baseline to 15 Months in Cardiometabolic Risk Factors in the Intention-to-Treat Population a**

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Usual Care</th>
<th>Coach-Led</th>
<th>Self-directed</th>
<th>Coach-Led vs Usual Care</th>
<th>Self-directed vs Usual Care</th>
<th>Coach-Led vs Self-directed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waist circumference, cm (n = 218)</td>
<td>–2.2 (1.1)</td>
<td>–5.8 (1.0)</td>
<td>–4.9 (1.0)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.20</td>
</tr>
<tr>
<td>Systolic BP, mm Hg (n = 237)</td>
<td>0.1 (1.6)</td>
<td>–1.2 (1.5)</td>
<td>–0.4 (1.5)</td>
<td>.21</td>
<td>.61</td>
<td>.45</td>
</tr>
<tr>
<td>Diastolic BP, mm Hg (n = 237)</td>
<td>–0.3 (1.1)</td>
<td>–1.9 (1.1)</td>
<td>–1.1 (1.1)</td>
<td>.04</td>
<td>.29</td>
<td>.30</td>
</tr>
<tr>
<td>Fasting plasma glucose level, mg/dL (n = 209)</td>
<td>0.2 (1.7)</td>
<td>–4.2 (1.6)</td>
<td>–2.7 (1.6)</td>
<td>&lt;.001</td>
<td>.01</td>
<td>.20</td>
</tr>
<tr>
<td>Triglyceride level, mg/dL (n = 208)</td>
<td>–18.8 (11.0)</td>
<td>–31.2 (10.5)</td>
<td>–28.8 (10.8)</td>
<td>.11</td>
<td>.18</td>
<td>.75</td>
</tr>
<tr>
<td>High-density lipoprotein cholesterol level, mg/dL (n = 218)</td>
<td>2.9 (1.4)</td>
<td>4.4 (1.3)</td>
<td>2.6 (1.3)</td>
<td>.11</td>
<td>.79</td>
<td>.06</td>
</tr>
<tr>
<td>Low-density lipoprotein cholesterol level, mg/dL (n = 217)</td>
<td>10.6 (5.0)</td>
<td>4.5 (4.8)</td>
<td>5.2 (4.9)</td>
<td>.08</td>
<td>.11</td>
<td>.85</td>
</tr>
<tr>
<td>Total cholesterol level, mg/dL (n = 218)</td>
<td>10.6 (5.5)</td>
<td>3.9 (5.6)</td>
<td>4.4 (5.6)</td>
<td>.05</td>
<td>.04</td>
<td>.98</td>
</tr>
<tr>
<td>Triglycerides to high-density lipoprotein cholesterol ratio (n = 218)</td>
<td>–0.5 (0.3)</td>
<td>–1.0 (0.3)</td>
<td>–0.8 (0.3)</td>
<td>.03</td>
<td>.18</td>
<td>.38</td>
</tr>
</tbody>
</table>

Abbreviations: BP, blood pressure; SE, standard error.

SI conversion factors: To convert total, high-density, and low-density lipoprotein cholesterol to millimoles per liter, multiply by 0.0259; to convert triglycerides to millimoles per liter, multiply by 0.0113.

The data for the 3 study groups are covariate-adjusted, mixed-model–based estimates for the intention-to-treat population.
management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript.

Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIDDK or the AHA.

Online-Only Material: The eTables and eFigure are available at http://www.jamainternalmed.com.

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REFERENCES