Long-Term Metformin Adherence in the Diabetes Prevention Program Outcomes Study

Supplemental Materials

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2. Metformin Safety and Adherence Form
3. List of Institutions and IRBs
4. Investigators Appendix
### Supplemental Materials

<table>
<thead>
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<th>Took Metformin&lt;sup&gt;7&lt;/sup&gt;</th>
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<tr>
<td><strong>Number of Eligible Participants</strong></td>
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<td></td>
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<tr>
<td><strong>Age at DPPOS baseline (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-49</td>
<td>62 (30.4%)</td>
<td>201 (30.3%)</td>
</tr>
<tr>
<td>50-64</td>
<td>98 (48.0%)</td>
<td>345 (52.0%)</td>
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<tr>
<td>&gt;= 65</td>
<td>43 (21.1%)</td>
<td>117 (17.6%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
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<td>0.572</td>
</tr>
<tr>
<td>White</td>
<td>115 (56.4%)</td>
<td>378 (56.9%)</td>
</tr>
<tr>
<td>Black</td>
<td>44 (21.6%)</td>
<td>128 (19.3%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>25 (12.3%)</td>
<td>103 (15.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>20 (9.8%)</td>
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<tr>
<td><strong>Sex</strong></td>
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</tr>
<tr>
<td>Male</td>
<td>69 (33.8%)</td>
<td>214 (32.2%)</td>
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<tr>
<td>Female</td>
<td>135 (66.2%)</td>
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<td><strong>Marital Status at DPP baseline</strong></td>
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<tr>
<td>Married/Living Together</td>
<td>78 (38.2%)</td>
<td>220 (33.1%)</td>
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<tr>
<td>Single, Separated, Divorced or Widowed</td>
<td>126 (61.8%)</td>
<td>444 (66.9%)</td>
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<td><strong>Marital Status at DPPOS baseline</strong></td>
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<tr>
<td>Married/Living Together</td>
<td>83 (40.7%)</td>
<td>225 (33.9%)</td>
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<tr>
<td>Single, Separated, Divorced or Widowed</td>
<td>120 (58.8%)</td>
<td>438 (66.0%)</td>
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<td><strong>Educational Status at DPP baseline</strong></td>
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<tr>
<td>&lt;= HS</td>
<td>43 (21.1%)</td>
<td>167 (25.2%)</td>
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<tr>
<td>Attended College</td>
<td>102 (50.0%)</td>
<td>314 (47.3%)</td>
</tr>
<tr>
<td>Attended Graduate School</td>
<td>59 (28.9%)</td>
<td>183 (27.6%)</td>
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<td><strong>Educational Status at DPPOS baseline</strong></td>
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<tr>
<td>&lt;= HS</td>
<td>37 (18.1%)</td>
<td>171 (25.8%)</td>
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<tr>
<td>Attended College</td>
<td>111 (54.4%)</td>
<td>310 (46.7%)</td>
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<tr>
<td>Attended Graduate School</td>
<td>55 (27.0%)</td>
<td>182 (27.4%)</td>
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<td>Full or part time</td>
<td>153 (75.0%)</td>
<td>513 (77.3%)</td>
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<tr>
<td>Retired</td>
<td>31 (15.2%)</td>
<td>83 (12.5%)</td>
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<tr>
<td>Other</td>
<td>20 (9.8%)</td>
<td>68 (10.2%)</td>
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<td><strong>Employment Status at DPPOS baseline</strong></td>
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<tr>
<td>Full or part time</td>
<td>134 (65.7%)</td>
<td>480 (72.3%)</td>
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<tr>
<td>Retired</td>
<td>43 (21.1%)</td>
<td>130 (19.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (12.7%)</td>
<td>53 (8.0%)</td>
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<tr>
<td><strong>Annual Family Income at DPP baseline</strong></td>
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<tr>
<td>&lt; $20,000</td>
<td>23 (12.5%)</td>
<td>79 (12.8%)</td>
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<tr>
<td>$20,000 to &lt; $75,000</td>
<td>130 (70.2%)</td>
<td>373 (60.6%)</td>
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<tr>
<td>≥ $75,000</td>
<td>31 (16.8%)</td>
<td>164 (26.6%)</td>
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**Early Adherence to Study Metformin (DPP 3mo)**

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<tr>
<td>N (%)</td>
<td>83 (43.0%)</td>
<td>110 (57.0%)</td>
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<tr>
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<td>157 (24.2%)</td>
<td>493 (75.8%)</td>
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<tr>
<th>Mental Component Score of SF-36</th>
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<td>Mental Component Score at DPP baseline</td>
<td>54.1±7.3</td>
<td>54.1±8.0</td>
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<tr>
<td>Mean during DPPOS†</td>
<td>53.9±7.1</td>
<td>53.6±6.7</td>
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<th>Physical Component Score of SF-36</th>
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<td>Physical Component Score at DPP baseline</td>
<td>50.4±7.4</td>
<td>50.2±7.0</td>
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<tr>
<td>Mean during DPPOS†</td>
<td>46.4±8.3</td>
<td>47.5±7.6</td>
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<table>
<thead>
<tr>
<th>Beck Anxiety Score</th>
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<td>Median Anxiety Score at DPP baseline</td>
<td>2.0 [0.0, 5.0]</td>
<td>3.0 [1.0, 5.0]</td>
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<tr>
<td>Median score during DPPOS‡</td>
<td>3.0 [1.1, 5.6]</td>
<td>3.0 [1.3, 5.6]</td>
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<table>
<thead>
<tr>
<th>Beck Depression Score</th>
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<td>Median DPP baseline score</td>
<td>4.0 [1.0, 7.0]</td>
<td>3.0 [1.0, 7.0]</td>
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<tr>
<td>Median score during DPPOS‡</td>
<td>3.1 [1.5, 6.0]</td>
<td>3.2 [1.4, 6.0]</td>
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<table>
<thead>
<tr>
<th>Number of Concomitant Medications§</th>
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<tr>
<td>Median Number of meds at DPP baseline</td>
<td>0.0 [0.0, 2.0]</td>
<td>1.0 [0.0, 2.0]</td>
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<tr>
<td>Median during DPPOS‡</td>
<td>2.2 [0.9, 3.9]</td>
<td>2.7 [1.4, 4.3]</td>
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</table>

**Table S1.** Comparison of characteristics in DPPOS participants (eligible to take metformin) who took metformin at one or more DPPOS visits (Yes) vs. those who took none (No).

N (column %), Mean ± SD or Median [25th %ile, 75th %ile]

†No=those who were eligible but never took any study metformin during DPPOS follow up
Yes=those who took study metformin at one or more DPPOS visits

‡Early adherence was measured at 3-months post-randomization during the DPP phase of the study.

§The median values during DPPOS for SF-36, Beck inventory and number of concomitant medications were calculated from all available DPPOS visits at which participants had non-missing values for these measurements.

§Concomitant medications at each DPPOS visit was reported as the number of prescription medications (excluding study metformin) taken within two weeks of the visit.
# F08 Metformin Safety & Adherence Form

This form is completed for MLS participants if the participant has taken any study metformin since the last scheduled visit. DO NOT COMPLETE THIS FORM FOR PARTICIPANTS WHO HAVE PERMANENTLY DISCONTINUED METFORMIN.

This form supplements the F01 Mid-Year Visit Inventory, F02 Annual Visit Inventory, F03 Interim Visit Inventory, and F04 Non-Clinic Visit Inventory forms.

## A. Participant Identification

1. Clinic number

2. Participant number

3. Nickname

4. Date of randomization

5. Sex

6. Outcome visit

7. Date of visit

## B. Metformin Status

1. Daily dose of METFORMIN per protocol

   - 850 mg
   - 1700 mg

   **CHECK ONE ONLY**

   - <80%
   - ≥80%
   - did not return pill container

2. What is your best estimate of the participant’s level of exposure to metformin per protocol?

3. Since the last visit, has the participant had any problems taking his/her metformin pills as prescribed?

   - Yes
   - No

   **IF YES, complete section C.**

---

Identification code of person reviewing completed form

Form entered in computer?
C. Barriers and Strategies

Complete this section if the participant had any problems taking his/her metformin pills as prescribed.

1. What are the main problems in taking pills as prescribed?

CHECK ALL THAT APPLY

a. Forgets to take pills in general
b. Forgets to take evening dose
c. Inconvenient to take pills as prescribed
d. GI reaction to pills
e. Disruption of regular routine
f. Hospitalization/new illness/medical reason
g. Lack of motivation
h. Lost/misplaced pills
i. Other

1. IF OTHER, specify:

2. What plan or strategy will the participant use to deal with this problem?

CHECK ONE MAIN STRATEGY

Continue current plan
New time routine
New strategy/routine
New reminder device
Change type and/or frequency of staff communication
Does NOT want to deal with the problem
Other main strategy

If option 1 (continue current plan) is selected,

CHECK ALL THAT APPLY

a. Time routine (e.g. time of day, meal time)
b. Strategy routine (e.g. takes with other pills; medication in a convenient place)
c. Reminder device (e.g. pill box, calendar)
d. Other

If 'Other main strategy' (question 2, option 7) or 'Other [current plan]' (question 2.d),

specify other strategy/plan:
This adherence interview was administered at study visits where participants were actively taking study metformin (i.e., interview was NOT conducted at study visits where participants were discontinued from study metformin).

**Question B.2** was used to compute the cumulative adherence variable which was used as the outcome in the GEE models and as a covariate in the Cox Proportional Hazards analysis of time to diabetes. Those participants who did not return their pill bottle were assumed to be non-adherent (i.e. ≤ 80% adherent).

**Questions C.1 and C.2** were used to determine both the number of barriers and strategies and the categories of barriers and strategies; both were used as covariates in the GEE and Cox Proportional Hazards models. Those who were temporarily off metformin were not administered this form and the number of barriers could not be computed (although it is presumed they were experiencing barriers, otherwise they would not have been temporarily suspended from taking metformin). They were assigned the mean number of barriers reported by those taking metformin (mean value imputation). When other barrier was reported (Question B.1.i) participants were asked to specify the barrier in an open text field. Authors (EAW, JSG) reviewed each of the text fields and coded these individuals into one of the standard barrier categories (B.1.a-h).
Table. DPPOS Institutional IRBs

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<tr>
<th>Institution</th>
<th>City</th>
<th>State</th>
<th>Name of IRB</th>
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<tr>
<td>Pennington Biomedical Research Center</td>
<td>Baton Rouge</td>
<td>LA</td>
<td>Pennington Biomedical Research Center IRB</td>
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<tr>
<td>University of Chicago</td>
<td>Chicago</td>
<td>IL</td>
<td>University of Chicago IRB</td>
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<td>Jefferson Medical College</td>
<td>Philadelphia</td>
<td>PA</td>
<td>Thomas Jefferson University IRB</td>
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<td>University of Miami</td>
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<td>University of Miami IRB</td>
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<tr>
<td>University of Texas Health Science Center at San Antonio</td>
<td>San Antonio</td>
<td>TX</td>
<td>UT Health IRB</td>
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<tr>
<td>University of Colorado</td>
<td>Denver</td>
<td>CO</td>
<td>Colorado Multiple Institutional Review Board</td>
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<td>Joslin Diabetes Center</td>
<td>Boston</td>
<td>MA</td>
<td>Committee On Human Studies Joslin Diabetes Center</td>
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<td>Seattle</td>
<td>WA</td>
<td>University of Washington IRB/Veterans Affairs IRB</td>
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<td>Memphis</td>
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<td>University Of Tennessee Health Science IRB</td>
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<tr>
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<td>Chicago</td>
<td>IL</td>
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<td>Boston</td>
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<td>Massachusetts General Hospital/Partners Human Research Committee</td>
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<tr>
<td>University of California, San Diego</td>
<td>San Diego</td>
<td>CA</td>
<td>UCSD Human Research Protections Program</td>
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<td>IN</td>
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<td>Hyattsville</td>
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<td>Bronx</td>
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<td>HI</td>
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</table>
# DPP and DPPOS I Research Group

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