Safety and Efficacy of Time Restricted Feeding in Patients with Type 2 Diabetes
Jonathan Junqua OMS; Elijah Lustig OMS, Jay H. Shubrook DO, Kim Pfotenhauer DO
Touro University California

Introduction

- Type 2 diabetes and obesity is at an all time high. ¹
- Lifestyle management through healthy nutrition and physical activity is a critical part of managing Type 2 diabetes. ²
- One lifestyle modification to tackle Type 2 diabetes is Intermittent Fasting or Time Restricted Feeding.
  - Restrict caloric consumption to specified hours of the day or days of the week.
  - Time Restricted Feeding has been found to have beneficial effects on glycemic control and insulin sensitivity in patients with pre-diabetes at risk for Type 2 Diabetes ³⁴
- Aim to assess safety and efficacy of Time Restricted Feeding for individuals with Type 2.

Methods

- Participants were recruited using convenience sampling for this randomized crossover study through inclusion/exclusion criteria (click to view specific parameters)
- Participants were provided continuous glucose monitors (CGM) and randomized using coin flip to Fasting vs Non-Fasting arm
  - Fasting arm: Eat unrestricted calories for 8 hours (12pm-8pm) and fast for 16 hours (8pm-12pm) for 14 days
  - Non-Fasting: Eat unrestricted diet as normal for 14 days (calorie count to maintain weight provided)
- Participants were asked to log meals to monitor calorie count and take ketone readings every day
- Weight, Calorie Count, and Ketone levels were analyzed before and after each study arm using T-tests and CGM data was extracted.

Study Participant Demographics

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>Sex</th>
<th>Mean Age (years)</th>
<th>Mean Weight (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>All Female</td>
<td>52.6 ± 14.8</td>
<td>207.5 ± 29.7</td>
</tr>
</tbody>
</table>

(CDC, 2017)
## Results

<table>
<thead>
<tr>
<th></th>
<th>Difference in Average</th>
<th>Standard Deviation</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss (Pre vs Post-Fasting in lbs)</td>
<td>3.04 lbs (207 lbs vs 203.96 lbs)</td>
<td>±2.8</td>
<td>.038</td>
</tr>
<tr>
<td>Diet (calories consumed fasting vs non-fasting)</td>
<td>-73.5 calories (1467.4 vs 1540.9)</td>
<td>±200.2</td>
<td>0.458</td>
</tr>
<tr>
<td>Ketones (Fasting vs Non-fasting)</td>
<td>0.038 (0.171 vs 0.134)</td>
<td>±0.027</td>
<td>0.045</td>
</tr>
</tbody>
</table>

*P-values calculated using T-tests; red signifies statistical significance
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Cgm Results: Two Types of Participants

**Fasting**
- Participant A: Improved Glucose Variability but Inadequate for Glucose Control
- Participant B: Improved Glucose Variability but Increased Probability for Hypoglycemia

**Non-Fasting**
- Participant A: Safe with Room for Increasing Fasting Intervals
- Participant B: Potential to be Unsafe without Close Monitoring
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<table>
<thead>
<tr>
<th>Fasting</th>
<th>Non-Fasting</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.6%</td>
<td>4.6%</td>
</tr>
</tbody>
</table>

*Hypoglycemia defined as falling below the target glucose range of 80 mg/dL*
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Conclusion

- Time Restricted Feeding with 16 hour fasting intervals was effective for weight-loss and decreasing glucose variability.
- Caloric Intake was not significantly different for participants between the fasting and non-fasting portion.
  - Decreased Glucose Variability between study arms is attributable to the Fasting Schedule
- Ketones levels were elevated while fasting versus non-fasting with no risk of Diabetic Ketoacidosis.
- CGM data shows that the Time Restricted Feeding schedule had varied levels of safety for participants based on their starting glucose levels
  - Fasting was safe for participants with very high blood glucose levels with potential for increasing the number of hours fasting.
  - Fasting should be approached with caution for participants whose blood glucose levels are more controlled due to the risk of hypoglycemic episodes.
- Average rates of hypoglycemia were not higher while fasting vs non-fasting.
- Completion rate of 100% speaks to the feasibility of Intermittent Fasting and Time Restricted Feeding.

References

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Age–Adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

**Obesity (BMI ≥30 kg/m²)**

- 1994
- 2000
- 2015

- No Data
- <14.0%
- 14.0%–17.9%
- 18.0%–21.9%
- 22.0%–25.9%
- ≥26.0%

**Diabetes**

- 1994
- 2000
- 2015

- No Data
- <4.5%
- 4.5%–5.9%
- 6.0%–7.4%
- 7.5%–8.9%
- ≥9.0%


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Inclusion Criteria

- Over the age of 18
- Diagnosed with type 2 diabetes for at least 1 year
- A1c between 6.5-9.0%
- English speaking
- Has a cell phone or landline to be able to contact the study team for any questions or concerns
- Willing to wear a continuous glucose monitor for 4 weeks
- Willing to log all food for 4 weeks.
- Has a smartphone or computer access to log foods daily
- Willing to fast for 16 hours per day for at least 10 days out of 14 days while in the study arm
- Willing to receive 2 venipunctures at each of 2 visits (4 times total)

Exclusion Criteria

- Is currently pregnant
- Uses short-acting/mealtime insulin injections or sulfonylureas
- Has an already unacceptable risk of hypoglycemia (as determined by the clinical team)
- Had any severe hypoglycemia (<50 mg/dL glucose and needing assistance from others to revive) in the past 6 months
- Has hypoglycemic unawareness
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Fasting

Non-Fasting

Participant B