

2024 RACHMIEL LEVINE-ARTHUR RIGGS

Diabetes Research Symposium

Time Restricted Eating – Clinical Perspective

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Director, Training Grant in Diabetes, Endocrinology and Metabolism (NIH/NIDDK T32)

University of Minnesota



Disclosures

- Grant/Research Support from Dexcom.

This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

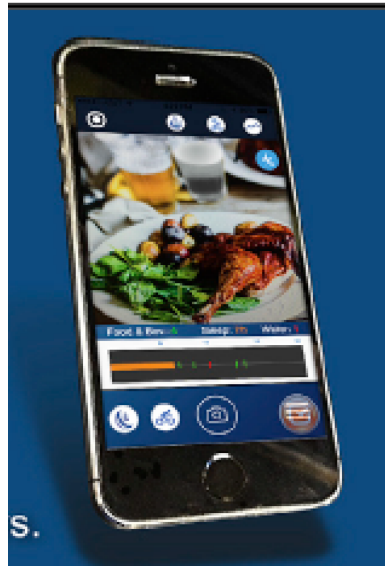
- *How time restricted eating accommodates diverse eating preference.*

Outline of Talk

- Rationale for TRE
- Current Evidence for TRE
 - In patients without diabetes
 - In patients with diabetes
- Considerations When Designing TRE studies

Rationale for TRE

**156 people
documented their food
intake for 3 weeks**



Gill Cell Metabolism 2015



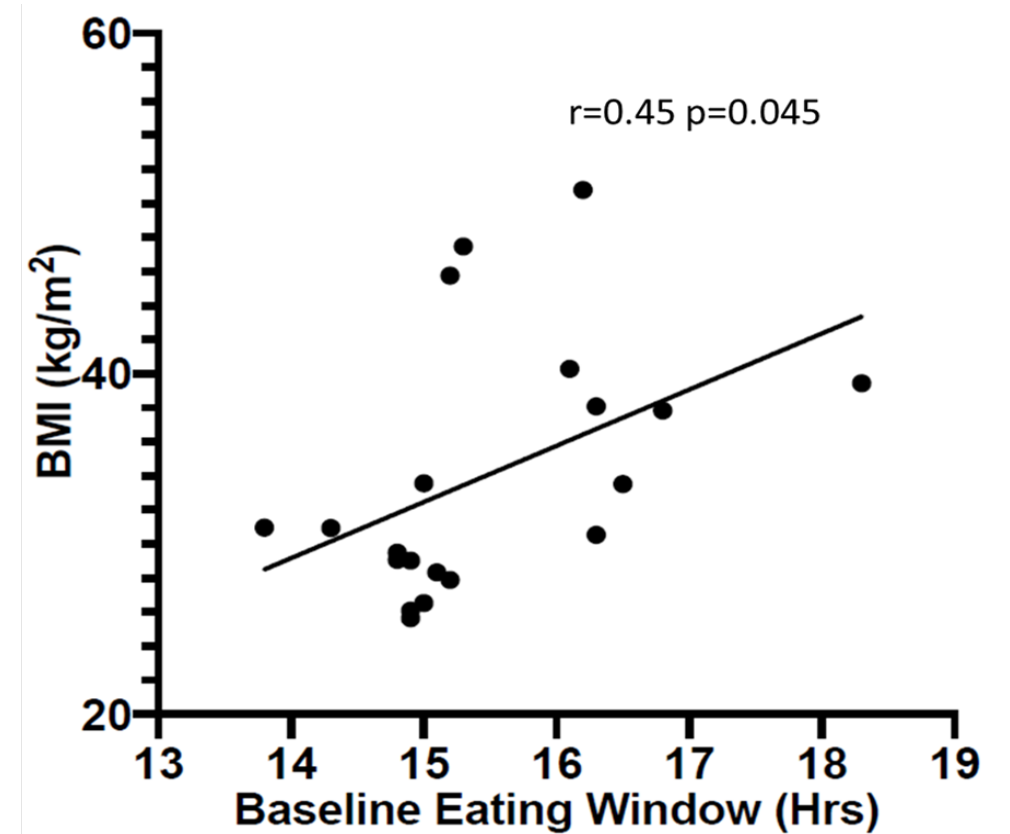
**50% of people ate ≥ 15 hours
Stop to eat when asleep**

Humans eat all the time

Ethnicity	Eating window (hours) Mean (SD)
Black (n=3)	13.7 (1.2)
Asian (n=53)	14.8 (1.8)
Hispanic (n=13)	14.4 (1.8)
NHW (n=69)	14.3 (1.5)
Mixed (n=17)	14.8 (1.1)
Eating window across all groups 14.5 (1.6)	

Unpublished
data

- Caloric restriction focuses on limiting calories
- Fasting focuses on limiting access to calories
 - **Agnostic to food quality and preferences**



Chow LS et al, Obesity, April 2020

The allure of fasting diets for successful people — and where it falls short

[Hilary Brueck](#) and [Gabby Landsverk](#)

Apr 3, 2024, 11:11 AM CDT

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Randy Holmes/Getty, Bryan Johnson/Magdalena Wosinska, Kevin Mazur/Getty, Justin Sullivan/Getty, Tyler Le/BI

- Intermittent fasting is hugely popular with tech CEOs, longevity-seekers, and movie stars.

Examples of celebrities who have supported intermittent fasting:

- Chris Hemsworth – “Thor”
- Hugh Jackman – “Wolverine”
- Dwayne Johnson – “The Rock”

~ 12% of Americans have tried intermittent fasting in 2023

(Industry backed survey :<https://foodinsight.org/>)

Different kinds of intermittent fasting:

- 5:2 plan
- Alternate day fasting
- Fasting week per month
- Daily eating window - TRE

Types of Fasting Programs

- Intermittent Fasting*

- Fast every other day [Alternate day fasting (ADF)] or for 1-2 days per week (5:2 plan)

*Unrestricted caloric intake

*Fasting is either no caloric intake or modified at <1000 kcal/day

- Intermittent Fasting*

- A few days per month

*Example: Eat normally 3 weeks, fasting/low calorie intake for 1 week

- Time Restricted Eating

- Eating window with *ad libitum* intake ~ 8-10 hours day

Outline of Talk

- Rationale for TRE
- **Current Evidence for TRE**
 - In patients without diabetes
 - In patients with diabetes
- Considerations When Designing TRE studies

TRE Trials in Humans:

- Since 2013 - 2022, there are about 40+ published TRE studies in humans
- Common design:
 - Typically small ($n < 50$) , not randomized, short duration (~ 8-12 weeks)
- Suggests TRE reduces caloric intake by about 5-20%
- Suggests TRE is associated with modest weight loss (~ 3-5%)

Endocrine Reviews, 2022, Vol. 43, No. 2, 405–436
<https://doi.org/10.1210/endrev/bnab027>
Review



Review

Time-restricted Eating for the Prevention and Management of Metabolic Diseases

Emily N. C. Manoogian,¹ Lisa S. Chow,² Pam R. Taub,³ Blandine Laferrère,⁴ and Satchidananda Panda¹

Manoogian E, *Endocrine Reviews* 2022

I thought TRE doesn't work?

Several studies suggest that TRE might not work

JAMA Internal Medicine | [Original Investigation](#)

Lowe D JAMA IM 2020

Effects of Time-Restricted Eating on Weight Loss and Other Metabolic Parameters in Women and Men With Overweight and Obesity The TREAT Randomized Clinical Trial

Dylan A. Lowe, PhD; Nancy Wu, MS; Linnea Rohdin-Bibby, BA; A. Holliston Moore, PhD; Nisa Kelly, MS; Yong En Liu, BS; Errol Philip, PhD; Eric Vittinghoff, PhD; Steven B. Heymsfield, MD; Jeffrey E. Olgin, MD; John A. Shepherd, PhD; Ethan J. Weiss, MD

Categories: [Heart News](#), [Scientific Conferences & Meetings](#) | Published: March 18, 2024

8-hour time-restricted eating
linked to a 91% higher risk of
cardiovascular death

American Heart Association Epidemiology and
Prevention|Lifestyle and Cardiometabolic Health Scientific
Sessions 2024, Abstract P192

Evidence Against TRE

JAMA Internal Medicine | [Original Investigation](#)

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Lowe D JAMA IM 2020

Premise

Compared TRE vs unrestricted eating

Study Design

- Participants
 - Healthy people without known diabetes.
 - **105** participants completed the 12 week study (50% remote, 50% local)
 - 46 participants completed four in-person measurements (local participants)
- Randomization
 - Control group -3 structured meals per day
 - TRE: 8 hour interval (12 to 8 pm)
 - Water, zero-calorie drink, coffee with calorie-free sweetener outside window
- Custom mobile study application -sent daily text about “adherence”
 - TRE group – click comply with 8 hour window
 - CMT group – click comply with eating 3 meals per day

Key Demographics

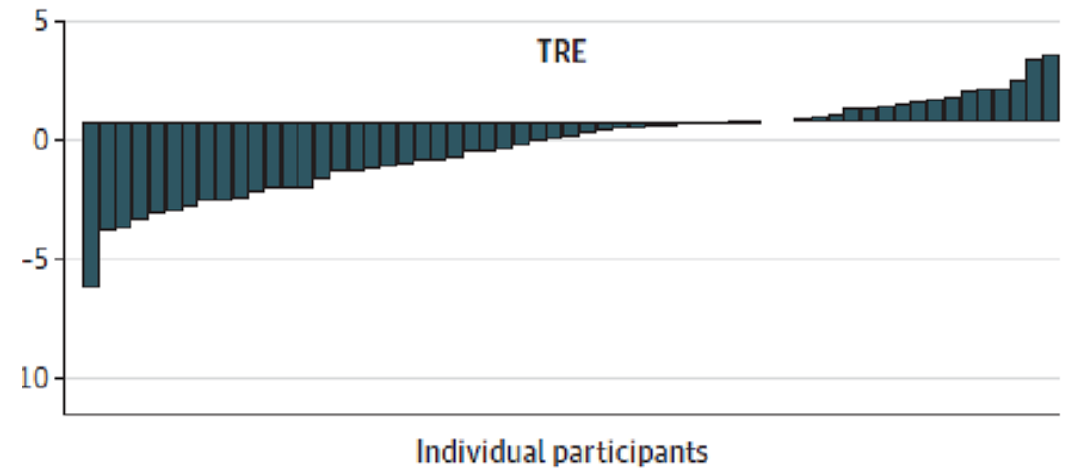
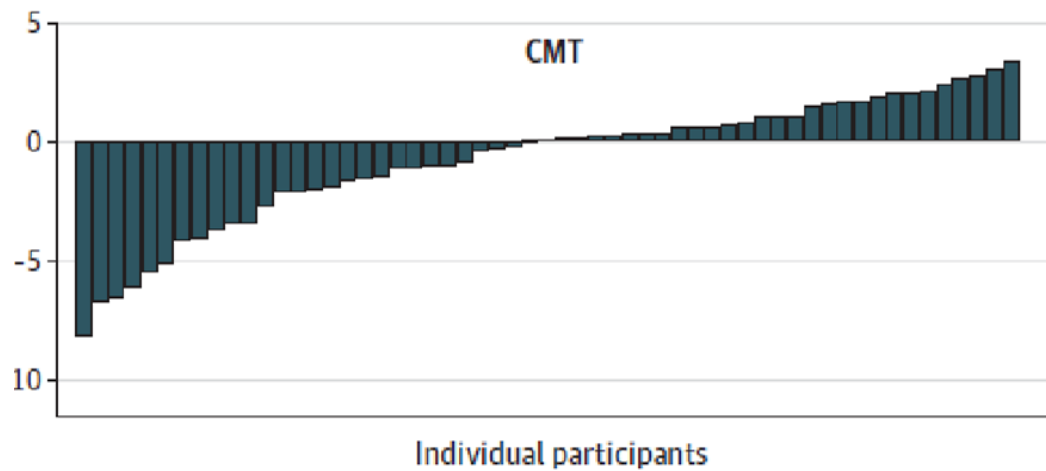
- Age~46.5 years (10.5)
- BMI~32.7 kg/m²(4.2)
- No diabetes
- No eating window measurements

Results

Table 2. Weight Change in the Total Cohort

Total Cohort (iHealth weight measurements)	CMT (n = 57 included in analysis)			Δ CMT P value	TRE (n = 59 included in analysis)			Δ TRE P value	Difference between groups	P value
	Preintervention	Postintervention	Δ CMT		Preintervention	Postintervention	Δ TRE			
iHealth weight, mean (SD), kg	99.2 (95.1 to 103.3)	98.5 (94.3 to 102.7)	-0.68 (-1.41 to 0.05)	.07	99.2 (95.1 to 103.2)	98.2 (94.1 to 102.4)	-0.94 (-1.68 to -0.20)	.01	-0.26 (-1.30 to 0.78)	.63

Percentage weight change



Conclusion

- TRE reduced weight relative to baseline
 - This was not significant compared with control group
- TRE was associated with lean mass loss
- TRE was not associated with alteration in glycemic measures (no hx of diabetes)

Main study criticisms

- Self report of TRE (yes/no)
- Change in eating window unknown
- Only 50% had in-person assessment
- Fasting period allowed zero-calorie drink, coffee with calorie-free sweetener

Another Report

Categories: [Heart News](#), [Scientific Conferences & Meetings](#) | Published: March 18, 2024

8-hour time-restricted eating linked to a 91% higher risk of cardiovascular death

American Heart Association Epidemiology and Prevention | Lifestyle and Cardiometabolic Health Scientific Sessions 2024, Abstract P192

Main criticism – Natural diet variability – TRE should not be defined by 2 dietary recalls, especially done 17 years ago

- **Poster Abstract**
- Observational study using NHANES data
 - 20000 adults
 - Average age 49 years
 - Follow up over 17 years
 - Used two 24 hour dietary recalls to calculate baseline eating window:
 - TRE: 8 hour window (**n=414 people**)
 - No difference in overall mortality
 - TRE group had higher risk for CV death (91%)
 - % rate of smoking higher in TRE than non-TRE (~ **27.1%** vs 17.9%)

AHA conference 2024

Outline of Talk

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 - In patients with diabetes
- Considerations When Designing TRE studies

Various Ways to Compare TRE Effects

- TRE vs non-TRE



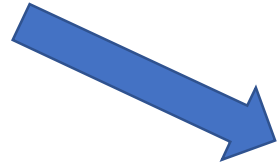
Time-Restricted Eating Effects on Body Composition and Metabolic Measures in Humans who are Overweight: A Feasibility Study

TRE vs unrestricted eating

*Lisa S. Chow*¹, *Emily N. C. Manoogian*², *Alison Alvear*¹, *Jason G. Fleischer*², *Honoree Thor*¹, *Katrina Dietsche*¹, *Qi Wang*³, *James S. Hodges*³, *Nicholas Esch*¹, *Samar Malaeb*¹, *Tasma Harindhanavudhi*¹, *K. Sreekumaran Nair*⁴, *Satchidananda Panda*², and *Douglas G. Mashek*^{1,5}

JAMA Internal Medicine | [Original Investigation](#)

- TRE vs CR



Effects of Time-Restricted Eating on Weight Loss and Other Metabolic Parameters in Women and Men With Overweight and Obesity The TREAT Randomized Clinical Trial

Dylan A. Lowe, PhD; Nancy Wu, MS; Linnea Rohdin-Bibby, BA; A. Holliston Moore, PhD; Nisa Kelly, MS; Yong En Liu, BS; Errol Philip, PhD; Eric Vittinghoff, PhD; Steven B. Heymsfield, MD; Jeffrey E. Olgin, MD; John A. Shepherd, PhD; Ethan J. Weiss, MD

- TRE timing - Early vs Late Eating

Change in eating pattern pre/post intervention

Key Demographics

- Age~45.5 years (12.1)
- BMI~34.1 kg/m²(7.5)
- No diabetes
- Baseline eating window ~ 15.4 hours (0.9)

Intervention

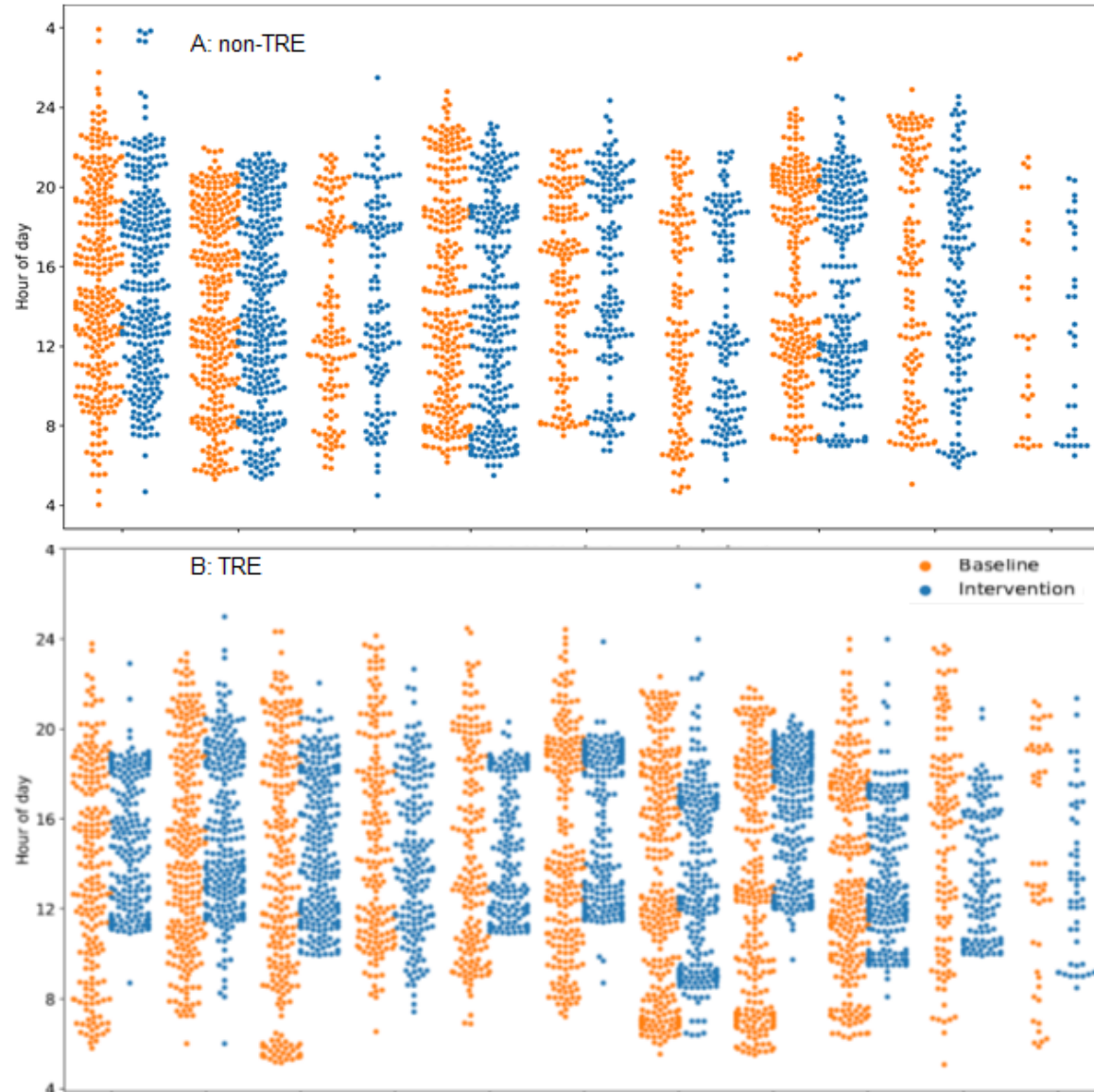
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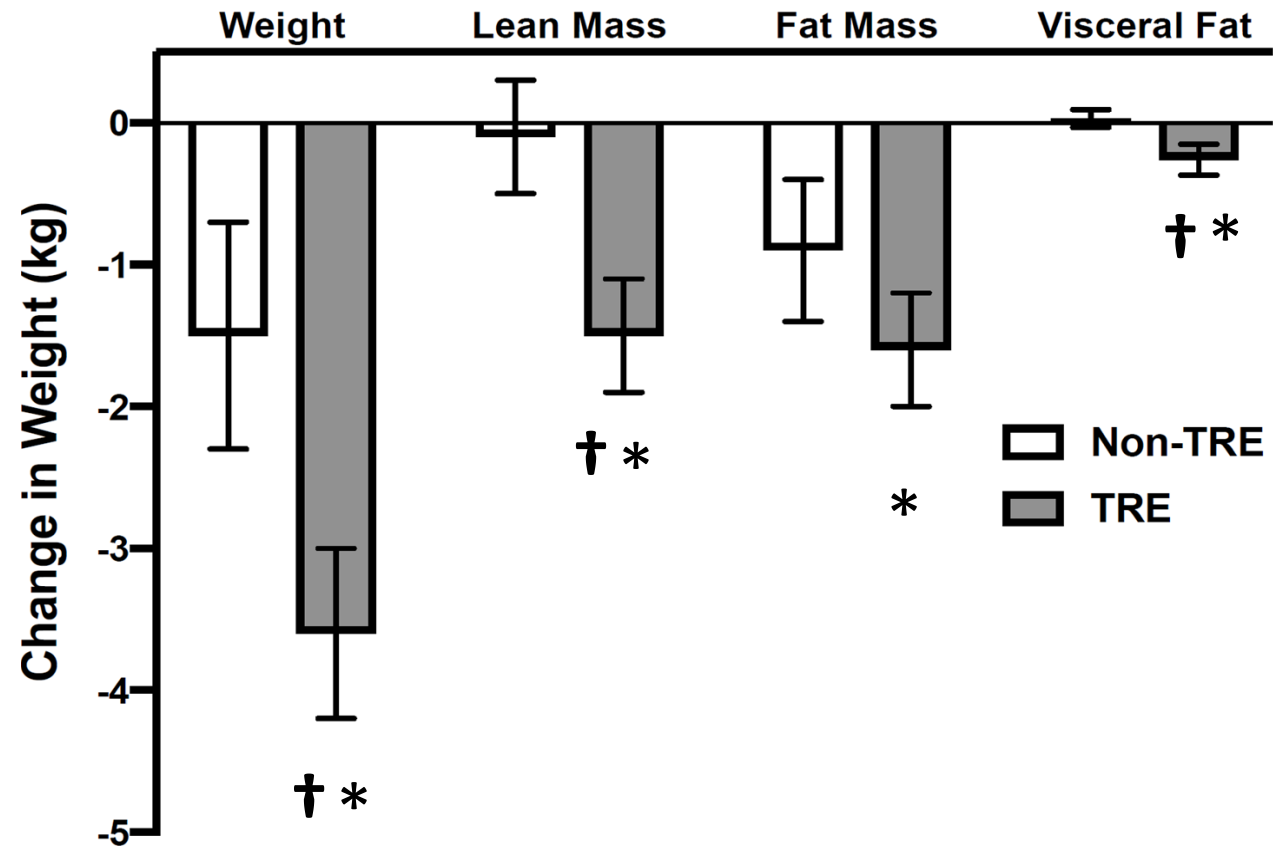
12 weeks ad libitum TRE (8 hours – self selected) vs unrestricted eating

Final window

TRE: 9.9 (2.0) hours

Non-TRE: 15.1 (1.1) hours





TRE alters body composition

TRE associated with ~ 3.5 kg weight loss
 ~50% fat mass loss
 ~50% lean mass loss

Effects of TRE

Reduces snacking and caffeine intake

Possible improvement in sleep duration but not sleep quality

In healthy humans, no effect on beta cell function



Article

Time-Restricted Eating Alters Food Intake Patterns, as Prospectively Documented by a Smartphone Application

Samar Malaeb ^{1,*}, Tasma Harindhanavudhi ^{1,†}, Katrina Dietsche ², Nick Esch ², Emily N. C. Manoogian ³, Satchidananda Panda ³, Douglas G. Mashek ^{1,4}, Qi Wang ⁵ and Lisa S. Chow ¹

The impact of a self-selected time restricted eating intervention on eating patterns, sleep, and late-night eating in individuals with obesity

Stacey L. Simon^{1†}, Jennifer Blankenship^{2†}, Emily N. C. Manoogian³, Satchidananda Panda³, Douglas G. Mashek⁴ and Lisa S. Chow^{5*}

ORIGINAL ARTICLE
Time-Restricted Eating



Time-restricted eating did not alter insulin sensitivity or β -cell function in adults with obesity: A randomized pilot study

Anne E. Bantle¹ | Kheng Joe Lau² | Qi Wang³ | Samar Malaeb⁴ | Tasma Harindhanavudhi¹ | Emily N. C. Manoogian⁵ | Satchidananda Panda⁵ | Douglas G. Mashek⁵ | Lisa S. Chow¹

¹Division of Diabetes, Endocrinology and Metabolism, Department of Medicine, University of Minnesota, Minneapolis, Minnesota, USA

²Endocrinology, Western Wisconsin Health, Baldwin, Wisconsin, USA

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⁴Department of Endocrinology, Park Nicollet Health Services, Saint Louis Park, Minnesota, USA

⁵Regulatory Biology Laboratory, Salk Institute for Biological Studies, La Jolla, California, USA

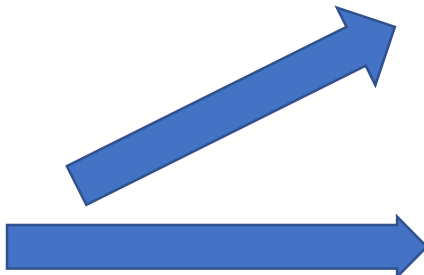
^{*}Department of Biochemistry, Molecular Biology, and Biophysics, University of Minnesota, Minneapolis, Minnesota, USA

Various Ways to Compare TRE Effects

- TRE vs non-TRE

- TRE vs CR

- TRE timing - Early vs Late Eating



Annals of Internal Medicine

ORIGINAL RESEARCH

Time-Restricted Eating Without Calorie Counting for Weight Loss in a Racially Diverse Population

A Randomized Controlled Trial

Shuhao Lin, MS, RD; Sofia Cienfuegos, PhD; Mark Ezpeleta, PhD; Kelsey Gabel, PhD, RD; Vasiliki Pavlou, MS, RD; Andrea Mulas, MS, RD; Kaitie Chakos, MS, RD; Mara McStay, MS, RD; Jackie Wu, MS, RD; Lisa Tussing-Humphreys, PhD, RD; Shaina J. Alexandria, PhD; Julianne Sanchez, MD; Terry Unterman, MD; and Krista A. Varady, PhD

JAMA Network | Open.



Original Investigation | Nutrition, Obesity, and Exercise

Effect of Time-Restricted Eating on Weight Loss in Adults With Type 2 Diabetes

A Randomized Clinical Trial

Vasiliki Pavlou, MS, RD; Sofia Cienfuegos, PhD; Shuhao Lin, MS, RD; Mark Ezpeleta, PhD; Kathleen Ready, MS, RD; Sarah Corapi, MS; Jackie Wu, MS, RD; Jason Lopez, BS; Kelsey Gabel, PhD, RD; Lisa Tussing-Humphreys, PhD, RD; Vanessa M. Oddo, PhD; Shaina J. Alexandria, PhD; Julianne Sanchez, MD; Terry Unterman, MD; Lisa S. Chow, MD, MS; Alaina P. Vidmar, MD; Krista A. Varady, PhD

TRE vs CR in Literature

Annals of Internal Medicine

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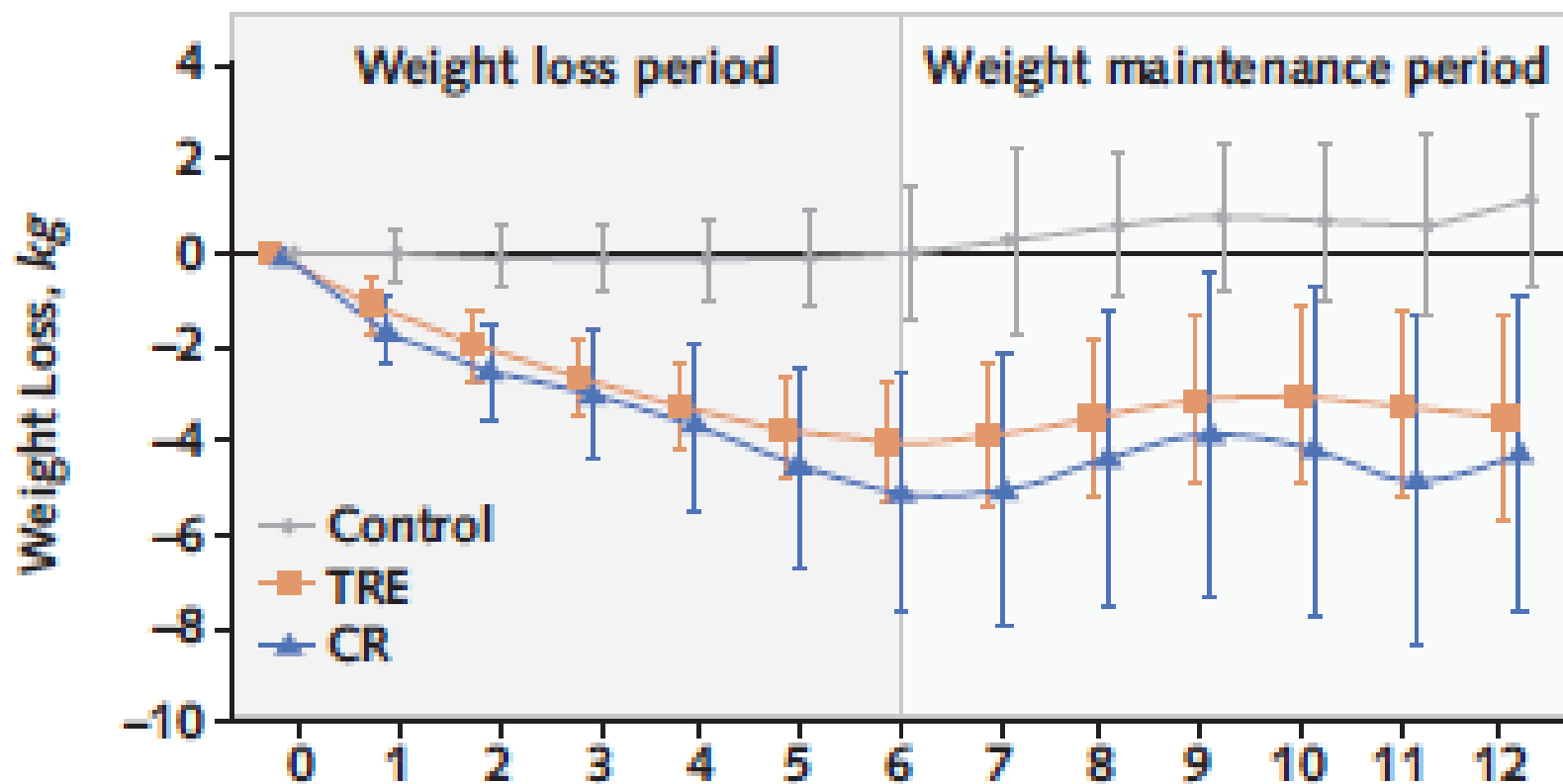
Key Demographics

- Age~40 years
- BMI~37 kg/m²
- No diabetes
- Baseline window~10.3 hours

Study Design

- N=77, 12 month trial, 6 month weight loss (8 hours vs 25% vs control) , 6 month weight maintenance (10 hours vs 15% vs control)

TRE vs CR in Literature



Weight change

- TRE: -3.5 kg
- CR: -4.3 kg
- Control: 1.12 kg

Body composition – similar loss between TRE and CR

- Fat mass (-2.4 kg)
- Lean mass (-0.6 kg)
- Visceral fat (-0.2 kg)

*no difference in glucose, BP or lipid measures

Conclusion: TRE similar to CR in weight outcomes

S. Lin Annals IM 2023

TRE vs CR in Patients with T2DM



Original Investigation | Nutrition, Obesity, and Exercise

Effect of Time-Restricted Eating on Weight Loss in Adults With Type 2 Diabetes A Randomized Clinical Trial

Vasiliki Pavlou, MS, RD; Sofia Cienfuegos, PhD; Shuhao Lin, MS, RD; Mark Ezpeleta, PhD; Kathleen Ready, MS, RD; Sarah Corapi, MS; Jackie Wu, MS, RD; Jason Lopez, BS; Kelsey Gabel, PhD, RD; Lisa Tussing-Humphreys, PhD, RD; Vanessa M. Oddo, PhD; Shalna J. Alexandria, PhD; Julianne Sanchez, MD; Terry Unterman, MD; Lisa S. Chow, MD, MS; Alalna P. Vidmar, MD; Krista A. Varady, PhD

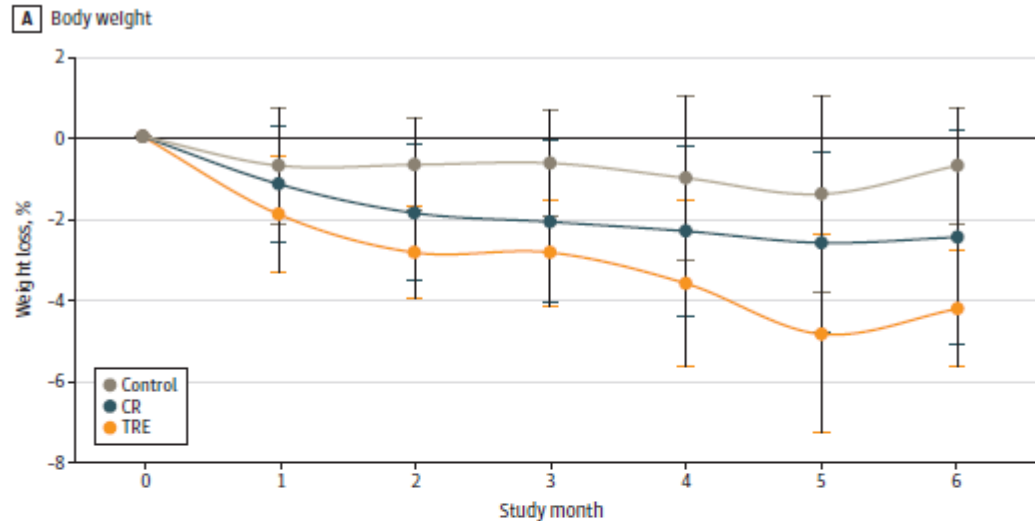
Key Demographics

- Age~56 years
- BMI~39 kg/m²
- Diabetes: Hgba1c ~8.1, 1/3 on insulin
- Baseline window ~11 hours

Study Design:

- N=75, 6 month study (8 hours vs 25% reduction vs control)

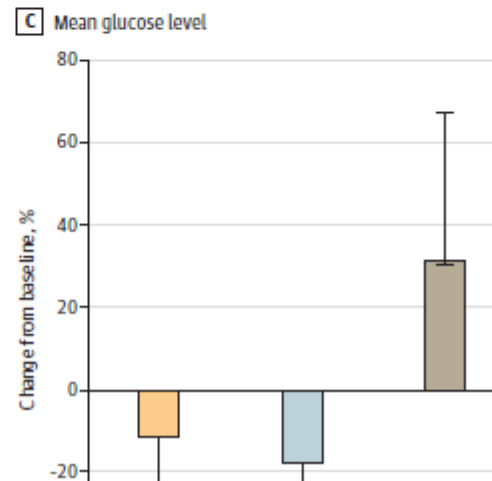
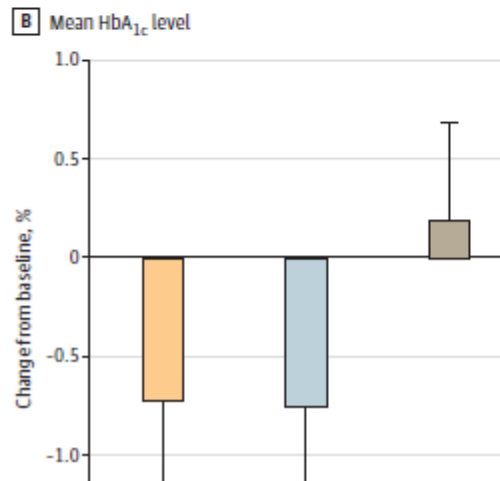
TRE vs CR in Patients with T2DM



Weight change

- TRE: -4.52 kg (sig c/w baseline/control)
- CR: - 2.63 kg (sig c/w baseline, not sig c/w control or TRE)
- Control: -1.07 kg

TRE had sig dec in fat mass c/w control



Change in HbA_{1c}

- TRE: -0.72 *sig c/w baseline/control
- CR: -0.75 *sig c/w baseline/control
- Control: 0.19

TRE and CR had sig decrease in mean CGM measured average glucose c/w control

Concluded that TRE had similar, if not slightly better benefits than CR in patients with T2DM

Various Ways to Compare TRE Effects






- TRE vs non-TRE

- TRE vs CR

- TRE timing effects— Early TRE?

Effect of Isocaloric, Time-Restricted Eating on Body Weight in Adults With Obesity: A

Randomized Controlled Trial

Authors: Nisa M. Maruthur, MD, MHS , Scott J. Pilla, MD, MHS , Karen White, MS, RDN , Beiwenn Wu, MSPH, RDN , May Thu Thu Maw, MBBS, MPH, Daisy Duan, MD , Ruth-Alma Turkson-Ocran, PhD, MPH, APRN , ... [SHOW ALL](#) ..., and Jeanne M. Clark, MD, MPH  | [AUTHOR, ARTICLE, & DISCLOSURE INFORMATION](#)

iScience

 CellPress
OPEN ACCESS

Article

Randomized controlled trial for time-restricted eating in overweight and obese young adults

JAMA Internal Medicine | [Original Investigation](#)

Effectiveness of Early Time-Restricted Eating for Weight Loss, Fat Loss, and Cardiometabolic Health in Adults With Obesity A Randomized Clinical Trial

Humaira Jamshed, PhD; Felicia L. Steger, PhD; David R. Bryan, MA; Joshua S. Richman, MD, PhD; Amy H. Warriner, MD; Cody J. Hanick, MS; Corby K. Martin, PhD; Sarah-Jeanne Salvy, PhD; Courtney M. Peterson, PhD

Early TRE with Isocaloric Intake

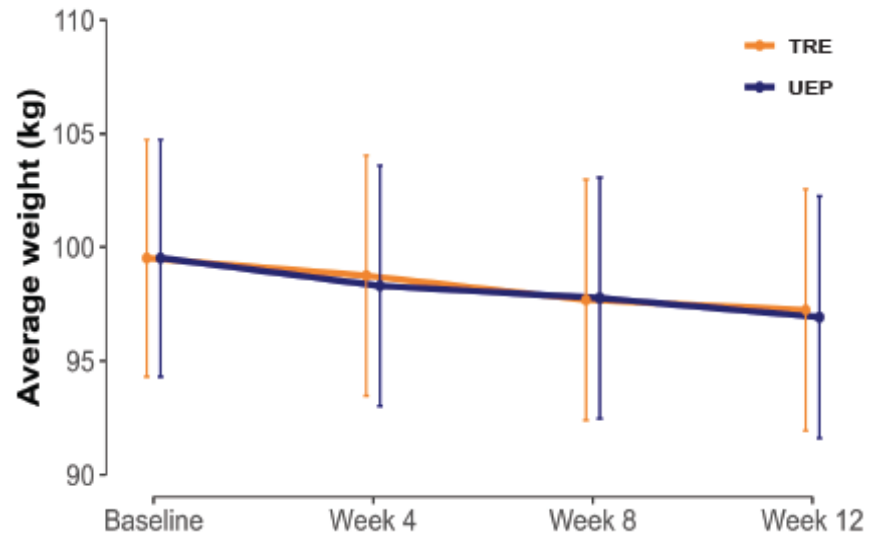
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[DISCLOSURE INFORMATION](#)

Maruthur N *Annals Internal Medicine* 2024



No difference in weight or glycemic measures (HOMA-IR, OGTT, fasting glucose) : TRE effects ->reduce caloric intake

Key Demographics (n=41)

- Age~59.4 years
- BMI~36 kg/m²
- 93% women and 93% Black
- Mean Hba1c: ~ 5.9
- Mean fasting glucose~105

- All food intake provided with observed food intake 3 meals/week
- 12 week intervention
- Allowed coffee/diet soda and alcohol outside window
- TRE group(10 hour window: 8-6 pm) instructed to consume 80% of intake by 1 pm
- Control group: Unrestricted window, 50% caloric intake after 5 pm

Evidence for Early TRE

iScience

CellPress
OPEN ACCESS

Article

Randomized controlled trial for time-restricted eating in overweight and obese young adults

Zhang L iScience 2022

Key Demographics

- Age~23 years(0.5)
- BMI~27 kg/m²(0.7)
- No hx of diabetes
- ~ 10 hour window

- Unique feature: Early TRE (7-1) with ad libitum intake vs normal TRE (12-6) vs control
- Both TRE groups had 4% weight loss c/w control, **early TRE with less hunger, lower SBP, HOMA-IR**

JAMA Internal Medicine | [Original Investigation](#)

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Key Demographics

- Age~43 years(11)
- BMI~39.6 kg/m² (6.7)
- No diabetes
- Baseline eating window ~ 12.6 hours (1.5)

- Unique feature: Early TRE (7-3) with CR
- **CR+TRE (-6.3 kg)** resulted in greater weight loss than CR alone (-4.0 kg)

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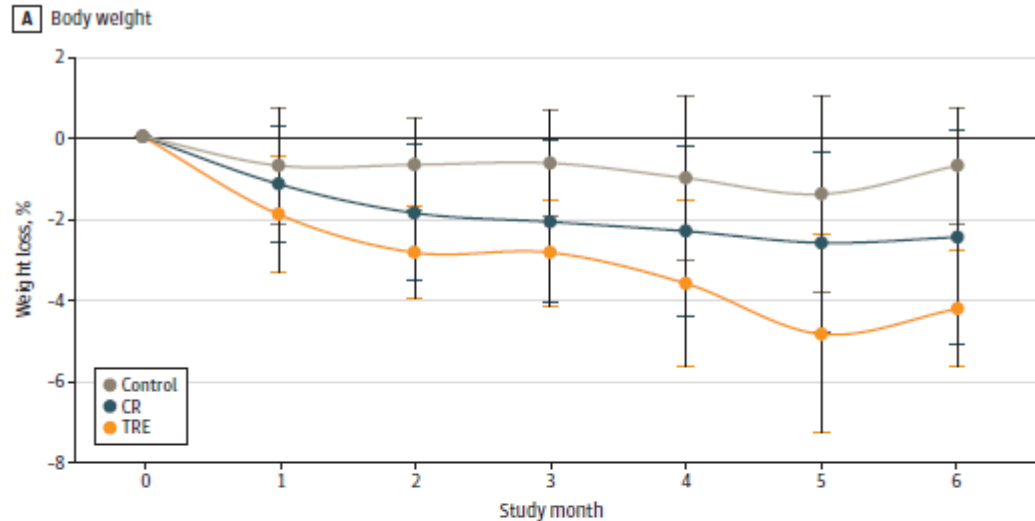
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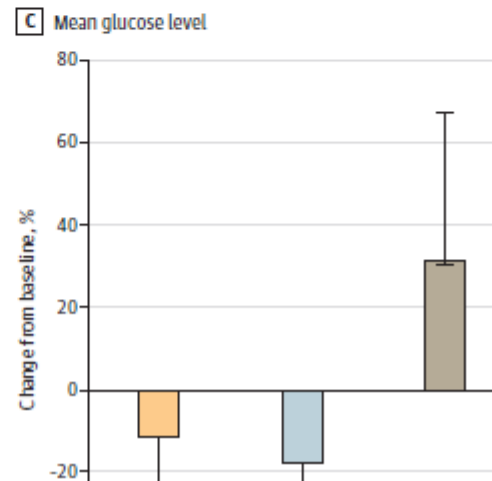
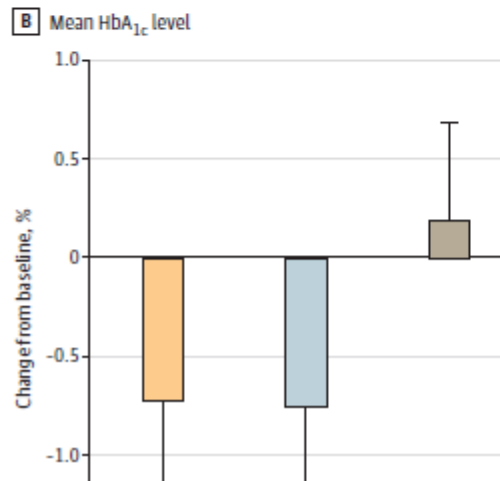
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Concluded that TRE had similar, if not slightly better benefits than CR in patients with T2DM

What about TRE in Type 1 diabetes?

- No published studies yet

Potential for Weight Loss in T1DM

- Historically, rare association between T1DM and obesity
 - 1980s – 3.4% of patients with T1DM are obese
 - 2000s – 22.7% of patients with T1DM are obese
 - 2020s – 28-37% of patients with T1DM are obese

Conway B Diabetes Med 2010

Fang, Annals of Internal Medicine 2023

*Data on intermittent fasting/TRE in T1DM sparse
Concerns about hypoglycemia and possibly ketosis

Considerations of Fasting in Diabetes : Type 1

- Often done for religious reasons
 - Can be prolonged (10-20+ hour)
 - Can be safe with teaching to avoid hypoglycemia
 - Can be safe with reduction of insulin requirements (10-50% depending on insulin program)

Considerations of Fasting in Diabetes : Type 1

- Compared 12 hour fasting vs 36 hour fasting
- Fasting done at home, came to clinical research unit for in-person evaluation (CGM during fasting period)
- Cross-over study
- If MDI – no change to basal insulin
- If pump – reduce basal rate by up to 25% - in reality, reduced by 4%

Key points

- N=20, T1DM
- Age~35 years
- BMI~24.8 kg/m²
- HbA1c~ 7.1
- Diabetes duration: 20 years
- Daily insulin ~ 40 units
- 9 were on pump tx

Considerations of Fasting in Diabetes : Type 1

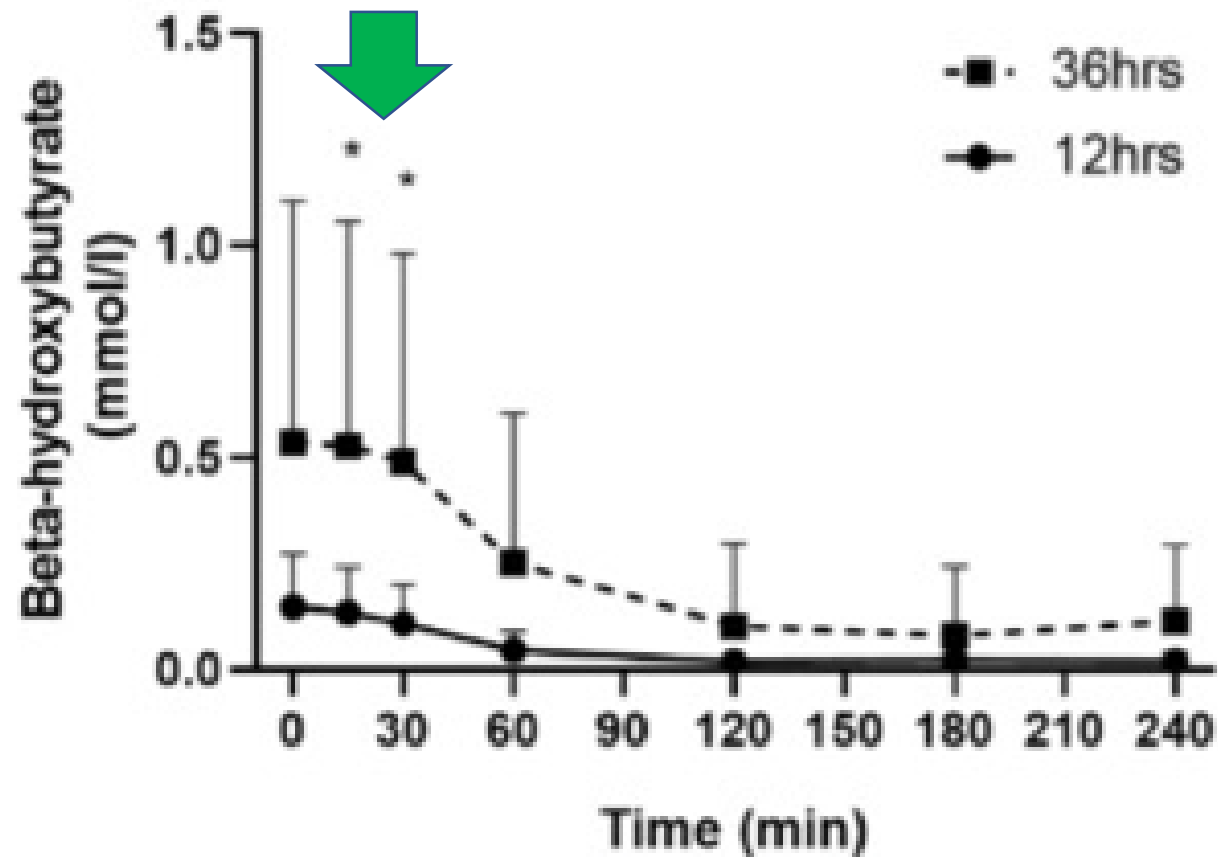
Glycemic Range	12 hrs fasting	36 hrs fasting	p-value
TAR 2 (>250 mg/dL; >13.9 mmol/L) (%)	2 ± 5	1 ± 2	0.99
TAR 1 (181–250 mg/dL; 10.1–13.9 mmol/L) (%)	19 ± 22	13 ± 11	0.93
TIR (70–180 mg/dL; 3.9–10.0 mmol/L) (%)	72 ± 23	80 ± 14	0.77
TBR 1 (54–70 mg/dL; 3.0–3.9 mmol/L) (%)	5 ± 7 **	4 ± 3 **	0.98
TBR 2 (<54 mg/dL; <3.0 mmol/l) (%)	2 ± 5 **	2 ± 2 **	0.99

**note no difference in time below range for hypoglycemia

Mean glucose: 12 hours 138 ± 35 mg/dL, SD 27 ± 12 mg/dl

Mean glucose: 36 hours 130 ± 17 mg/dl, SD 29 ± 10 mg/dL

Considerations of Fasting in Diabetes : Type 1



36 hour fast: B-OH butyrate increased to 0.5 mmol/L and decreased with insulin bolus

For reference, B-OH butyrate with DKA ~ 3.0 mmol/L (1.5 -3.5 mmol/L)

Conclusion: Fasting up to 36 hours in patients with T1DM is associated with low rate of hypoglycemia and ketosis

Potential for prolonged fasting/TRE in T1DM

Participants in Fasting Program

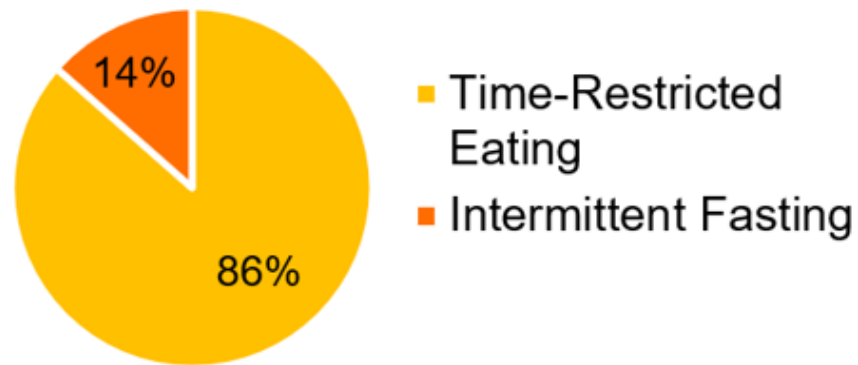
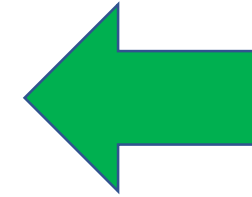


Figure 1: IF vs TRE breakdown.

- 122 survey respondents, 37 (30.3%) reported that they participate in a fasting program.
- Of the 37 respondents, 5 engaged in IF and 33 engaged in TRE.

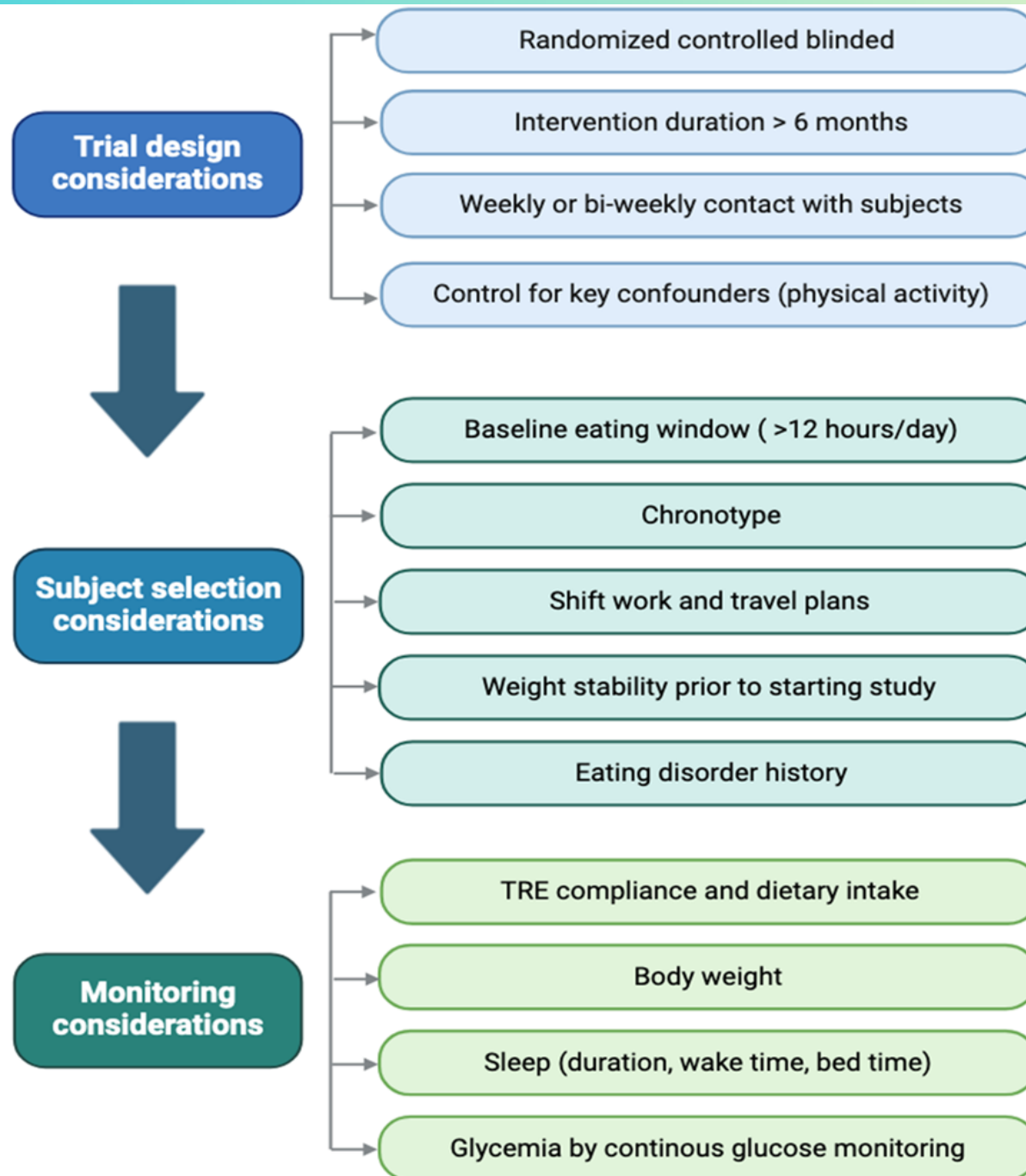


30% fasting program

Outline of Talk

- Rationale for TRE
- Current Evidence for TRE
 - In patients without diabetes
 - In patients with diabetes
- Considerations When Designing TRE studies

Considerations for conducting TRE studies in humans



Outline of Talk

Rationale for TRE



People eat all the time – longer eating window, greater opportunity to eat

Current Evidence
For TRE



Agnostic to food preferences and quality
Earlier eating window is likely better
Extent of eating window restriction matters
Effects

Modest Weight loss (3-5%)

Reduce HbA1c by 0.3 to 1.0% (in DM)

Findings are significant c/w UE and similar c/w with CR

Likely possible in T1DM - ~ 24% already doing it

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