

Low-Carbohydrate Diabetes
Prevention Program Among
Veterans With Prediabetes (VA LC-
DPP)

Prepared for ClinicalTrials
Resubmission 4/20/21

Statistical Analysis Plan:

Quantitative analysis

Descriptive statistics will be used for baseline survey response data including demographic and socioeconomic characteristics. For all continuous outcomes, we will calculate mean change and standard deviation from baseline to 6 months and 12 months and compare outcomes from baseline to 6 months and 12 months using paired t-tests. For all categorical outcomes, we will use chi-square or Fisher's exact tests to examine changes from baseline to 6 and 12 months. All analyses will be conducted using Stata 14.

Qualitative analysis:

Semi-structured interviews will be recorded and transcribed verbatim. Interviews will then be imported into qualitative analysis software. Two investigators will independently read and code transcribed interviews. Interviews will then be coded jointly using consensus conferences. Interviews will be analyzed using directed content analysis²⁷, which is to say that codes will be created to reflect the main topics in the interview guide and to characterize the patterns and themes that emerged from the data.²⁸

**Cravings:
Control of Eating Questionnaire**

Over the past 7 days...

How strong was your desire to eat sweet foods?	Q1	Answer choices on a sliding scale from 0 to 100 with anchors at 0 and 100:	Items on the CoEQ are assessed by 100 mm VAS with items relating to each subscale being averaged to create	Dalton M, Finlayson G, Hill A, Blundell J. Preliminary validation and principal components analysis of the Control of
How strong was your desire for non-	Q2	0- not at all strong 10 20	to create	

Over the past 7 days, how often have you had cravings for

Sweet foods like	Q3	Answer choices	
Other sweet foods (cakes, pastries, cookies, etc)?	Q4	on a sliding scale from 0 to 100 with anchors at 0 and 100:	
Fruit or fruit juice?	Q5	0- not at all	
Dairy foods (cheese, yogurts, milk, etc)?	Q6	10 20 30 40 50 60 70 80 90 100-	
Starchy Foods that are not sweet like French fries, potato chips,	Q7 Q8	70 80 90 100- extremely often	

Stress Eating

Please indicate how you usually experience a stressful event

I eat more of my favorite foods to	Q1	Answer choices 1 through 4 with anchors on 1 and 4:	Reverse code and sum, so that higher scores indicated	Tsenkova, V., Boylan, J. M., & Ryff, C. (2013). Stress
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Below is a list of reasons that people sometimes give for eating tasty foods and drinks such as:

- Sweets like chocolate, doughnuts, cookies, cake, candy, ice cream, other desserts.
- Salty snacks like chips, pretzels, and crackers.
- Fast foods like hamburgers, cheeseburgers, pizza, fried chicken and French fries.
- Sugary drinks like soda, sweet tea, milkshakes, and smoothies.

To forget y	Q3	1 =	Coping	Burgess,
Because it	Q4	Almost	score:	E. E.,
To cheer u	Q5	never/Ne	Average	Turan, B.,
To forget a	Q6	ver	of four	Lokken, K.
		2 = Some	responses	L., Morse,
		of the	.	A.. &

Energy Levels between Meals

In the past week, two hours after you ate BREAKFAST, how do you feel?

Alert	Q1	Answer	NA	NA
Energetic	Q2	choices 1		
Tired	Q3	through		
Brain fog o	Q4	7, with		
Food cravii	Q5	anchors		
Hunger	Q6	on 1, 7:		
Moodiness	Q7	1- Not at		
		all		
		7		

In the past week, two hours after you ate LUNCH, how do you feel?

Alert	Q8	Answer	NA	NA
Energetic	Q9	choices 1		
Tired	Q10	through		
Brain fod o	Q11	7, with		
Food cravii	Q12	anchors		
Hunger	Q13	on 1, 7:		
Moodiness	Q14	1- Not at		
		all		

Physical Symptoms

How often have you experienced the following over the past week?

Acne	Q1		NA	NA
Bad breath	Q2			
Bloating or	Q3			

Cold hands Q4
Constipation Q5
Diarrhea Q6
Dizziness Q7
Dry mouth Q8
Constant tiredness Q9
Food intolerance Q10

Headaches Q11

Heart palpitations or a racing heart Q12

Heartburn Q13

Joint or muscle pain Q14

Muscle cramps Q15

Nausea Q16

Trouble concentrating Q17

Weakness Q18

Hair loss Q19

Sexual problems Q20

Numbness (loss of sensation) in the feet, legs, or hands Q21

Tingling or prickling sensation in the feet, legs, or hands Q22

Not at all
1 day a week
2-3 days a week
4-5 days a week
6-7 days a week

Burning or shooting pain in the feet, legs, or hands

Q23

Blurred or deteriorating vision

Q24

Please describe any other psychological or physical symptoms that you experienced during the past month.

Q25

Participants may enter free text of whatever they choose.

Health
Global Health PROMIS Questionnaire:

Please respond to each item by marking one box per row

In	Q1	5-	Re-code:	PROMIS
In	Q2	Excellent	Q7 (pain	Health
general,		4- Very	on	Organizati
would		good	average):	on and
you say		3- Good	0 = 5	PROMIS
your		2- Fair	1,2,3 = 4	Cooperati
quality of		1- Poor	4,5,6 = 3	ve Group,
life is:			7,8,9 = 2	2008-
In	Q3		10 = 1	2012.
general,				https://w
how			Global	ww.iconq
would			Physical	uerms.org
you rate			Health	/sites/all/
your			Score:	files/attac
physical			Sum	hments/p
health?			responses	dfs/PROM
In	Q4		to 3, 6, 7,	ISGlobalH
general,			8.	ealthScale
how			Fatigue	V1.0-
would			on	1.1.pdf
you rate			average,	
your			pain on	
mental			average,	
health,			extent to	
including			carry out	
your			physical	
mood and			activities,	
your			how	
ability to			would	
think?			you rat	

In general, how would you rate your satisfaction with your social activities and relationships?

Q5

your physical health.

Global Mental Health score:
SUM: 2, 4, 5, 10
How often bothered by

In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)

Q6

emotional problems, rate your mental health, rate your satisfaction, quality of life.

To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair? Q7

5- Completely
4- Mostly
3- Moderately
2- A little
1- Not at all

In the past 7 days:

How often have you been bothered by emotional problems such as feeling anxious, depressed, or irritable? Q8

5- Never
4- Rarely
3- Sometimes
2- Often
1- Always

How would you rate your fatigue on average? Q9

5- None
4- Mild
3- Moderate
2- Severe
1- Very severe

How would you rate your pain on average?	Q10	Answer choices 0 through 10 with anchors on 0, 10: 0- No pain 1 2 3 4 5 6 7 8 9 10- Worst pain imaginable
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Program Evaluation

How would you rate your overall satisfaction with the program?	Q1	Answer choices 1-7 with anchors on 1,7: 1- Not at all satisfied 2 3 4 5 6 7- Very satisfied	NA	NA
If a friend were in need of similar	Q2	1- No, definitely not 2- No, not		

What's the most meaningful thing you've learned or gotten out of this program?

Q3

Participants may enter free text of whatever they choose.

How helpful have the classes been?

Q4

Answer choices 1-7 with anchors on 1,7:
1- don't include them, they were not helpful
2
3
4
5
6
7- you must include them, they were very helpful

Do you have any suggestions about how we can improve the classes? Which were your favorite or least favorite topics?

Q5

Participants may enter free text of whatever they choose.

How helpful were the handouts? How much would you recommend that we include them in the next study?

Q6

Answer choices 1-7 with anchors 1,7:
1- don't include them, they were not helpful
2
3
4
5
6
7- you must include them, they were very helpful

Do you have any suggestions about how we can improve the handouts? Which were your favorite or least favorite topics?

Q7

Participants may enter free text of whatever they choose.

Social Support

How often in the last 30 days has your family or friends

Encourage	Q1	1 =	Average	Norman,
Discuss	Q2	Almost	responses	G. J.,
Remind	Q3	never	of the 6	Carlson, J.
you to		2 = Once	questions.	A., Sallis,
choose		in a while	**NOTE:	J. F.,
healthy		3 =	this just	Wagner,
foods.		Sometime	appears	N., Calfas,
Share	Q4	s	to be how	K. J., &
ideas on		4 = Often	it is in the	Patrick, K.
healthy		5 =	scoring,	(2010).
eating.		Almost	but	Reliability
Eat	Q5	always	doesn't	and
healthy			actually	validity of
meals			say how	brief
with you.			to do it.	psychosoc
Complain	Q6			ial
about				measures
eating				related to
healthy				dietary
foods.				behaviors.

Open Ended Support

<p>Have you gotten any feedback from family, friends, or physicians /healthcare providers about this program or your experience with it? If so, what did they say?</p>	<p>Q1</p>	<p><i>Participants may enter free text of whatever they choose.</i></p>	<p>NA</p>	<p>NA</p>
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Medication Changes

6- month question

<p>Did any of your medications or doses change since starting this program?</p>	<p>Q1</p>	<p>Yes/No</p>
<p>If yes, please specify which medications were changed or added.</p>		<p>Free text</p>

If yes,	Q2	Increased
was the		Decrease
dose		d
increased		I don't
or		know
decreased		
?		

12-month question

Did any of your medications or doses change over the past 6 months program (i.e. maintenance phase)?	Q1	Yes/No
If yes, please specify which medications were changed or added.		Free text
If yes,	Q2	Increased
was the		Decrease
dose		d
increased		I don't
or		know
decreased		
?		

Diet Evaluation

How much do	Q1	Answer choices 1-	NA	NA
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How much do you think this diet has improved your physical health? Q2 7 with anchors 1,7: 1- Not at all 2 3 4 5

How much do you think this diet has Q3 6 7- Very much so

How hard is it to stay on your diet? Q4 Answer choices 1-7 with anchors 1,7: 1- Very easy 2

How often do you cheat on your diet? Q5 Answer choices 1-7 with anchors 1,7: 1- Not at all 2 3 4 5 6 7- Very often

Open Ended Diet

When you Q1
follow
this low-
carbohydr
ate food
plan:
What
about
your
health got
better?

Participa NA NA
nts may
enter free
text of
whatever
they
choose.

When you Q2
follow
this low-
carbohydr
ate food
plan:
What
about
your
health got
worse?

Participa
nts may
enter free
text of
whatever
they
choose.

When you Q3a
follow
this low-
carbohydr
ate food
plan, how
much do
you tend
to pay for
food?

Answer
options 1-
7 with
anchors
given at
1,4,7:

1- Much
less
money
than
before
2
3
4- About
the same
as before
5
6
7- Much
more
money
than
before

Why or Q3b
why not?

*Participa
nts may
enter free
text of
whatever
they
choose.*

Treatment Self-Regulation Questionnaire

There are a variety of reasons why patients may take

Because I Q1
feel that I
want to
take
responsibi
lity for my
own
health.

Answer
options 1-
7 with
anchors
given at
1,4,7:

1- Not

Autonom
ous score:
Average
responses
for items
1, 3, 6, 8,
11, 13.

Williams
et al.
Health-
Care, Self-
Determin
ation
Theory
Questionn

<p>Because I would feel guilty or ashamed of myself if I didn't take steps to prevent diabetes.</p> <p>Because I personally believe it is the best thing for my health.</p> <p>Because others would be upset with me if I didn't take steps to prevent diabetes.</p> <p>I really don't think about it.</p> <p>Because I have carefully thought about it and believe it is very important for many aspects of my life.</p>	<p>Q2</p> <p>Q3</p> <p>Q4</p> <p>Q5</p> <p>Q6</p>	<p>true at all</p> <p>2</p> <p>3</p> <p>4-</p> <p>Somewha</p> <p>t true</p> <p>5</p> <p>6</p> <p>7- Very</p> <p>true</p>	<p>Controlle</p> <p>d score:</p> <p>Average</p> <p>responses</p> <p>for items:</p> <p>2, 4, 7, 9,</p> <p>12, 14.</p> <p>Amotivati</p> <p>on score:</p> <p>Average</p> <p>responses</p> <p>for items</p> <p>5, 10, 15.</p>	<p>aire</p> <p>Packet via</p> <p>selfdeter</p> <p>minationt</p> <p>heory.org</p>
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Because I Q7

would
feel bad
about
myself if I
didn't
take steps
to
prevent
diabetes

Because it Q8

is an
important
choice I
really
want to
make.

Because I Q9

feel
pressure
from
others to
take steps
to
prevent
diabetes

Because it Q10

is easier
to do
what I am
told than
think
about it.

Because it Q11

is
consistent
with my
life goals.

Because I Q12

want
others to
approve
of me.

Because it Q13
is very
important
for being
as healthy
as
possible.

Because I Q14
want
others to
see I can
do it.

I don't Q15
really
know
why.

Physical Activity Questionnaire

Think about all the vigorous activities which take hard

During Q1 *Participa* Scored by Craig et
 the last 7 *nts may* taking the al.
 days, on *enter* sum of Internatio
 how *days per* time nal
 many *week* (hours Physical
 days did *including:* and Activity
 you do 0-7 minutes) Questionn
vigorous 8: Don't and then aire: 12-
 physical Know/Not weighting Country
 activities? Sure values Reliability
 9: according and
 Refused to Validity.
 average 2003.

How Q2 *Participa* MET
 much *nts enter* values for
 time did *values in* vigorous,
 you *two* moderate
 usually *boxes:* and
 spend Hours per walking.
 doing day: Weighted
vigorous Minutes values
 physical per day: summed
 activities to get
 on one of final
 those physical
 days? activity

Now think about activities which take moderate

During Q3 *Participan*
 the last 7 *ts may*
 days, on *enter*
 how *days per*
 many *week*
 days did *including:*
 you do 0-7
moderate 8: Don't
 physical Know/Not
 activities? Sure
 9:
 Refused

How much time did you usually spend doing moderate physical activities on one of those days? Q4 *Participants enter values in two boxes:*
Hours per day:
Minutes per day:

Now think about the time you spent walking in the last

During the last 7 days, on how many days did you walk for at least 10 minutes at a time. Q5 Participants may enter days per week including:
0-7
8: Don't Know/Not Sure
9:
Refused

How much time did you usually spend walking on one of those days? Q6 *Participants enter values in two boxes:*
Hours per day:
Minutes per day:

Now think about the time you spent sitting on week

During the last 7 days, how much time did you usually spend *sitting* on a week day?

Q7

Participants enter values in two boxes:
Hours per day:
Minutes per day:

Fatigue

During the past 7 days...

I feel fatigued I have trouble starting things because I am tired

Q1

1 = Not at all

Q2

2 = A little bit

3 = Somewhat

4 = Quite a bit

Sum of responses for the raw score. Included on PDF is the conversion chart to determine the T-score.

Kemper-Gascon, Global Health and Well-being. The Ohio State University. (See PDF)

In the past 7 days...

How run down did you feel on average?

Q3

5 = Very much

Q4

Sleep Disturbance

In the

My sleep quality was

Q1

5 = Very poor

4 = Poor

3 = Fair

2 = Good

1 = Very good

Sum of responses for the raw score. Included on PDF is the conversion chart to determine the T-score.

Kemper-Gascon, Global Health and Well-being. The Ohio State University. (See PDF)

In the

My sleep was refreshing

Q2

5 = Not at all

4 = A little bit

3 = Somewhat

1 = Not at all

Q3

1 = Not at all

I had difficulty falling asleep

Q4

all e the T-
2 = A little score.
bit
3 =

Demographics

Do you have any significant medical diagnosis, surgery, hospitalizations, or other major health issue? If so, please describe.

Q1

Participants may enter free text of whatever they choose.

NA NA

Do you take metformin for your diabetes? (It's also called Glucophage, Glumetza, and Fortamet. If so, how much (total) do you take per day? For example, you might take 500 or 2,000mg a day.

Q2

Participants may enter free text of whatever they choose.

What other Over the past 7 days, how many cigarettes have you smoked per day on average?

Q3

Q4

Participants may enter free text of whatever they choose.

What is the highest level of formal education you have completed? Q5
Some high school
High school graduate
Some college
College graduate
Some post-college education
Master's degree
PhD degree

What is How long have you had type 2 diabetes, in years? Q6 Q7
Single, *Sliding scale from 0-50 years with anchors every 5 years.*

What is yo How old ar Q8 Q9
Text box w
18-25
26-35

What is yo Q10
Participant

What is yo Q11
Participant

What is yo Q12
Male

Are you Hi: Q13
Yes

No

What is your race or ethnic background? Check ALL that apply. Q14

White
Black or African American
American Indian or Alaska Native
Asian
Native Hawaiian or Pacific Islander
Other
Prefer not to answer

What is the highest grade completed? Q15

8th grade or less
Some high school but did not graduate
High school graduate or GED
Some college or a 2-year degree
4-year college graduate
More than 4-year college degree
Prefer not to answer

What is	Q16	Less than
your		\$10,000
annual		\$10,000-
total		\$19,999
househol		\$20,000-
d income		\$29,999
from all		\$30,000-
sources		\$39,999
before		\$40,000-
taxes?		\$49,999
		\$50,000-
		\$59,999
		\$60,000-
		≤60 000

Treatment Self-Regulation

Questionnaire

There are a variety of reasons why patients may take steps to prevent diabetes. Please consider the following behaviors and indicate how true each of these reasons is for you. The reason I would take steps to prevent diabetes is:

- Because I feel that I want to take responsibility for my own health. Q1
- Because I would feel guilty or ashamed of myself if I didn't take steps to prevent diabetes. Q2
- Because I personally believe it is the best thing for my health. Q3
- Because others would be upset with me if I didn't take steps to prevent diabetes. Q4
- I really don't think about it. Q5

Answer

options 1- Autonomous
7 with score:
anchors Average
given at responses for
1,4,7: items 1, 3, 6, 8,
11, 13. Williams
1- Not et al.
true at all Controlled score: Health-
2 Average Care, Self-
3 responses for Determin
4- items: 2, 4, 7, 9, ation
Somewha 12, 14. Theory
t true Questionn
5 Amotivation aire
6 score: Packet via
7- Very Average selfdeter
true responses for minationt
items 5, 10, 15. heory.org

Because I have carefully thought about it and believe it is very important for many aspects of my life. Q6

Because I would feel bad about myself if I didn't take steps to prevent diabetes Q7

Because it is an important choice I really want to make. Q8

Because I feel pressure from others to take steps to prevent diabetes Q9

Because it is easier to do what I am told than think about it. Q10

Because it is consistent with my life goals. Q11

Because I want others to approve of me. Q12

Because it is very important for being as healthy as possible. Q13

Because I want others to see I can do it. Q14

I don't really know why. Q15