The How Can I Help "Chore" List: Learning Through the Lens of a Clinical Research Specialist

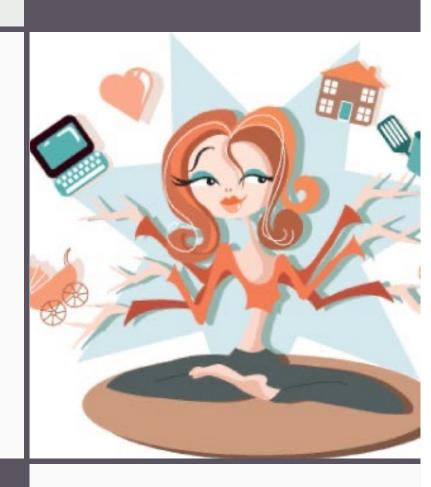
Carin Clingan, MS, CNS, LDN

### **About me**

- B.S. in Exercise Science (2 Minors in Coaching and Sports Studies)
- M.S in Clinical Nutrition
- 4 children (17 yr old son, 15 yr old triplet girls)
- Former HS and Collegiate swimmer and track athlete
- Competed in fitness competitions for 10 years
- Worked as a lifeguard and in fitness centers
- Have my own Nutrition and Personal training company
- Track & Field Coach (Club and HS)
- Clinical Nutrition Research Specialist



# DAY IN THE LIFE OF ME...



## MORNINGS= ME TIME... FOR 30 MIN

Wake up at 6a

Surf Facebook

Then coffee!





### At work

- Check/ respond to emails
- Look at my weekly to do list
- See potential participants
- Mail equipment
- · Nutrition assessments if scheduled
- Check in calls with participants
  - Check for hospitalizations or visits to ED

### Long-term goal:

 Address persistent cancer-related fatigue using nutritional approaches

### Time-restricted eating:

 Consuming food and beverages within a defined eating window every day, for example 10 hours

Supportive Care in Cancer (2025) 33:353 https://doi.org/10.1007/s00520-025-09394-w

#### RESEARCH

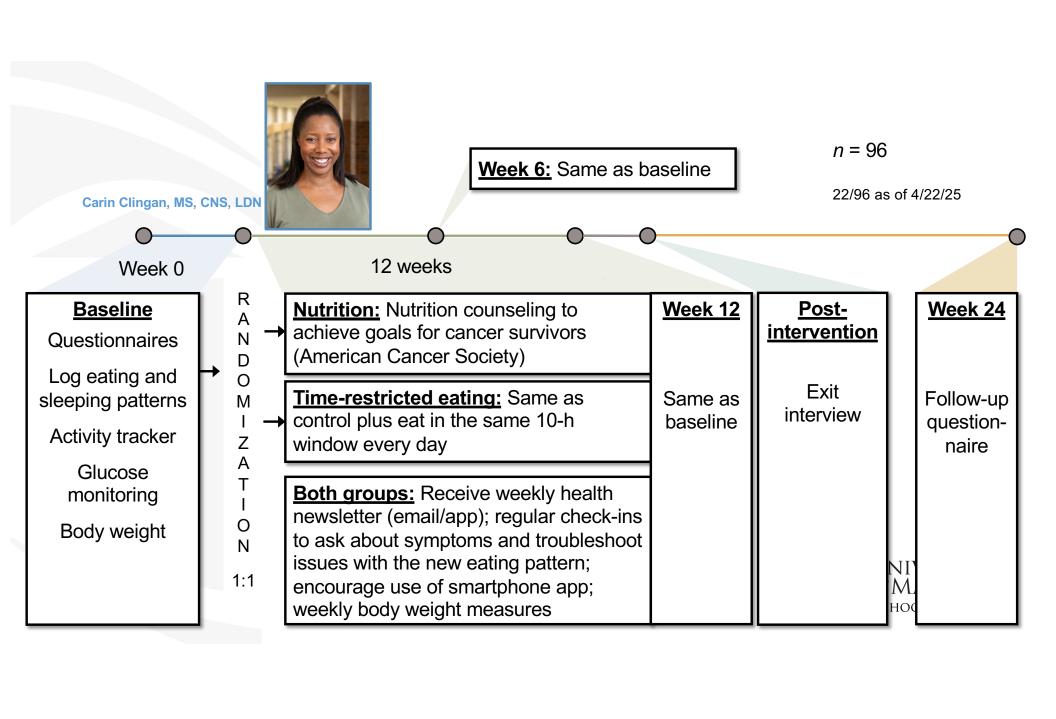
Time-restricted eating to address persistent cancer-related fatigue among cancer survivors: a randomized controlled trial

Amber S. Kleckner <sup>1,2</sup> · Carin L. Clingan <sup>1</sup> · Shari M. Youngblood <sup>1,3</sup> · Ian R. Kleckner <sup>1,2</sup> · Lauren Quick <sup>1,4</sup> · Rebecca D. Elrod <sup>1</sup> · Shijun Zhu <sup>5</sup> · Emily N. C. Manoogian <sup>6</sup> · Satchidananda Panda <sup>6</sup> · Ashraf Z. Badros <sup>2,7</sup> · Ashkan Emadi <sup>2,7,8</sup>



PMID: 40186671





TIL25- WLID ( Check m) & already member strong ATR35-ukid (checkin) send quest. TTR 30- ext whenever TTR 35 excl wherew? TTR 310- WK 11 (send egrup) TTR37- WG TTR 38 - We ID Laudin ATP 43 - We be (check in) send grest. TTP 44 - WES (send egres) TTR 39 - WC 10 ( checken) TR42 WL7 TTR 43- WE 7 TTR 44- We le (checkin) sund grestions TTRUS- WC3 TTR 47- boschni; random expet 11-70 2p TR 48- baschni; random appt. 11-7@10a TTR45- Uk 4 (check m) TTRUT- MLI TTR48- WK) My checklist - replace int in pen - Blood Borne pathogens training - next ule - look who ways to dierease water retention chambea for 7 cheek is on Thrisday

Participant ID: TTR007	_	carin.clingan@umaryland.edu									
		410.706.7786									
After consent checklist	Dates		Adverse eve								
10.22CC Update screening log	Baseline dates	10/22-10/28/25			unexpected events sh					OSMB) in an expec	lited manner.
10.22CC Send questionnaires			Grade 4 or 5	5 events r	egardless of attributio	n should be r	eported to the	RSRB at each cor	ntinuing review.		
11.6CC Add to OnCore	Week 1	11/3/2025									
10.22CC Write PtID on paper consent (if applicable) and file	Week 2	11/10/2025	Greater tha	n 5% char	ige in body weight in t	wo weeks is	considered an a	dverse event			
10.22CC Add pt in Regulatory binder	Week 3	11/17/2025									
10.22CC Email pt with appt details to go over study packet	Week 4	11/24/2025									
10.22CC Update shipping log	Week 5	12/1/2025									
	Week 6	12/8/2025									
	Week 7	12/15/2025	Payments		Date	Co	ompensation Tr	acking Form	Study Payme	ent Log	
	Week 8	12/22/2025		Baseline							
	Week 9	12/29/2025		Neek 6							
	Week 10	1/5/2026	V	Neek 12							
	Week 11	1/12/2026									
	Week 12	1/19/2026									
	Week24										
Calendar of events											
Baseline appointment (asap after consent)											
Ask participant to:											
10.22CC Log into myCircadianClock and log food for 7 days, with a	n emphasis on first an	d last calorie									
10.22CC Wear the pedometer for 7 days											
10.22CC Wear the glucose monitor for 7 days											
10.22CC Complete online questionnaires											
10.22CC Log body weight in myCircadianClock				_		_					
10.22CC Schedule intervention delivery appt 10.30@ 11a				<b>7</b> /					$\Lambda$ $\Lambda$		
					۱R			ı			
Before randomization/intervention delivery appointment					711				$\frown$		
10.30CC Ensure questionnaires are complete before intervention	s delivered		-	-	~ 1 ~	-	<u> </u>	'			
10.30CC Ensure food entries have been logged in MCC											
10.30CC Randomize in REDCap											
Randomization/intervention delivery appointment				<b>\</b> I	HE			T	<b>\</b>		
10.30CC Ask participant to mail back pedometer, glucose reader a	and charger			L							
10.30CC Ask participant to continue to get weekly body weight me							<b>^</b>				
10.30CC Deliver intervention				_			<b>\</b> L		J		
				_							

## OTHER DOCUMENTS- COMM LOG, SHIPPING LOG, NUTRITION ASSESSMENT

1	PtID	Assessment	Date shipped	Actigraph No.	Glucose Monitor	Last 4 digits	Date Returned	Notes
2	TTR01	Baseline	11.4.24	13286	JLGC089-K0002	7492	12.5.24	
3	TTR02	Baseline	11.7.24	13215	JFGX020-K0205	7829	11.18.24	
4	TTR03	Baseline	11.12.24	13214	JLGC089-K0102	7850	12.5.24	
5	TTR04	Baseline	11.18.24	6955	JLGC089-K0619	5543	It was returned-	date unknown
6	TTR02	Week 6	12.18.24	14735	JLGC089-K0121	6685	1.2.25	
7	TTR01	Week 6	1.2.25	16249	JLGC089-K0019	4225	1.23.25	
8	TTR03	Week 6	1.2.25	16248	JLGC089-K0102	7949	7.8.25	**watch was not returned as of 10.3- he can't find
9	TTR05	Baseline	1.13.25	16247	JLGC089-K0619	7867	2.5.25	
10	TTR06	Baseline	1.28.25	10877	JFGX020-K0205	6678	2.5.25	
11	TTR02	week 12	1.29.25	14734	JLGC089-K0019	9394	2.13.25	
12	TTR07	Baseline	1.30.25	16245	JLGC089-K0263	7874	2.13.25	
13	TTR01	week12	2.12.25	10877	JFGX020-K0205	3505	2.27.25	
14	TTR08	Baseline	2.18.25	16245	JLGC089-K0643	7843	3.20.25	
15	TTR09	Baseline	2.19.25	16249	JFGX020-K0081	7836	3.11.25	
16	TTR10	Baseline	2.25.25	16246	JLGC089-K0263	5288	4.17.25	
17	TTR11	Baseline	2.26.25	16250	JLGC089-K0019	6178	3.13.25	
18	TTR12	Baseline	3.4.25	16135	JLGC089-K0619	6208	3.24.25	
19	TTR05	Week 6	3.4.25	10877	JFGX020-K0205	4680	3.20.25	
20	TTR13	Baseline	3.5.25	16634	JFGX020-K0325	6185	3.24.25	
21	TTR14	Baseline	3.5.25	16508	N/A	6215	3.25.25	
22	TTR15	Baseline	3.5.25	12237	JLGC089-K0002	6169	3.24.25	
23	TTR16	Baseline	3.5.25	16530	JLGC089-K0121	6138	3.18.25	
24	TTR06	Week 6	3.11.25	13215	JLGC089-K1034	6678	4.4.25	
25	TTR17	Baseline	3.18.25	16537	JLGC089-K1874	6145	10.9.25	box not returned
26	TTR07	Week 6	3.18.25	16250	JLGC089-K0019	4837	4.4.25	
27	TTR18	Baseline	3.20.25	16251	JFGX020-K0195	6152	10.13.25	box not used
28	TTR19	Baseline	3.25.25	16634	JLGC089-K0624	4055	5.5.25	did not return charging cable or wall plug-in
29	TTR20	Baseline	3.37.25	10877	JFGX020-K0205	9349	5.5.25	
30	TTR09	Week 6	4.1.25	14734	JLGC089-K0698	7788	4.17.25	
31	TTR05	week 12	4.15.25	16135	JLGC089-K0564	1708	5.15.25	
32	TTR11	Week 6	4.15.25	16250	JLGC089-K0526	1715	5.9.25	
33	TTR13	Week 6	4.15.25	16635	JFGX020-K0081	1739	5.7.25	no new data

Tarto-park 121
Date of meeting:
Interventionalist:
Clinical Nutrition Take The Reins (TTR) Study Visit
Nutrition Assessment
Nutrition Issues:
Recent Oral Intake:
Vitamins/Minerals/Herbal Supplements:
Food Allergies
Physical:
Usual Body Weight:
Body Mass Index (BMI):
TEE:
Protein Intake:
Lab Data:
Nutrition Intervention:
Nutrition Goals:



### WHAT'S A REPORTABLE EVENT?

A reportable event is a situation that happens outside of the of the protocol description. There are Adverse Events, Protocol Deviations and Reportable New Information.

# EXAMPLES OF REPORTABLE EVENTS

#### Participant Adverse Event Form

Protocol Title: Take the Reins: The effects of nutrient timing on cancer-related fatigue				
IRB/Protocol #: HP-00110284	Principal Investigator: Amber Kleckner, PhD			
Subject #:	Subject Initials:			

Severity	Relationship	Action Taken	Outcome
1-Mild	1 - Unrelated	1 - None	1 - Resolved/Returned to Baseline
2 – Moderate	2 - Unlikely	2 - Medication	2 - Continuing
3 – Severe	3 – Possible	3 - Procedure	3 - Death
4 - Life Threatening/Disabling	4 - Probable	4 – Study Intervention Changed	
5 - Death	5 - Definite	5 - Study Intervention Stopped	
		6 - Hospitalization	
		7 – Other	

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome	Expected (Yes or No)	Serious (Yes or No)	Date Study Team	PI Initials / Date
									Aware	

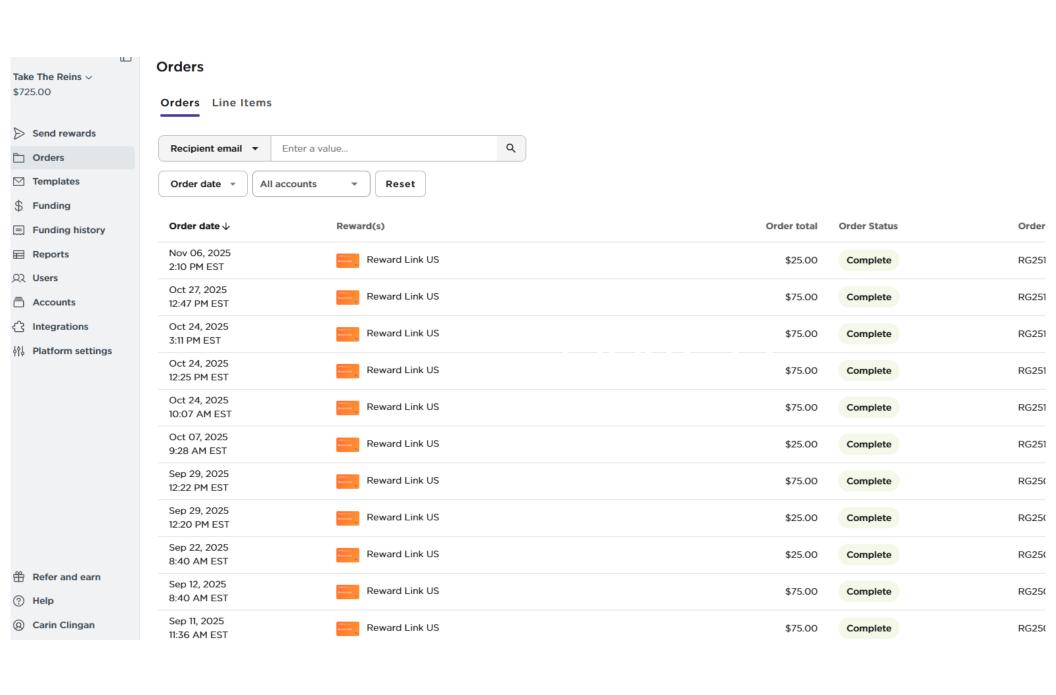
Attention! Review IRB Reportable New Information (RNI) sheet for reporting requirements

### Protocol Deviation Tracking Log

	Protocol ID/Number: HP-00110284  Protocol Title (Abbreviated): Take the Reins: The effects of nutrient timing on		Site Name/Number:						
Protoc	OI TITIE (AD	breviated):	cancer-relate	_					
Princip	pal Investiga	ator:	Amber Kleck	ner, PhD	Page nu	mber [1]:			
Ref No.	Subject ID	Date of Deviation	Date Identified	Deviation Description	Dev. Type [2]	Resulted in AE?	Did Subject Continue in Study?	Meets IRB Reporting Req. (Yes/No)	IRB Reporting Date
1	TTR14	3.21.25	3.21.25	Does not want to do glucose monitor	E	No	Υ	N	
2	TTR07	5.2.25	5.2.25	Didn't wear the glucose monitor for week 12	E	No	Υ	N	
3									
4									
5									
6									
7									

REPORTABLE NEW INFORMATION			nation TRACKING LOG	
INIORMATION	IRB/Protocol #: HP-0011		Investigator: Amber Kleckner,	
	RNI#	Date RNI event occurred	Date RNI submitted to IRB	Re-consent Required?





## Advice for a junior coordinator

Show up and be present

Take initiative

Organize/ prioritize (checklist??)

## GOALS FOR MY POSITION:

Build a primer

SOPs

Take some items off my PI's to do list

Meet with other coordinators to see how they do things

Listen to participant feedback and implement wherever possible



#### Checklist

- ☐Put watch on for 7 days (it does not light up or turn on)
- ☐Wear glucose sensor for 7 days and sync to reader every 8 hours
- ☐Fill out food log for 7 days
- ☐Weigh yourself once a week
- ☐ Fill out questionnaires

## **Examples of participant feedback**

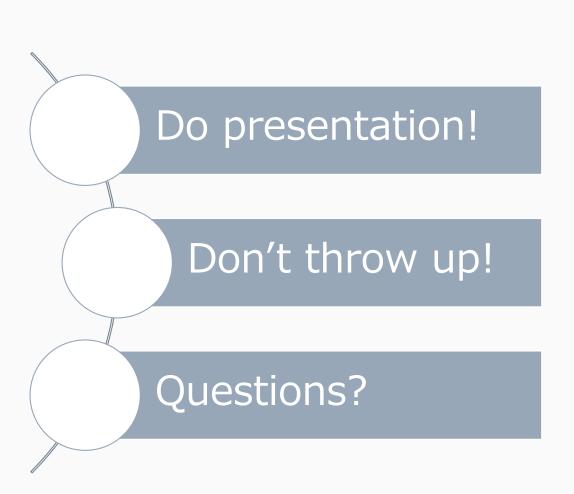
Reminder phone calls before nutrition appt.

Ask participants how the want check in calls done (call, text, email, or zoom)

## Final tips & takeaways-What I still need to learn

- · Become more of an expert in my position
- Supervise interns and other coordinators
- Create the REDcap database for future studies
- TBD

Checklist complete?



THANK YOU	Carin Clingan 410-706-7786 Carin.Clingan@umaryland.edu