

(FS)²

Framingham State
Food Study

WORKGROUPS MEETING

Wednesday, August 31, 2016

Alumni Room, McCarthy Campus Center



Framingham
State University



new balance FOUNDATION
Obesity Prevention Center
Boston Children's Hospital

Agenda

Greetings from the University	Dr. Vaden Goad
Introduction of (FS) ² Team from Assabet Valley	Dr. Luoto
Screening and Enrollment Updates	Ms. Klein
Study Marketing	
Ancillary Studies Enrollment	Dr. Wong
Assessment Metrics	
Intervention Metrics	Ms. Bielak
Intervention Updates	
Participant Exit Survey from Cohorts 1 and 2	Dr. Luoto
Benefits to the University	
Timeline	Dr. Ebbeling

Enrollment: C1 and C2

	Cohort 1	Cohort 2
Telephone Screening	250	422
Information Visit	89	129
Screening Visit (<i>Screening Consent</i>)	61	104
Baseline Assessment (<i>Informed Consent</i>)	43	75
Started Intervention	42	73
Post-Weight Loss Assessment	26	57
Randomized	26	57
Week 10 Assessment	25	52
Week 20 Assessment	25	51

Enrollment: C3

	C3-FSU	C3-AV
Telephone Screening	723	286
Information Visit	216	78
Screening Visit (<i>Screening Consent</i>)	156	54
Baseline Assessment (<i>Informed Consent</i>)	85	31
Started Intervention	35	-
Post-Weight Loss Assessment	-	-
Randomized	-	-
Week 10 Assessment	-	-
Week 20 Assessment	-	-

Screening and Enrollment Totals

Work Completed through August 25, 2016

	TOTAL
Telephone Screening	1681
Information Visit	512
Screening Visit (<i>Screening Consent</i>)	375
Baseline Assessment (<i>Informed Consent</i>)	234

Role: C3

	C3-FSU	C3-AV
	n=85	n=31
Faculty member	0	7
Staff member	13	1
Student	15	N/A
Community member	57	23

Study Withdrawals

COHORT 1

- 18/43 (42%) consented participants failed to complete protocol
- 17/18 (94%) were students
- 1 withdrawal occurred after randomization

COHORT 2

- 24/75 (32%) consented participants failed to complete protocol
- 14/24 (58%) were students; 6 (25%) community members; 4 (17%) Fac/Staff
- 6 withdrawals occurred after randomization

COHORT 3

- 2 withdrawals to date. Both community members
- More withdrawals to come...

Study Marketing

- How did we complete recruitment?
 - We consulted with experts & heeded their advice
 - We embraced new strategies
 - We expanded our recruitment area
 - We called on corporate & community partners
 - We benefitted from a strong referral base



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fs2foodstudy.org

Study Marketing: Recruitment Source



Study Marketing

- What did we learn?
 - Marketing is not for the faint of heart
 - Create a public Web site
 - Identify experts and listen to them
 - Increase your marketing budget and be prepared to add more money
 - Use strategies in parallel and track results for decision-making
 - Social media is a powerful marketing tool; especially in combination with other strategies
 - Revise the marketing plan and then revise it again

Ancillary Study Participation

PROTOCOL	C1	C2	C3
Metabolic Fuels (Shams)	9	21	N/A
Cognitive Function (Remington) /Psychology (Hourigan)	31	54	99
Lipoprotein (Knapp/Johnson)	43	75	116
Microbiome (Hron)	16	29	65
Genomics (BCH)	33	44	99
Functional MRI (Holsen)	11	27	TBD
Attitudes of Body Weight (Gorman/Sachs)	--	--	102

n=reflects the number of subjects providing consent for each ancillary study, not those completing all protocol requirements

Assessment Metrics

Biospecimen Samples Stored at BCH – C1 and C2

	Cohort 1	Cohort 2	TOTAL
Main Study			
Blood*	7120	13658	20778
Urine	2880	5457	8337
Ancillary Studies			
Microbiome	310	1351	1661
Metabolic Fuels**	1656	4234	5890
Total Samples	11,966	24,700	36,666

*Total includes Lipoprotein Ancillary Study sample

**Total includes plasma only. Fat cell aspiration samples are stored at BMC

Assessment Metrics

Participants Entering each Assessment Period				
	C1	C2	C3	TOTAL
Baseline Assessment (<i>Informed Consent</i>)	43	75	116	234
Post-Weight Loss Assessment	26	57	-	83
Randomization	26	57	-	83
Week 10 Assessment	25	52	-	77
Week 20 Assessment	25	51	-	76

Assessment Metrics

C1 Visits Completed

- N=1097 Study Visits Completed/1108 Study Visits Expected (99.0% visit completion)

C2 Visits Completed

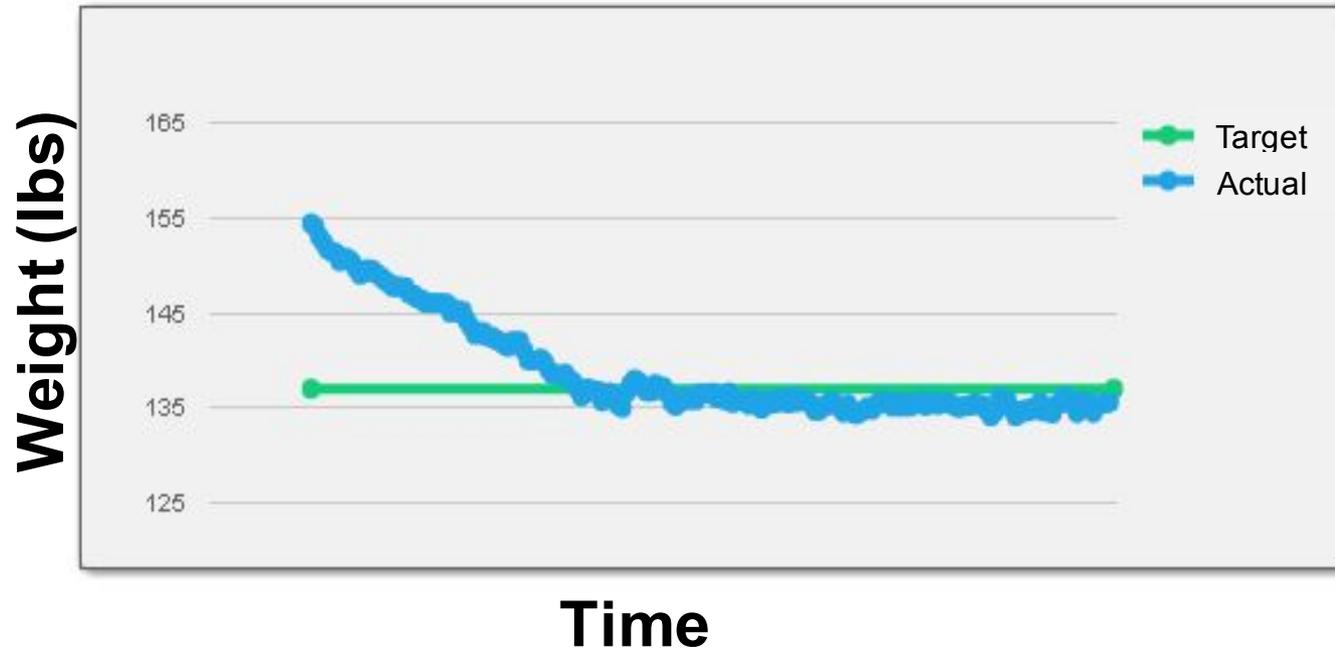
- N=2275 Study Visits Completed/2292 Study Visits Expected (99.3% visit completion)



Intervention Metrics

(FS)² Portal Compliance – Cohort 2

Daily Survey	91%
Daily Food Tracking (Meal Log)	83%
Daily Weight	97%



Intervention Metrics

End-of-Trial Dietary Counseling Appointments

	Initial Visit	Follow-up Visit #1	Follow-up Visit #2
C1 (N=25)	18	--	--
C2 (N=51)	29	19	12

n = number of subjects completing each Counseling Visit

Intervention Metrics

Number of Meals/Snacks Served in Cohorts 1 and 2

	Cohort 1	Cohort 2	TOTAL
Meals	19320	39984	59304
Snacks	6440	13328	19768
TOTALS	25,760	53,312	79,072



Intervention Updates

FSU Updates

- Wave A up and running
- FS2K Staffing
- Support – workshops and office hours

Intervention Updates

AV Updates

- Starts with Wave B on 9/14
- Site is ready
- Production Manager – Dina Wiroll
- FS2K @ AV Staffing
- Support - workshops

(FS)² Kitchen at AV



(FS)² Exit Survey

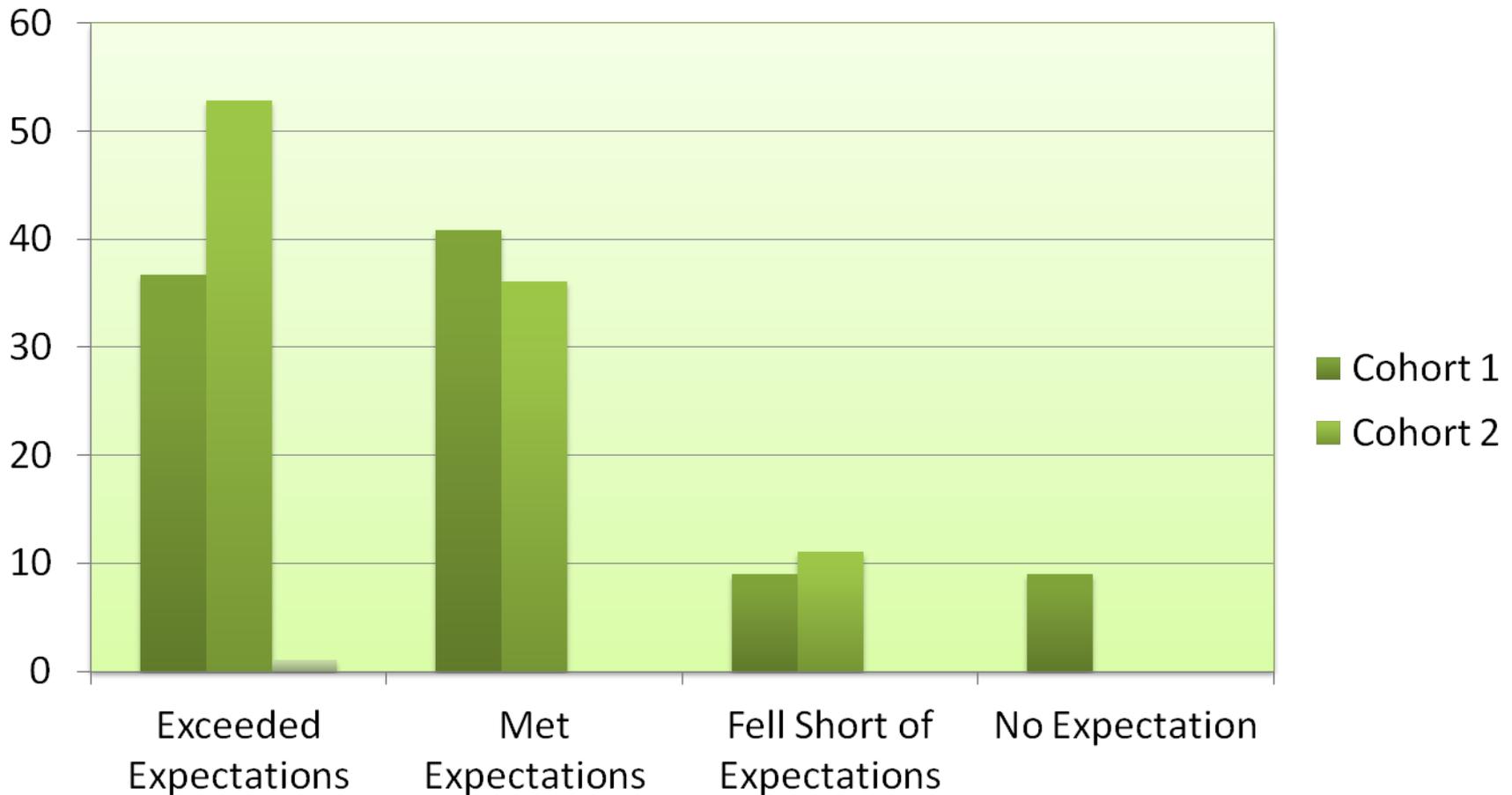
- Cohort 1:
 - Conducted surveys at mid-point and study end
 - Used survey tool in Blackboard with multiple reminders
- Cohort 2:
 - Conducted exit survey (only)
 - Distributed via Portal with multiple reminders
- All surveys were anonymous
- Results reviewed with research staff

(FS)² Exit Survey

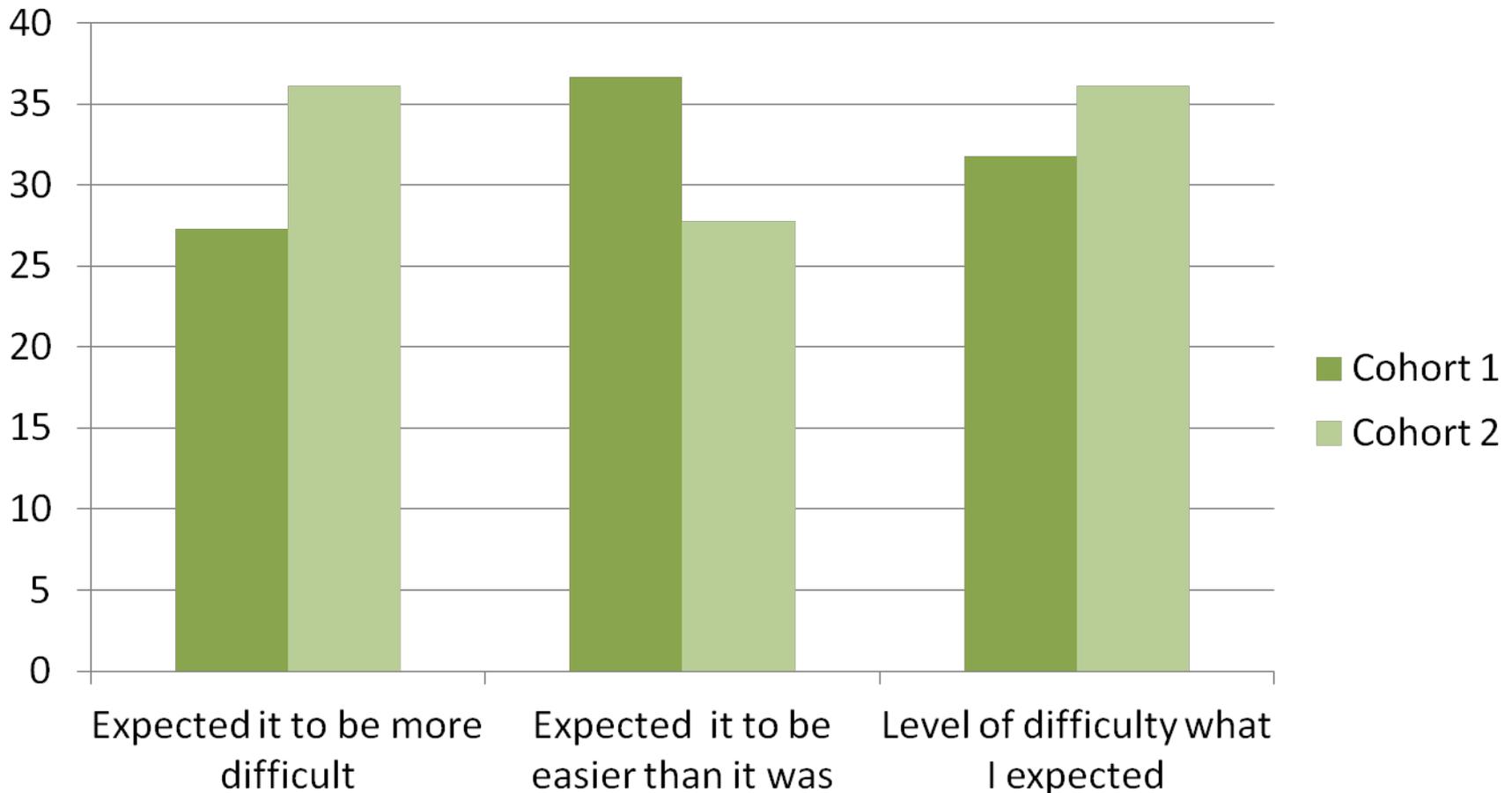
- **Cohort 1:** 22/25 (88%) participants completing the study responded to the Exit Survey
- **Cohort 2:** 36/51 (71%) participants completing the study responded to the Exit Survey



Compared to my original expectations, the Framingham State Food Study



Which of the following best describes the reality of being a participant?



eat well

ADVANCE SCIENCE

What did C1 participants say?

I have a greater interest and understanding of my eating habits.

I lost my ideal amount of weight and I feel great!

Not having to think about my next meal or preparing it, it's all set and ready to go!

...an added bonus I did not expect was getting to know the other people in the cohort and bonding over this. That's been nice.

Working with the (FS)² staff. They have ALL been wonderful to work with.

I feel like I am contributing to science, and that's why I try and do all extra studies to give you as complete a set of data [as] I can before I am no longer a participant.

I get to have meals prepared everyday by a professional chef, something that is very hard to get. I am being paid to lose weight and then maintain that loss.

What did C2
participants say?

Most of the food was excellent! Would love for recipes to be made available.

Had a great experience and would happily do it all over again.

I wish to share my appreciation to the staff. Everyone was always approachable and helpful.

It was quite challenging but I enjoyed every bit of it and I lost a lot of weight as well.

More off-hours and weekends would have been helpful [for assessments].

This was a great program – couldn't have lost weight without it. [I] feel a year younger for every pound lost.

Given what you [had] to accomplish—I thought the entire team and process was first rate.

(FS)² Exit Survey

- What did we learn?
 - Assessments/scheduling were challenging
 - Individual and group support are a must
 - Developing a sense of camaraderie
 - Meal logs: moved from manual to automated but still presents problems
 - C-1 suggestions  menu revisions
 - C-1 daily weight checks were a challenge;
 C-2 wireless scales and portal

(FS)² Exit Survey Action Items

- Action Items from research team's discussion
 - Opening 1 weekend day and holidays to help with scheduling
 - Add master schedule to portal
 - Individual RD counseling/support throughout and at end of study. Additional support for transition time from weight loss to maintenance.
 - Extend deadline of electronic meal logs through Monday midnight
 - Add special meal in April to reduce monotony
 - Add customer service training for NRAs

WIIF—FSU?

- Community based research study on our campus to answer elusive question of weight loss maintenance
- Employing
 - 12 SRAs
 - 10 student nurses (3 grads)
 - 40 NRAs
- (FS)² Research House
- \$12M grant; about \$280K allocated back to FSU
- 3 ancillary grants; total of 7 faculty involved

(FS)² Staffing during Cohort 2

Study Center	#FTEs	# Personnel
Boston Children's Hospital	13.7	20
Framingham State University*	5.5	36
Sodexo Dining Services†	18.15	50
TOTALS	37.35	106

* FSU Personnel includes Student Research Assistants (n=18) and Student Nurses (n=16)
† Sodexo Personnel includes Nutrition Research Assistants (n=42)

Timeline

Main Study

Ancillary Studies (FSU Faculty)

	Specimens	Data	
May 2017	<ul style="list-style-type: none"> Complete data collection Ship specimens to Baylor 	<ul style="list-style-type: none"> Ongoing quality control 	
June 2017	<ul style="list-style-type: none"> Transfer specimens from Biorepository to Lab 		
July 2017		<ul style="list-style-type: none"> Study close-out Data management 	<ul style="list-style-type: none"> Transfer specimens to LipoScience
August 2017			<ul style="list-style-type: none"> Receive data from LipoScience
September 2017	<ul style="list-style-type: none"> Receive DLW data from Baylor (primary outcome) 		
October 2017	<ul style="list-style-type: none"> Receive data from Lab (secondary outcomes) 	<ul style="list-style-type: none"> Data analysis Manuscript preparation 	<ul style="list-style-type: none"> Planning meetings Data management (Fall 2017)
November 2017			
December 2017			
January 2018		<ul style="list-style-type: none"> Primary results manuscript to NuSI 	<ul style="list-style-type: none"> Begin data analysis and manuscript preparation (Spring 2018)