



eat well. advance science.

Participant Support Protocol

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Face-to-face Support Group Schedule & Objectives

1. **Aug/Sept:** Group cohesion
 - a. Set the tone: we are in this together, and FS2 wants you to be a success
- How can we help? How can you help each other?
 - b. Introductions, starting with group leader
 - c. No pressure sharing-big picture
 - i. Your goals/reasons for participating/worries/anticipated obstacles

Identifying immediate challenges

Survey for future meeting topics (#5 & 7) (Bb anonymous survey)

Consider introducing the CBT Triangle as a conceptual tool to help participants organize their efforts

First Week (Start) of Run-In Phase (usually September): Group Cohesion

- ii. Set the tone
 - We are “in this” together.
 - The (FS)² team wants to support you in losing weight and maintaining weight loss. How can we help?
 - How can you help each other?
 - iii. Introductions, starting with group leader.
 1. “No pressure” sharing regarding “big picture” topics
 - Goals and/or reasons for participating
 - Concerns, immediate challenges, and anticipated obstacles
 - iii. Introduce CBT Triangle as a conceptual tool to assist participants in organizing their efforts.
 - iv. Introduce anonymous survey conducted via Bb to obtain input on topics for future support group sessions (i.e., Sessions 5 and 7)
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2. **Sept.:** Mindful eating
 - Participants will be able to identify location, pace, and distractions surrounding meal times.
 - Participants will be able to complete a mindful eating exercise.
- Importance of good data in the study
- Participants will identify at least 2 reasons it is important to report accurate data, honestly, at the prescribed times.

The intent is three-fold: 1) asking participants to identify 2 reasons may promote commitment 2) this type of group activity can also bring to the surface any questions, misunderstandings, hesitancy and the like. This can then be discussed and sorted out. 3) this kind of group activity may help promote group cohesion. To help fulfill these objectives the group leader may want to consider framing the discussion as a conversational exchange of ideas

rather than as a kind of quiz. If there is a large number of people at such a meeting it may also be advisable to break into small groups first, then have the small groups report out to the whole group, workshop style.

3. **Sept/Oct.:** Mobilizing problem solving to meet *immediate needs*, and *anticipating challenges*. At this point it will be worth starting a discussion about the transition from weight loss to maintenance. This transition may be jarring for some participants, and anticipating it may soften any jolt. Similarly, it may be a good opportunity to begin talking about the holidays: Halloween, Thanksgiving, Christmas. The objective is to invite anticipatory problem solving.
4. **Oct.:** Self-monitoring
Visit from last year's participants: continued support for transition into the maintenance phase.
5. **Nov.:** Group selected topic / Process group: Very short pep talk by leader followed by open discussion
6. **Dec.:** Mobilizing problem solving to meet immediate needs
 - Preparing for the holidays / vacationsVisit from last year's participants: staying motivated during the maintenance phase –thinking ahead to the end of the study
7. **Jan.:** Group selected topic / Process group: Very short pep talk by leader followed by open discussion. How was the break? What were the biggest victories and challenges? What solutions were tried?
8. **Feb.:** Mindful eating re-visited: Practice makes perfect
9. **March:** Reading labels (using *up-to-date* food label)
 - Participants will learn label reading by bring two labels from food items they typically eat to share with the group.
 - Participants will be able to rank order food items based on the food labels (lowest fat to highest fat content)Farm or Factory
 - Participants will be able to use the food label to identify Farm vs. Factory of ingredients (e.g. Wheat thins vs. Triscuits)Go-Slow-Whoa
 - Participants will be able to identify 2 foods each for the go, slow, and whoa categories of foods.
(http://kidshealth.org/kid/stay_healthy/food/go_slow_whoa.html#)

10. **March:** Process group, anticipating the transition from the study. Concerns?

11. **April:** Transitioning back to making your own food choices

- Participants will identify on a scale of 1-10 how confident they are in their ability to make their own food choices after the study. (MI)

Recipe substitutions

- Participants will be able to identify at least 3 healthier ingredients that may be substituted for less healthy ingredients in some of their favorite recipes.

Knowing portion sizes

- Participants will be able to state common portion sizes associated with one food from each food group.

Supplemental topic suggestion(s) if needed:

Calorie & macronutrient breakdown of wt maintenance phase diets

- Participants will be able to describe the nutritional content and value of macronutrients in the weight maintenance phase diets.
- Participants will identify at least 2 healthful foods they are receiving in their meals that they had not tried before.
- Participants will use measuring tools (cups and spoons) to estimate portion sizes of foods provided.

Blackboard Collaborate



Blackboard (Bb) Collaborate can be used to provide recorded sessions or provide live group discussions.

Recorded Sessions: Not all participants may be able to attend in-person support sessions. A modified version of support sessions may be provided utilizing Bb Collaborate. A specific topic/speaker can utilize this method to record face and/or voice, display document files, etc. and record desired content for participants to access at a later date and time that is more convenient.

Live group discussions: Bb Collaborate allows for live group discussions as well. The same feature permits multiple participants to join in with the moderator of the session for live discussion and feedback. This online version of group chat may also be used to have a one-on-one live conversation with an individual participant as well. This method of communication can be especially helpful for those living at a distance from campus.

The screenshot shows a Blackboard Collaborate session window titled "OBESITY WEIGHT MANAGEMENT ROOM". On the left, there is a video feed of a woman named Andrea Gorman, who is the moderator. Below the video feed are controls for audio and video, and a list of participants. The main area of the window displays a presentation slide titled "Personalized Fitness & Nutrition Goals". The slide contains the following text:

The user inserts personal data (sex, height, weight, activity level) and goal weight. It then tells the user how many calories one should aim for per day in order to reach the goal.

The slide also features a "myfitnesspal" logo and a "Account Created!" message. Below this, there is a table of suggested fitness and nutrition goals:

Nutritional Goals		Target
Net Calories Consumed* / Day		1,230 Calories / Day
Carbs / Day		168.0 g
Fat / Day		21.0 g
Protein / Day		62.0 g

*Net calories consumed = total calories consumed - exercise calories burned. So the more you exercise, the more you can eat!

Fitness Goals		Target
Calories Burned / Week		420 Calories / Week
Workouts / Week		2 workouts
Minutes / Workout		30 minutes

If you follow this plan...
Your projected weight loss is 1 lb/week
You should lose 5 lbs by July 6

Technology resources and documentation are listed on this hyperlink. Contact the Education Technology and Interactive Media Office team by email at eto@framingham.edu or call 508-626-4927 if you are interested in using any of the education tools or are experiencing a technical problem.
<http://elearning.fscmedia.com/faculty-2/technology-and-resources/#blackboardcollaborate>



Atomic Learning

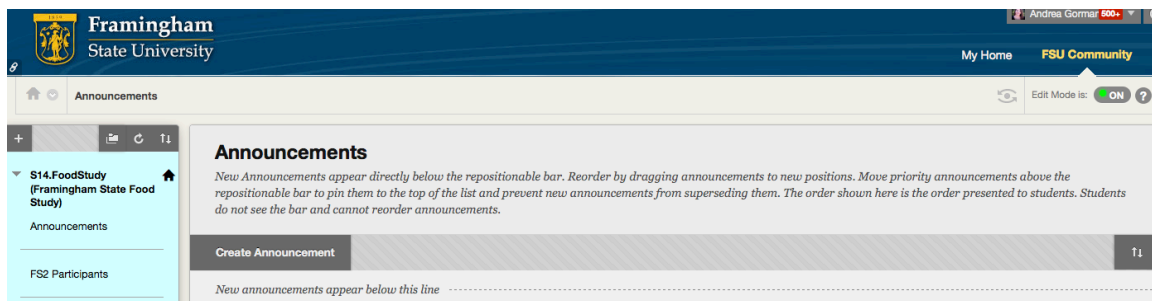
Atomic Learning on-demand video tutorials provide access to over 130 common applications and technology resources including Blackboard Learn, Windows 7, Podcast, Photoshop, iMovie, Office 2010, iPad training and many more.

Log in to Atomic Learning from <https://framingham.blackboard.com> to stay current with the latest technology applications and get answers to your common “how to” questions 24 hours a day, 7 days a week – at your own pace. Give it a try! (Firefox is the preferred browser.)

Blackboard Messaging



Creating periodic announcements in Blackboard (Bb) to participants is a good way to keep in contact and communicate updates on important information. Participants responded well to learning the groups' progress with weight loss on a regular basis during phase 1. Additionally, motivational messages and helpful tips for success throughout the entire study will support and motivate participants. A schedule is provided below as a guide as we do not want to overwhelm participants with too frequent communications.



Recommended Announcement Schedule:

Weekly: Amount weight loss by group (Monday or Tuesday)
One motivational message TBD (Fridays) – challenge of weekend, reminders, etc.

Bi-weekly: Selected messages: Getting ready for X holiday – Tips for success

These announcements should be posted in Bb as well as sent via email.

WEB ANNOUNCEMENT OPTIONS

Duration

Not Date Restricted

Date Restricted

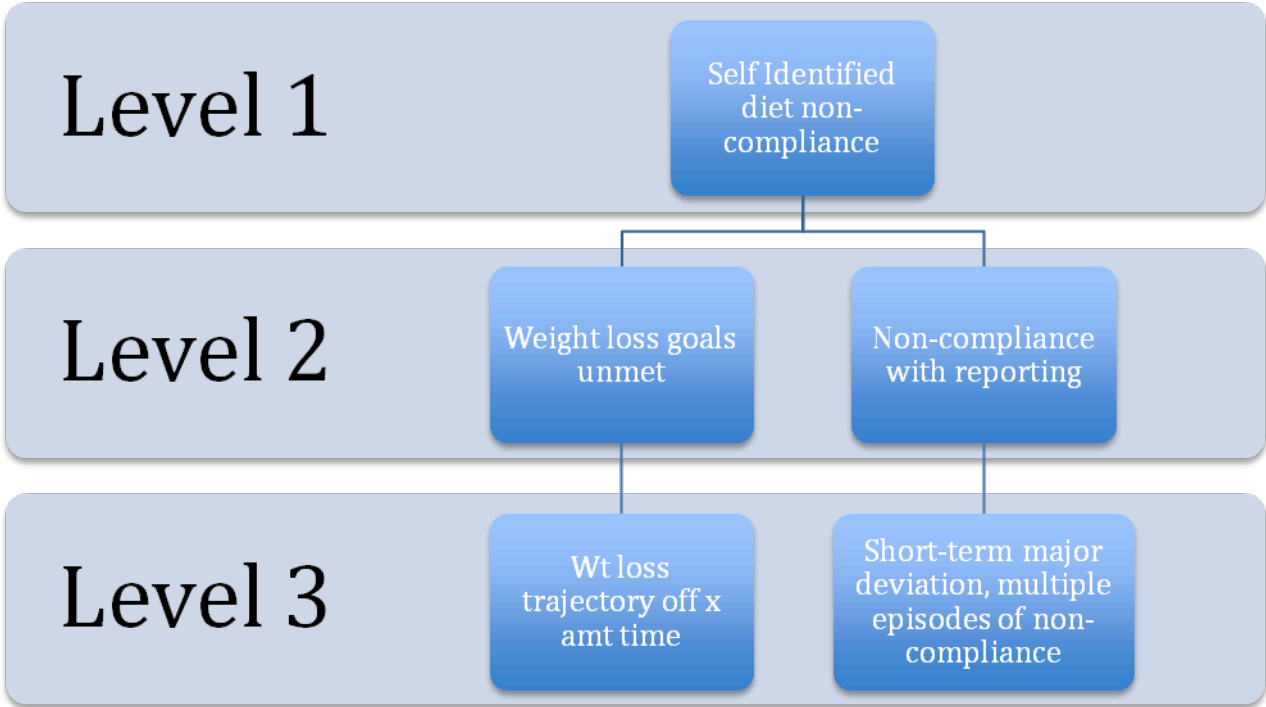
Email Announcement

Send a copy of this announcement immediately

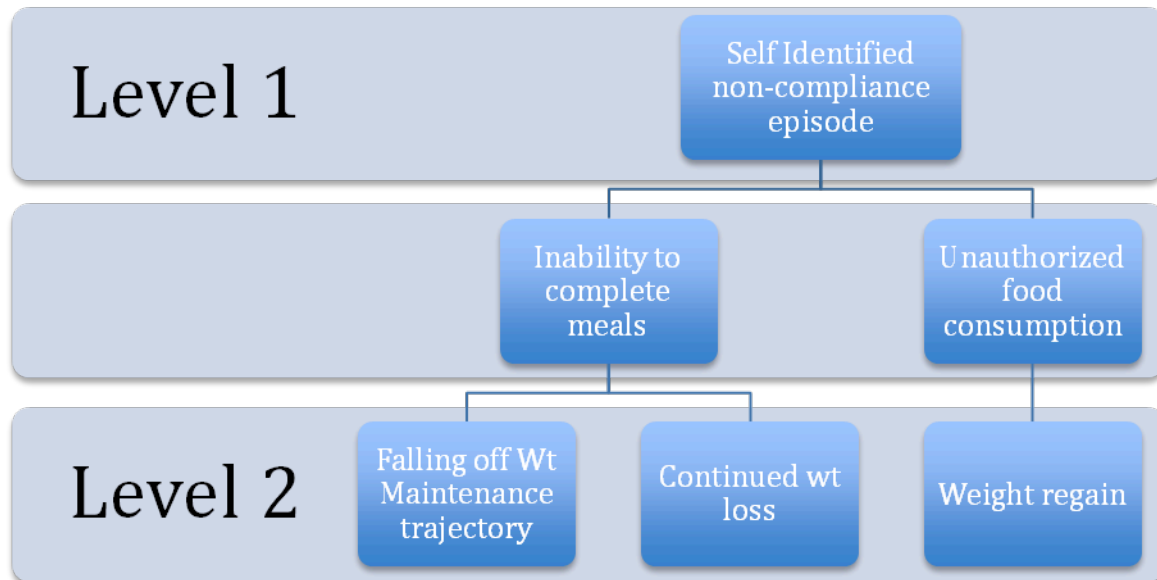
Students are still notified of this announcement even if this option is not selected

FS² Triage Algorithm

RUN-IN PHASE



TEST PHASE



Run in Phase

LEVEL 1:

Self-identified non-compliance

1. Daily self-report questionnaires in SPH – short-term deviation related to consumption of study foods, non-study foods, daily multivitamin, or alterations in weekly exercise.

INTERVENTION:

- Initial Contact: Email or in-person at meal pick-up check-in.
- Consider use of CBT Triangle; encourage participation in support group

LEVEL 2:

Weight loss goals unmet

1. Daily weight reporting in SPH – weight loss goals unmet for past 1 week.

Non-compliance with reporting

2. SPH reports non-compliance with weight reporting for 2 or more consecutive days.

INTERVENTION:

- Contact: Email to schedule telephone contact for trouble-shooting specific issues. (See telephone counseling guide)
- Participant may select follow-up contact frequency.

LEVEL 3:

Weight loss trajectory off X amount of time

1. SPH reports show weight loss is off trajectory for 2 or more consecutive weeks.

Short-term major deviation, multiple episodes of non-compliance

2. Daily self-report questionnaires in SPH – short-term major deviation related to under-consumption of study foods or consumption of non-study foods in excess of 500 kcals/day or more for 3 or more episodes.

INTERVENTION:

- Contact: Telephone contact and/or schedule 1:1 meeting for participant-centered support and addressing specific issues. (See telephone counseling guide)
- Participant may select follow-up contact frequency with a minimum weekly contact.

Test Phase

LEVEL 1:

Self-identified non-compliance

1. Non-compliance with daily self-report questionnaires in SPH or daily weight submissions.

Inability to complete meals

2. Daily self-report questionnaires in SPH or other self-report indicating inability to complete daily study meals/snacks due to satiety.

Unauthorized food consumption

2. Daily self-report questionnaires in SPH – short-term deviation related to consumption of study foods, non-study foods, daily multivitamin, or alterations in weekly exercise.

INTERVENTION:

- Contact: Email to schedule telephone contact for trouble-shooting specific issues. (See telephone counseling guide)
- Participant may select follow-up contact frequency.

LEVEL 2:

Falling off weight maintenance trajectory

1. Continued weight loss - Daily weight reporting in SPH – weight maintenance goals unmet for past 1 week due to continued weight loss.
2. Weight regain- Daily weight reporting in SPH – weight maintenance goals unmet for past 1 week due to weight gain greater than 2 lb./week for two weeks.

INTERVENTION:

- Contact: Telephone contact and/or schedule 1:1 meeting for participant-centered support and addressing specific issues. (See telephone counseling guide)

- Participant may select follow-up contact frequency with a minimum weekly contact.

FS² Telephone Counseling Guide

Appropriately qualified study staff should provide telephone counseling.

1. Build Rapport & Set Agenda

- a. Hello, this is _____ from the FS2 Study calling for our telephone counseling session. Is now still a good time to talk?
- b. How are you? (*Build Rapport. Ask additional questions as appropriate.*)
- c. Today's call will take about 15 minutes. I'd like to discuss the following:
 - i. Talk about how things have been going with the meal plan in general and how it relates to your weight.
 - ii. Learn more about how you've been eating day-to-day, and lastly
 - iii. If appropriate, set a small goal for you to work on and continue moving forward in the study.
- d. How does this sound? Was there anything else you wanted to talk about today? (*Answer direct questions at this time. Return to open ended questions in the next portion of the call.*)

2. Assessment: Understand general adherence and participant perceptions.

- a. **Goal Weights:** Your current weight is X. Your goal weight that we discussed back at our in-person visit is X. You are X lbs. away from your goal weight at this point in time.
 - i. If patient is *losing* weight during phase I:
 1. What do you think has made you successful so far?
 2. What will you need to do to keep supporting your weight loss?
 3. What areas of your meal plan are rewarding?
 - ii. If patient is *losing* weight during phase II:
 1. What do you think is challenging about your meal plan so far?
 2. What will you need to do to keep supporting your weight maintenance?
 3. What would it take for you to continue with the meal plan?

iii. If patient is *weight stable* during phase I:

1. Your weight has remained the same for some time now. What do you think of this?
2. How can you jump-start weight loss again?
3. What would it take for you to continue to lose weight?
4. What areas of your meals or dining could be improved?

iv. If patient is *weight stable* during phase II:

1. Your weight has remained the same for some time now. What do you think of this?
2. How can you jump-start weight loss again?
3. What would it take for you to continue to maintain weight?
4. What areas of your meal plan are rewarding?

v. If patient is *gaining weight* in phase I or phase II:

1. It looks like you have gained X lbs. in the last few days/weeks. Why do you think this is happening?
2. What areas of your meal plan are challenging?
3. What do you think you can do to stop your weight gain?

vi. **Summarize:** It sounds like you think your weight has been (increasing/decreasing/stabilizing) because of _____. Let's talk some more about what else has been causing this.

3. Assessment: Understand general adherence and participant perceptions, continued.

Note: Nutrition questions can be variable. Answer questions that participants have, but maintain focus on the main aim of the contact.

a. Follow-up Goal Check-In (If goal was set at last call)

- i. When we last spoke, we established a goal of.... How have you been doing with this?
- ii. **Summarize:** It sounds like you've achieved/somewhat achieved, and then stopped doing/had difficulty with your goal of X. You were able to make the goal happen because of _____. You had difficulty with the goal because of _____.

purpose of this section is to obtain information from the participant that will aid in active, patient centered goal setting during the call. In this section, engage in "change talk" to assess readiness/motivation to change. Utilize OARS, below, to facilitate. Allow the participants' comments to guide what questions you will ask from suggestions below.

b. Discussion Points:

Open Ended Questions:

- Tell me about...*
- To what extent...?*
- What would make it difficult for you to...?*
- What could you do differently...?*
- How confident are you in your ability to...?*

R: Reflective Listening

- *It sounds like/What I'm hearing is...*
- *For you, it's a matter of...*
- *Your belief/concern/fear is that...*
- *It's hard to imagine how...*
- *You're not much concerned about...*

Reinforcing affirmations:

- It must be hard to...*
- This has been totally...for you*
- It's great that you...*
- You took a big step by...*
- You have overcome...*

S: Summarize

- *To wrap up our conversation...*
- *You mentioned...*
- *You have decided to...*

- i. How has the meal plan been going, in general?
- ii. What do you struggle with the most when it comes to food?
- iii. What are you most successful with when it comes to food?
- iv. What are some of your biggest challenges?

- v. How have you been able to plan ahead for meals in difficult situations such as parties, holidays, or other social events?
- vi. How have you been able to identify those who are supportive of your nutritional plan?
- vii. **Summarize:** It sounds like you've done a good job with X, Y, and Z but are really struggling with ___ in terms of your overall eating. Do I have that right?

c. Hunger/Satiety/Mindfulness

Note: If participants perceive that they are doing well with the diet and time allows, consider asking questions about hunger, satiety, and mindfulness while eating. This should not be the focus of the call, but can be used to support differentiation and adherence to the assigned diet.

- i. How has your hunger been lately?
- ii. How is your pace of eating?
- iii. How often do you ask yourself "Am I really hungry?" when you want to eat? (Help participants determine if they want to eat out of boredom, stress, or other reasons.)
- iv. What makes it hard to listen to what your body is telling you?
- v. Tell me about how you might serve yourself a meal or a snack. (Assess if participants are multi-tasking during meals/snack instead of focusing on the food and enjoyment.)

4. Advise: Patient Centered Intervention

(Note: Listen to participant response to the following question and use information gathered from the participant to aid in specific goal setting to be followed up at next call. If appropriate, be directive by asking "Would it be okay if I offer some suggestions?" Use OARS communication style to facilitate directive patient centered goal setting, starting with the directive statement below.)

- a. Hearing what I said about not getting enough/too much [food] and thinking about the success and challenges you brought up earlier in our conversation, (would it be okay if I offer some suggestions?) -or- (where do you think you need to go from here?)

5. Summarize Patient Goal

- a. To summarize, we have agreed together today that you will [task/small change] so that you can [goal].

- b. Would it be okay to check in with you at next phone call to see how you've been doing with this goal?
- c. What other concerns do you have today, if any?
- d. When is a good day/time to call you next week?
- e. It was so nice getting a chance to talk one-on-one today. Please feel free to reach out to members of the FS2 team if you have any questions or concerns. Goodbye.

TOOLS

CBT Triangle

