

CHAPTER 7

RANDOMIZATION

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Study Documents Referred to in this Chapter:

- Telephone Screening Interview
- SPPB
- CHAMP S-18
- Main Informed Consent
- Blood Pressure, Radial Pulse and Weight
- ECG
- Physical Exam
- 400 m Walk Test
- 3MSE

CHAPTER 7

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7.1. RANDOMIZATION OVERVIEW

Randomization can only occur after all eligibility requirements have been met and all key baseline data have been data entered.

Randomization is stratified by field center (8) and by gender (2). This will ensure nearly equal sample sizes for the two intervention groups within each center and for men and women. Stratification by center is important because we expect that the cohorts recruited by centers will vary, depending on local populations and recruitment strategies. Stratification by gender is important because we anticipate there may be differences in how women and men respond to the intervention.

Clinic sites will routinely determine the randomization assignment for each participant by using the LIFE web-based data management system. Because internet connections are occasionally not available, the LIFE DMAQC center has developed a back-up randomization process that is not dependent on the internet.

7.2. RANDOMIZATION PROCEDURE

The following forms must be entirely entered in the LIFE database prior to randomization:

Telephone	Screening Interview:	Telephone Screening Interview Form
Screening	Visit 1:	SPPB
		Battery
		CHAMPS-18
		Full Informed Consent with date
		BP, Radial Pulse and Weight
		Physical Exam
		400m Walk Test (or SV2 if not completed at SV1)
		3MSE
		ECG

As each form is entered, an eligibility check is automatically performed to confirm that all elements of the form have been completed and to confirm eligibility or partial eligibility. For example, once all Screening Visit 1 forms are entered, the eligibility check may be used to determine whether a Screening Visit 2 should be scheduled.

If the eligibility check is not successful (i.e., it shows the screenee is currently ineligible), several steps should be taken. First, you should confirm that the data were entered correctly by comparing the hard copy of the form with the data screens (or compare with the report that indicates areas of ineligibility). If an error has been made in data entry, the data can be corrected and the eligibility check can be run again. All changes made to the eligibility data will be documented in the system in a “journal file” and reviewed periodically by the DMAQC and study committees.

Second, you should confirm that all activities have occurred within the allowable timeframe (see Allowable Time between Activities, below). If it appears that the participant is indeed ineligible, determine whether it is a temporary ineligibility (e.g., blood pressure out of range) and discuss this with the participant. Re-screening can be conducted at a later date. If the participant is permanently ineligible, thank them for their time and kindly dismiss them from the screening visit.

If the eligibility check is successful, proceed to the next level of screening or randomization. The process of implementing a LIFE randomization is described in Chapter 23, Data Management.

For specific instructions on the procedures for informing a participant of his/her intervention assignment, please see Appendix A and B at the end of this chapter.

Participant web-based randomization requires that the LIFE DMAQC server, the clinic computer, and internet are all operational. In the event of a failure of any of these systems, web-based randomization cannot be performed. The following steps should be followed. First, inform ___ at the DMAQC (phone ___, or ___), particularly if you are having difficulty reaching the DMAQC server. If you are unable to reach ___, please contact ___. Second, if you can _____ delay randomization, do so. (It may be only a short time before the system is operational again.) If randomization must be performed immediately (e.g., an intervention group is due to begin the following day), contact ___ at the _____ DMAQC in order to use the back-up manual plan for randomizing without the computer system.

In the event you have made an error in randomization, (i.e. with data entry or printing a form) contact ___ at the DMAQC.

7.3. RANDOMIZATION ERRORS and ISSUES

Occasionally the clinic or the DMAQC uncovers information that indicates that a randomized participant was not eligible. One reason for this is that a participant may not have revealed information that made him/her ineligible until after the randomization. Alternatively, a data entry error may have been made that has led to an incorrect eligibility assessment. When a randomization error is known to

have occurred: (1) a memorandum signed by the Program Coordinator and Principal Investigator must be sent to the DMAQC as soon as the situation is uncovered and (2) the participant remains a part of the LIFE study. The DMAQC will be monitoring the frequency and type of randomization errors and reporting them regularly to the Data Safety Monitoring Board.

Once a participant is randomized, NO CHANGES CAN BE MADE to the forms used to determine eligibility, these data entry screens will be locked. If you discover an error to a screening (eligibility) form that has been entered, these changes can be made by the DMAQC. In this situation contact ____ at the DMAQC to determine the correct action to take. If the entered data needs to be corrected, written notice of the needed change must be received.

Errors during the screening process:

In some cases, the status of a participant with respect to eligibility criteria determined at Screening Visit 1 changes by the time of Screening Visit 2. For example, a screenee has a cardiovascular event after Visit 1 but prior to Visit 2. If this happens, the individual is no longer eligible and the appropriate Visit 1 form should be edited to reflect this.

If, however, a change in eligibility criteria is not detected until after the participant has been randomized, as above, the individual is still a LIFE study participant and should be followed. However, a safety assessment may be required to ensure that the assigned study intervention is appropriate.

7.4. ALLOWABLE TIME BETWEEN ACTIVITIES

The allowable time from the date of the telephone screening interview to randomization is 60 days. The allowable time from the date of prescreening (SPPB, and CHAMPS) to randomization is 45 days. The allowable time from the date of main informed consent (date the participant signs the form) to randomization is 28 days or 45 days in extenuating circumstances. The website will not permit randomization of a participant who does not meet these criteria. The allowable time from the date of randomization to the date of the first individual intervention is two months.

The DMAQC will monitor these activities and provide regular reports to the study leadership.

Appendix A

Physical Activity Intervention Randomization Protocol

- **Congratulations!** You have just been assigned to the physical activity intervention group.

- **Provide brief overview of the program**

1. **Purpose:** Intervention is designed to help older adults improve their physical function and to prevent disability.
2. **Center-based physical activity:** explain that participants are expected to attend supervised physical activity sessions
 - 2 X's each week for the duration of the study

In addition, they should be told that they will be asked to complete home-based physical activity on days that they do not exercise at the center. The amount of exercise will gradually increase over time to the point that they will eventually be active on most days of the week.

- **Provide and review information packet:**

1. Interventionists contact information
2. Maps/location of facility
3. Other material as needed
4. Encourage the participant to call if he/she has any problems or questions.

- **Inform participant** that the physical activity program coordinator will contact her/him to schedule their initial face-to-face contact.

- **Answer any questions** that the participant may have at this point in time. Tell the participant that you look forward to working with him/her and that you believe they are going to be very pleased with the changes that they experience over the duration of the study.

- Let the participant know that you are going to be sending a letter to their PCP advising them that you are participating in this study.

- **Complete Physical Activity Participant-Staff Contract**

- **Discuss participant's transportation options** (i.e., to the intervention)

- Follow all clinic **Check out Procedures; Validate parking (if necessary)**

- **Remember to instruct the participant to not discuss their group assignment (physical activity or successful aging) with any LIFE assessment staff.**
- **Thank** the participant and **say good-bye.**
- Print a hard copy of the randomization assignment and store in a locked intervention cabinet to protect against unblinding.
- **Update** contact database.

Physical Activity Intervention Description and Expectations Contract

Congratulations! You are now part of the LIFE Physical Activity Program. You will participate in a structured, supervised physical activity program that is designed to enhance your health and prevent disability. A trained exercise specialist will teach you how to do the exercises and ensure your safety. The program consists of walking and strength, flexibility, and balance training.

Expectations for Participation:

- ♦ For the duration of the LIFE study, you will come to the center **2 times** each week to participate in the physical activity program.
- ♦ You will also receive instruction on how to be more physically active **on your own** on the other days of the week for the entire duration of the study.
- ♦ Attend your scheduled health evaluations. These will occur every 6 months until the study ends.
- ♦ Keep in contact with the staff so that we know how you are doing.

Your signature below indicates that you understand your LIFE study condition and what we have asked you to do.

Signed (participant): _____ Date: _____

Witness: _____ Date: _____

Appendix B

Successful Aging Workshop Randomization Protocol

- **Provide the participant with a binder or folder which includes a list of Successful Aging Workshops and a current Calendar.** This binder should also include other important information (e.g., contact numbers, directions, maps). See below for specifics.
- Explain that the participant is expected to attend weekly for the first 6 months, then monthly. Let the participant know that they will continue to receive updated calendars in the future, and a monthly newsletter.
- Have participant sign the **Expectations Contract** (posted on the study website).
- Schedule the 45-minute initial individual face to face interview to introduce participant to the study arm and to build rapport and excitement for the study or tell the participant that their interventionist will be calling them to schedule.
- Let the participant know that you are going to be sending a letter to their PCP advising them that you are participating in this study.
- **Give business card** of workshop coordinator and encourage him/her to call if he/she has any problems or questions.
- **Contact** workshop leader and give the new participant's name and date of randomization.

Answer any questions about group the participant was assigned. Tell participant that you believe in his/her ability to benefit from this condition, and that you look forward to working with him/her.

- **Thank** the participant and **say good-bye.** Remember to instruct the participant to not discuss their group assignment (physical activity or successful aging) with any LIFE assessment staff.
- Print a hard copy of the randomization assignment and store in a locked intervention cabinet to protect against unblinding.
- **Update** contact database and **file hardcopies.**

Binder/folder Contents for Successful Aging

The following is a suggested format for the Workshop binders that are distributed at the randomization visit. A similar binder should be distributed to the Physical Activity Group upon randomization. All binder materials can be found under Study Tools on the LIFE website.

- Front cover should have LIFE logo.
- Inside front cover should have a sticker with participant's name and phone number (To call if left behind after a session).
- Welcome note from PI
- Welcome note from Interventionist
- Contact Sheet: Names/Phone number/Address Successful Aging staff
- Include session day, time, location, etc.
- Monthly group calendar and newsletter
- Parking Information & Map
- Copy of Contract
- Physical Activity Guidelines (posted on the study website)
- Tufts Food Pyramid and supporting materials (posted on the study website)
- Successful Aging Stretching routine (found in MOP Chapter 10)

Successful Aging Health Education Program Expectations Contract

Congratulations! You have been selected to participate in the Successful Aging Health Education Program. The workshop series has been carefully designed to provide topics relevant to healthy living and aging. Examples of workshop topics include: diet and nutrition, successfully navigating the health care system, and legal and financial planning, wellness, disease prevention and treatment and happiness in the home and community planning. As part of this group, you are expected to attend and participate in regularly scheduled meetings.

<p style="text-align: center;"><u>Workshop is offered:</u></p> <p>Day: _____</p> <p>Time: _____</p> <p>Location: _____</p> <p>Workshop Leader: _____</p> <p>Phone Number: _____</p>

Expectations for Participation:

- You are expected to attend one meeting per week for 6 months. After 6 months, you are expected to attend at least one meeting per month. There will be at least two sessions/mo offered.
- Notify your workshop leader in advance if you are unable to attend any workshop sessions. A monthly calendar will be sent to you with our upcoming events.
- Attend scheduled health evaluations. These will occur every 6 months.
- Maintain contact with LIFE staff so we know how you are doing.

Your signature below indicates that you understand your role in the Successful Aging Workshop Group and agree to meet the expectations outlined above.

Signed (participant): _____ Date: _____
Interventionist: _____ Date: _____