



RECRUITMENT

1. General Information

The goal of the Study of Muscle, Mobility and Aging (SOMMA) is to enroll 875 participants across the 2 clinical centers at Wake Forest University and the University of Pittsburgh. Both men and women aged 70 and older are eligible for this study. Participants also must have a gait speed between XXXX and XXXX as measured by a 4m usual pace walk.

2. Recruitment Strategies

Each clinical center has site specific strategies for recruiting cohorts of older men and women. Direct mailing campaigns will be used to distribute study informational brochures and introduction letters to potential participants. Sites may also present information about the study at health fairs, church functions, senior centers or other community organizations. Other methods that may be utilized include: XXXX

All methods of recruitment are documented by each of the SOMMA clinical centers. During the telephone screening interview, potential participants are asked about where they heard about the study, and their response is tracked on the data collection forms. . These data are used to generate regular reports through the recruitment period to track the method(s) that provide the greatest yield of eligible participants. These reports are provided to clinical sites on a monthly basis and provide data on the number of potential participants screened from each of the recruitment sources, eligible participants from the various recruitment sources, and eligible minority participants from the recruitment sources. This information is transmitted between the field center sites so field centers can learn which methods are most successful and which methods are not worth pursuing.

3. Telephone Screening Questionnaire

A preliminary telephone screen will be used to determine initial eligibility

1. Background and Rationale

Muscle strength is an indicator of muscle function and therefore an important outcome of this study. Fiatarone et al¹ have postulated that strength is a more important limiting factor than cardiovascular endurance in the ability of older individuals to maintain an independent lifestyle.

Muscle strength decreases with age but little is known about the influence of changes in muscle mass, fat mass, and physical activity on this decrease.

Grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty. Grip strength in both hands will be measured using an adjustable, hydraulic grip strength dynamometer.

2. Equipment and Supplies

- Jamar Hydraulic Hand Dynamometer which registers maximum kilograms of force during a trial, with adjustable handgrip.
- Standard chair
- Table (moveable tray table preferred)
- Mouse pad

2.1 Dynamometer Use and Maintenance

For routine maintenance, follow the instructions in the Jamar dynamometer owner's manual.

To use the dynamometer:

1. Please remember that it is a precision instrument and its accuracy can be impaired by abuse. Never force the handles or subject the instrument to unnecessary impact.
2. Set the adjustable handle to the desired spacing. (Before moving the handle from one position to another, note that the handle clip is located at the lower (furthest) post from the gauge. If the handle is not replaced in the correct position, the readings will not be accurate.)
3. Rotate the red peak-hold needle counter-clockwise to 0. Always look straight ahead at the dial when reading.
4. After the participant has used the instrument, reset the peak-hold needle to zero before attempting a new reading.

Service Tips: To make sure the instrument is reading accurately, it's a good idea to make a few checks each month, as listed below. If you detect a problem, report this to the quality control (QC) officer.

Posts: Remove the adjustable handle and check that each post moves up and down freely (through a very small distance, about 1/8") within the plastic aperture (the guide) even when you exert pressure on the side of the post. About once a year, place a small amount of grease on the two guides. If excessive friction exists between the post and guide, return the dynamometer to the QC officer.

Hydraulics: To check the hydraulic mechanism, first remove the adjustable handle. While watching the top post, push down on the bottom post. Normally, both posts should move about 1/8", with top and bottom posts moving in opposite directions. Movement less than 1/16" indicates a probable leak in the hydraulic system, which requires service. Return the dynamometer to the QC officer.

Handle: Grasp the instrument normally and look carefully at the way the forks of the adjustable handle are supported on the posts. Each fork should touch the post at approximately its mid-point. If this is not the case, return the instrument to your supervisor.

Peak-Hold Needle: Check for excessive friction in the peak-hold assembly by turning the peak-hold knob counter-clockwise. If the peak-hold needle causes the gauge needle to move, return the gauge for service.

If the peak hold needle is knocked off its support pin, it can readily be repositioned. Unscrew the crystal and turn it upside down. Locate the brass pin in the center of the crystal (the pin is part of the chrome knob on the outside of the crystal). Locate the slot on the brass pin and place the peak-hold needle into this slot.

2.2 Calibration check:

Every week: Check the calibration of the grip strength dynamometer by hanging 5 kg and 20 kg (or 10 and 50 lb) weights across the handle using two velcro straps, one strap on each side of the dynamometer handle, or one wide strap that covers the whole handle. Lift the weights slowly from the floor while they are strapped to the dynamometer handle and record the maximum kilograms registered. The lifting motion should be very slow and smooth, and the weight should remain evenly distributed between the two sides of the handle. Repeat the procedure three times and record each result.

Average the three calibration trials. The dynamometer should be accurate within ± 2 kgs for the average of the three calibration trials. If the calibration check is not within these limits, notify the QC officer. It may be necessary to send the dynamometer to the manufacturer for repair and recalibration. DO NOT attempt to recalibrate the dynamometer yourself. Calibration problems can be caused by dropping the dynamometer or by leaks in the hydraulic system.

Recalibration Directions for QC Officer:

Before the start of MrOS Visit 4, sites were asked to have their dynamometers recalibrated. Devices were sent to Grip Repair. The website for this company is www.griprepair.com.

3. Safety Issues and Exclusions

This test should not be performed in the affected hand if the participant:

- has a current flare-up of pain in their wrist or hand; for example arthritis or tendonitis.
- has undergone fusion, arthroplasty, tendon repair, synovectomy, or other related surgery of the upper extremity in the past 3 months.

If only one side is affected, test the unaffected side.

4. Participant and Exam Room Preparation

The participant should be seated at a standard height table or on a seat with a moveable tray table attached.

5. Measurement Procedures

5.1 General Issues

Grip strength will be measured in two trials of each hand (unless there are extenuating circumstances - see above) using a hydraulic, isometric dynamometer.

5.2 Administration

1) Screening Questions.

Determine if the participant has an acute or recent flare of pain in the hand (e.g., due to arthritis), or surgery on the hand or wrist in the past 3 months (12) weeks. "Recent pain" is considered to be pain in the last month.

Script: "Has any pain in your hands gotten worse recently? Have you had any surgery on your hands or wrists in the past three months (12 weeks)?"

Record answer on form.

If they have had a current flare-up of pain or arthritis or have had surgery on the hands or wrists (fusion, arthroplasty, tendon repair, synovectomy, or other related surgery) in the past 12 weeks, then do not test grip strength on the affected side. If both sides are affected or the participant refuses the procedure because of concerns about pain or injury, do not test grip strength.

If the participant asks to test his grip strength even though the screening questions indicate that the test is not necessary, you may allow the participant to complete the task and record maximum strength for each trial on the data collection form.

2) Demonstration and practice

The examination is done with the participant in the sitting position with the arm to be tested resting positioned naturally on the table and the elbow held at approximately a right angle. The dynamometer is held in the hand to be tested and is resting on a mousepad.

Script: "This device measures your arm and upper body strength. I will demonstrate how it is done. I'd like you to take your right/left arm, rest it on the table, and bend your elbow. Grip the bars in your hand, like this. Please slowly squeeze the bars as hard as you can."

Demonstrate the correct grip and arm position. As you demonstrate, instruct the participant to squeeze the hand maximally.

Hand the participant the dynamometer.

Script: "Does that feel like a comfortable grip?"

Adjust the grip size so that the participant holds the dynamometer comfortably (this will almost always be the second setting). Allow one submaximal practice trial to determine if the procedure is understood by the participant and the grip size properly adjusted. If the participant's finger nails are digging into their palm the dynamometer needs to be adjusted to a larger grip size.

Script: "Now try it once just to get the feel of it. For this practice, just squeeze gently. It won't feel like the bars are moving, but your strength will be recorded. Don't let your arm touch the side of your body. Are the bars the right distance apart for a comfortable grip?"

Show dial to participant. Adjust the handgrip again, if necessary.

NOTE: The grip should not be adjusted between trial 1 and 2 on the right side.

3) Test grip.

Script: "Good. Now this time counts. We'll repeat this twice on the right side and then twice on the left side. Be sure to squeeze as hard as you can. Ready? Okay. Squeeze! Squeeze! Squeeze! Now, stop."

Have the participant perform the test, starting with the right hand.

Record the kilograms pulled from the dial to the nearest 2 kilograms (rounding down). Reset the dial to "0" after each trial.

Perform two trials with at least 15 to 20 sec rest in between.

Script: "Now, one more time. Squeeze as hard as you can. Ready. Squeeze! Squeeze! Squeeze! Now, stop."

4) Repeat the procedure on the left side, unless contra-indicated. A trial of sub-maximum strength should be allowed on the left side to ensure comfortable grip.

NOTE: The grip should not be adjusted between trials 1 and 2 on the left side.

6. Alert Values/Follow-up/Reporting

When the test is completed tell the participant how many kilograms were read on the dial and that they did just fine.

Record kilograms for each side on participant's results form.

7. Quality Assurance

7.1 Training Requirements

The technician requires no special qualifications for performing this assessment. The training should include:

- Read and study manual
- Attend MrOS training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

7.2 Certification Requirements

- Complete training requirements
- Demonstrate maintenance check of dynamometer
- Demonstrate the proper adjustment of dynamometer handles
- Demonstrate the calibration check procedures
- Recite exclusions
- Conduct exam on 2 volunteers:
 - According to protocol, as demonstrated by completed QC checklist
 - ± 2 kgs on repeat assessment of volunteer

7.3 Quality Assurance Checklist

- Participant is asked about pain, arthritis, and recent surgery on hands
- Correct instructions given while demonstrating procedure
- Recording dial reset to zero after sub maximal practice
- Sub maximal practice; grip adjusted if necessary
- Forearm resting on table, elbow bent to approximate right angle
- Standard encouragement (motivation and feedback) offered to participant
- Recording dial (peak hold needle) reset to zero after first trial
- Measurement taken twice on each side (unless contra-indicated)
- Key points from script delivered clearly
- Reviews form for completeness
- Correctly completes form
- Log indicates calibration check up to date

8. References

1. Fiatarone MA, Marks EC, Ryan ND, Meredith CN, Lipsitz LA, Evans WJ.: The etiology and reversibility of muscle dysfunction in the aged. JAMA 1990;263:3029-3034.

Acknowledgment. This chapter is adapted from the Fracture Intervention Trial (FIT) Operations Manual and the Health ABC (HABC) Operations Manual

