

Manual of Procedures FLADEX project

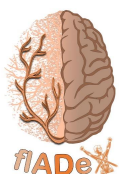
MOP Chapter 2.1: Familiarization



Promoting Fitness & Health
through Physical Activity



UNIVERSIDAD
DE GRANADA



Chapter 2.1. Familiarization

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1. Introduction

This MOP chapter describes the workflow and the sequence of tasks to be performed during the familiarization session. This session includes providing participants with the information sheet and informed consent, measuring blood pressure, administering the Montreal Cognitive Assessment (MoCA) cognitive test, and completing few questionnaires: Medical Information, MRI and Blood Baseline questionnaire. Additionally, the session involves taking anthropometric measurements and testing the two exercise conditions. The person in charge of each evaluation or measurement will fill the information in REDCap directly, through a tablet. Familiarization will take place at IMUDS and a maximum of 12 participants will be assessed per day. To perform the familiarization session, 1 project coordinator for ethical consent, 1 MoCA evaluator, and 3 trainers will be needed. One room is required for the project information and informed consent, three rooms are required for all questionnaires, one additional room for the MoCA, the room of anthropometry and a space in the gym for both exercise conditions.

2. Required materials

- Information sheet and informed consent (x12, paper). Annex 1.2 Information sheet. Annex 1.3 Informed consent
- Blood pressure monitor (x1).
- MoCA material (x12, paper). Annex.5.1.MoCA_Record, Annex 5.2.MoCA_Identification and Annex.5.3.MoCA_Manual.
- Tablets (x3).
- Polar Material: HR bands (x12), Polar watches (x12), Polar chips (x12).
- Medical information questionnaire (x12, Tablet).
- MRI questionnaire (x12, paper). Annex7.2.MRI_compatibility_questionnaire.
- Blood Baseline questionnaire (x12, tablet). Annex 6.2. RedCap data forms.
- Stadiometer (x1).
- Weight scale (x1).
- Tape measure (x1).
- Elastic bands (x12).
- Static bike (x2).
- Staff (x5) → Trainers (x3) + MoCA Evaluator (x1) + Project Coordinator (x1)
- Rooms (x5) → Space for Questionnaires (x3) + MoCA room (x1) + Anthropometry (x1)
- Gym (x1)

3. Workflow

3.1 Pre-test procedures

The following instructions must be considered before familiarization session:

- Send session procedures to participants 1 week before, and 1 day before as a reminder (Anexx A. 2.1 Standard Messages):

*“¡Hola! ¿Qué tal está? Le escribimos para recordarle que nos vemos el próximo (X) día (X) a las (X) en IMUDS (Instituto mixto universitario de deporte y salud). En la sesión habrá preguntas sobre los **medicamentos** que toma, así que, por favor, traiga la información necesaria para poder responder. Por otro lado, si para leer utilizas **gafas** tráelas para poder leer y completar los cuestionarios. Habrá ejercicio así que hay que venir con **ropa deportiva**. Cualquier duda no dude en contactar con nosotros □ ¡Un abrazo!”*

- Staff must be ready 15 min before participant’s appointment.
- Arrangements for exercise conditions must be prepared 30 minutes before the exercise session.

3.2 Test procedures

The person in charge of each part of the familiarization will fill the information in REDCap in the corresponding instrument in the moment of each evaluation or measurement.

3.2.1 Participant information sheet and informed consent.

This task lasts 20 min and is performed by the project coordinator with the following steps:

- Inform participants about project’s characteristics and potential consequences making sure that everything is clear for them. Participants will receive an information sheet that includes all project features (specifically, Annex 1. Ethics committee and insurance). This is the moment for the participant to ask about any question related to the project.
- Provide participants with the informed consent form (i.e.. Annex 1.2 Informed Consent), and ensure it is fully completed and signed.

3.2.2. MoCA

The MoCA is used to describe general cognition, not for participant screening. The MoCA will be performed for the same evaluator at every assessment. Full description of MoCA assessment is detailed in the following documents:

- MoCA general procedures: see *Chapter 5.1. Cognitive_test*
- MoCA’s manual: see *Annex 5.3. MoCA_Manual, Annex 5.1. MoCA_Record, Annex 5.2. MoCA_Identification*

3.2.3 Heart rate (resting and maximal) and blood pressure measurement:

To measure the heart rate resting and blood pressure, the participant must move upstairs to the stretcher of the Lab 1. The participant should have been relaxed approximately 5 minutes.



Then, in the Polar app the trainer should start an activity for 5 minutes. The mean heart rate of the 5 minutes will be the resting heart rate that we will use for the conditions.

Additionally, blood pressure will be measured with a blood pressure monitor twice with one-minute rest between measurements. Blood pressure will be always always taken on the left arm. The mean systolic and diastolic blood pressures will be recorded. Both measures of heart rate and blood pressure will be registered while the participant lays on the stretcher. To calculate the maximal heart rate, we will use the formula: $220 - \text{participant's age}$.

All the information will be recorded directly in the instrument of REDCap titled Familiarization.

3.2.4 Medical information and medication

We must fill out the REDCap instrument about the medical information and medication. The name of the instrument is “Medical records”, the instrument records the medicaments per categories and the dosis.

- Questionnaire of the medical information and medication:
see “Chapter 5.2. Questionnaires”.

3.2.5 MRI Quest

We must fill out the questionnaire of compatibility with the MRI. It is impressed in paper and completed with a pen.

- Questionnaire of the MRI compatibility:
see “Annex7.2MRI_compatibility_questionnaire”

3.2.6 Blood Baseline Quest

This questionnaire must be completed directly in the REDCap instrument, it is called Blood Baseline Quest, the aim is to collect some general information regarding sex/gender, blood, symptoms, and blood draws.

- Questionnaire about blood:
see “Annex 6.2. RedCap data forms”.

Questionnaires CHECK

At this point you have to fill this instrument called Questionnaires CHECK to make sure that the participants have completed all the previous questionnaires.

3.2.7 Anthropometry

In the instrument called Familiarization must be recorded all the information of the anthropometry evaluations.

- **Height measurement:**

Participants must stand with their feet together in a V-shape, against the wall of the stadiometer. A natural upright position must be maintained during the measurement. The measure will be taken twice. It should be performed wearing comfortable and light clothing, and without footwear. The participant will stand on the scale with an integrated stadiometer, facing away from it. The researcher will position the participant's head so that the Frankfurt plane, which connects the lower edge of the eye orbit to the upper edge of the external auditory meatus, is horizontal, with feet together, knees extended, heels, buttocks, and back in contact with the vertical piece of the measuring instrument (Figure 1). The arms will remain extended along the sides with the palms of the hands facing towards the thighs. The horizontal piece and the movable part of the stadiometer will be lowered until contacting the participant's head, lightly pressing the hair. The nearest whole unit indicated by the stadiometer will be recorded, with an approximation of 1 mm. For example, a result of 157.3 cm will be recorded as 157.3.

Plano de Frankfort

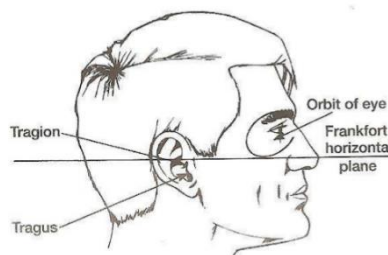


Figure 1. Frankfort plane.

- **Weight measurement:**

The participant should wear comfortable and light clothing. It will be performed twice. Place the participant on the scale, barefoot, without being able to lean on anything, and always keeping their gaze forward. Record the nearest whole unit displayed on the scale's marker, with an approximation of 100 g. For example, a result of 58 kg will be recorded as 58.0. It is important to remind the participant to always wear the same clothing whenever weight measurement is to be taken.

- **Hip height measurement:**

Participants must maintain a natural position. This measure is to select the height of the static bike. The tape must be used to measure the distance from the trochanter to the ground.

3.2.9 Familiarization of physical condition

At this point the trainer must introduce the data of heart rate, height, hip height and weight into REDCap. Also, the trainer must create the “player” in the Polar teams and in two different tablets.

- The guide to configure the Polar App: see information in: "Chapter 8. Intervention protocol" (3.3 Polar Configuration).

During the condition A and B, some information must be registered in the instrument of REDCap called Familiarization, that are the Feeling Scale Pre and Post, the RPE and Mental Fatigue of both conditions and the color of the Elastic Bands for the proper stimulation.

- **Condition A (Aerobic training):**

The exercise will be performed during 8 minutes in a static bike. The intensity target will be a continuous moderate intensity at the 60%-70% of the heart rate max and a 4-6 in the RPE scale.

The 60% and 70% heart rate max will be automatically calculated by REDCap with the blood pressure and resting heart rate measured recorded previously during this familiarization session, with the formula:

$$220 - \text{age} = \text{HrMax} \rightarrow 70\% \text{HrMax} = 0.7 * \text{HrMax} ; 60\% \text{HrMax} = 0.6 * \text{HrMax}$$

After the condition, the participant will be asked about the RPE and Mental Fatigue,

- To see the questions of the RPE and Mental Fatigue see: "8. Exercise intervention\Annex 8.1. Questions"
- The guide of the protocol of aerobic exercise: "8. Exercise intervention\Chapter 8. Intervention protocol" (5.2 Aerobic training condition (A))

- **Condition B (Resistance training):**

Eight different exercises will be performed with a duration of 40 seconds of work and 20-second of rest between each exercise, while a one-minute break will be taken between each set. In total, one set will be completed. The exercises will be conducted in circuit (Figure 2).

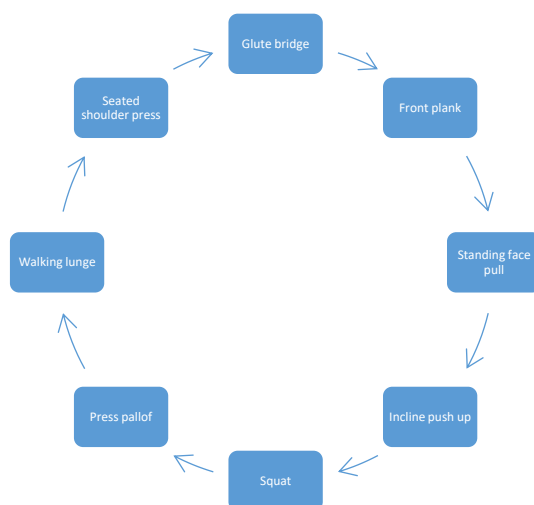


Figure 2. Circuit training exercises.

The elastic bands to be used are the Theraband, which can be seen in Figure 3. The elastic bands are available in 8 different colors that correspond to different intensities, the colors from lowest to highest, correspond to: Beig-Extra Soft, Yellow-Soft, Red-Medium, Green-Strong, Blue-Extra Strong, Black-Strong Special, Silver-Athletic, Gold-Olympic.



Figure 3. Theraband elastic bands.

The speed of execution of the different exercises has been proposed as another measure to control the intensity and adaptations that occur at the muscular level, using the maximum speed of execution, demonstrating its benefits in older people. To do this, a fast and controlled execution speed (3" eccentric and 1" concentric) will be used.

During the session, the subjective perception of effort will be recorded. We will use the BORG Subjective Perception of Effort (RPE) scale.

After the condition, the participant will be asked about the Mental Fatigue,

- To see the questions of the RPE and Mental Fatigue go to:
"8. Exercise intervention\Annex 8.1. Questions"

To extend information of the condition and exercise technique:

- Information of the condition:
"8. Exercise intervention\Chapter 8. Intervention protocol" (5. 3 Resistance training condition (B))
- Exercise technique: "8. Exercise intervention\Annex 8.2. Exercises technique description"

3.3 Post-Test Procedures

The data obtained from the MoCA test will be corrected by two independent evaluators.

- To know how to correct the MoCA: see
"5. Cognitive assessments and questionnaires\Annexes\Annex.5.3.MoCA_Manual"



All the paper-based questionnaires/tests will be scanned and upload to the correct folder in the server (these routes are examples; the document will have to be uploaded to the actual participant):

- MoCA: "\\profith2.ugr.es\Agueda\fladex\Participants\PILOT\194\ses-0\194_moca.pdf"
- MRI questionnaire:
\\profith2.ugr.es\Agueda\fladex\Participants\PILOT\194\ses-0\194_MRIQ.pdf
- Informed Consent:
\\profith2.ugr.es\Agueda\fladex\Participants\PILOT\194\ses-0\194_cons.pdf

Before the participant leaves the building, the trainer must revise if the tablet-based questionnaires and exercise conditions are properly recorded in REDCap.

4. Graphic workflow

Figure 4 shows the workflow of one familiarization session; each participants' familiarization session lasts 90 min. Per familiarization session will be a maximum of 12 participants. Figure 5 shows the name and places of the gym upstairs.



	DAY										
Time	Mins										
8h	0 → 5	ID / BEA / Tablet 1 & Polar 4									
	5 → 10	Arrival of the participant	SITE								
	10 → 15	Informed Consent and Project Information	Round Table								
	15 → 20										
	20 → 25			ID / JAVI F. / Tablet 2 & Polar 8							
	25 → 30			Arrival of the participant	SITE						
	30 → 35										
	35 → 40	MoCA	34								
	40 → 45	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	45 → 50	Medical information and medicaments									
50 → 55	MRI Quest	JAVIS. / Tablet 3 & Polar 10									
55 → 60	Blood Questionnaire + PA quest	Arrival of the participant				SITE					
60 → 65	Anthropometry (weight, height and hip height)	52				Resting heart rate + blood pressure					
9h	0 → 5	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	5 → 10	Condition A + Feeling scale									
	10 → 15	Condition A + RPE									
	15 → 20	Condition B									
	20 → 25	Condition B + RPE									
	25 → 30	Leaving of the participant									
	30 → 35										
	35 → 40	ID / BEA / Tablet 1 & Polar 4									
	40 → 45	Arrival of the participant	SITE								
	45 → 50	Informed Consent and Project Information	Round Table								
50 → 55	Leaving of the participant										
55 → 60	ID / JAVI F. / Tablet 2 & Polar 8										
60 → 65											
65 → 70											
10h	0 → 5	MoCA	34								
	5 → 10	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	10 → 15	Medical information and medicaments									
	15 → 20	MRI Quest				JAVIS. / Tablet 3 & Polar 10					
	20 → 25	Blood Questionnaire + PA quest				Arrival of the participant	SITE				
	25 → 30	Anthropometry (weight, height and hip height)				52	Resting heart rate + blood pressure				
	30 → 35	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	35 → 40	Condition A + Feeling scale									
	40 → 45	Condition A + RPE									
	45 → 50	Condition B									
50 → 55	Condition B + RPE										
55 → 60	Leaving of the participant										
60 → 65											
65 → 70	ID / BEA / Tablet 1 & Polar 4										
70 → 75	Arrival of the participant	SITE									
75 → 80	Informed Consent and Project Information	Round Table									
80 → 85			Leaving of the participant								
85 → 90			ID / JAVI F. / Tablet 2 & Polar 8								
90 → 95			Arrival of the participant	SITE							
95 → 100			Informed Consent and Project Information	Round Table							
11h	0 → 5	MoCA	34								
	5 → 10	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	10 → 15	Medical information and medicaments									
	15 → 20	MRI Quest				JAVIS. / Tablet 3 & Polar 10					
	20 → 25	Blood Questionnaire + PA quest				Arrival of the participant	SITE				
	25 → 30	Anthropometry (weight, height and hip height)				52	Resting heart rate + blood pressure				
	30 → 35	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	35 → 40	Condition A + Feeling scale									
	40 → 45	Condition A + RPE									
	45 → 50	Condition B									
50 → 55	Condition B + RPE										
55 → 60	Leaving of the participant										
60 → 65											
65 → 70	ID / BEA / Tablet 1 & Polar 4										
70 → 75	Arrival of the participant	SITE									
75 → 80	Informed Consent and Project Information	Round Table									
80 → 85			Leaving of the participant								
85 → 90			ID / JAVI F. / Tablet 2 & Polar 8								
90 → 95			Arrival of the participant	SITE							
95 → 100			Informed Consent and Project Information	Round Table							
12h	0 → 5	MoCA	34								
	5 → 10	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	10 → 15	Medical information and medicaments									
	15 → 20	MRI Quest				JAVIS. / Tablet 3 & Polar 10					
	20 → 25	Blood Questionnaire + PA quest				Arrival of the participant	SITE				
	25 → 30	Anthropometry (weight, height and hip height)				52	Resting heart rate + blood pressure				
	30 → 35	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	35 → 40	Condition A + Feeling scale									
	40 → 45	Condition A + RPE									
	45 → 50	Condition B									
50 → 55	Condition B + RPE										
55 → 60	Leaving of the participant										
60 → 65											
65 → 70	ID / BEA / Tablet 1 & Polar 4										
70 → 75	Arrival of the participant	SITE									
75 → 80	Informed Consent and Project Information	Round Table									
80 → 85			Leaving of the participant								
85 → 90			ID / JAVI F. / Tablet 2 & Polar 8								
90 → 95			Arrival of the participant	SITE							
95 → 100			Informed Consent and Project Information	Round Table							
13h	0 → 5	MoCA	34								
	5 → 10	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	10 → 15	Medical information and medicaments									
	15 → 20	MRI Quest				JAVIS. / Tablet 3 & Polar 10					
	20 → 25	Blood Questionnaire + PA quest				Arrival of the participant	SITE				
	25 → 30	Anthropometry (weight, height and hip height)				52	Resting heart rate + blood pressure				
	30 → 35	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	35 → 40	Condition A + Feeling scale									
	40 → 45	Condition A + RPE									
	45 → 50	Condition B									
50 → 55	Condition B + RPE										
55 → 60	Leaving of the participant										
60 → 65											
65 → 70	ID / BEA / Tablet 1 & Polar 4										
70 → 75	Arrival of the participant	SITE									
75 → 80	Informed Consent and Project Information	Round Table									
80 → 85			Leaving of the participant								
85 → 90			ID / JAVI F. / Tablet 2 & Polar 8								
90 → 95			Arrival of the participant	SITE							
95 → 100			Informed Consent and Project Information	Round Table							
14h	0 → 5	MoCA	34								
	5 → 10	Resting heart rate + blood pressure	Lab1	Informed Consent and Project Information	Round Table						
	10 → 15	Medical information and medicaments									
	15 → 20	MRI Quest				JAVIS. / Tablet 3 & Polar 10					
	20 → 25	Blood Questionnaire + PA quest				Arrival of the participant	SITE				
	25 → 30	Anthropometry (weight, height and hip height)				52	Resting heart rate + blood pressure				
	30 → 35	GET READY FOR CONDITION	GYM floor 0	Informed Consent and Project Information	Lab2						
	35 → 40	Condition A + Feeling scale									
	40 → 45	Condition A + RPE									
	45 → 50	Condition B									
50 → 55	Condition B + RPE										
55 → 60	Leaving of the participant										
60 → 65											
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70 → 75	Arrival of the participant	SITE									
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80 → 85			Leaving of the participant								
85 → 90			ID / JAVI F. / Tablet 2 & Polar 8								
90 → 95			Arrival of the participant	SITE							
95 → 100			Informed Consent and Project Information	Round Table							

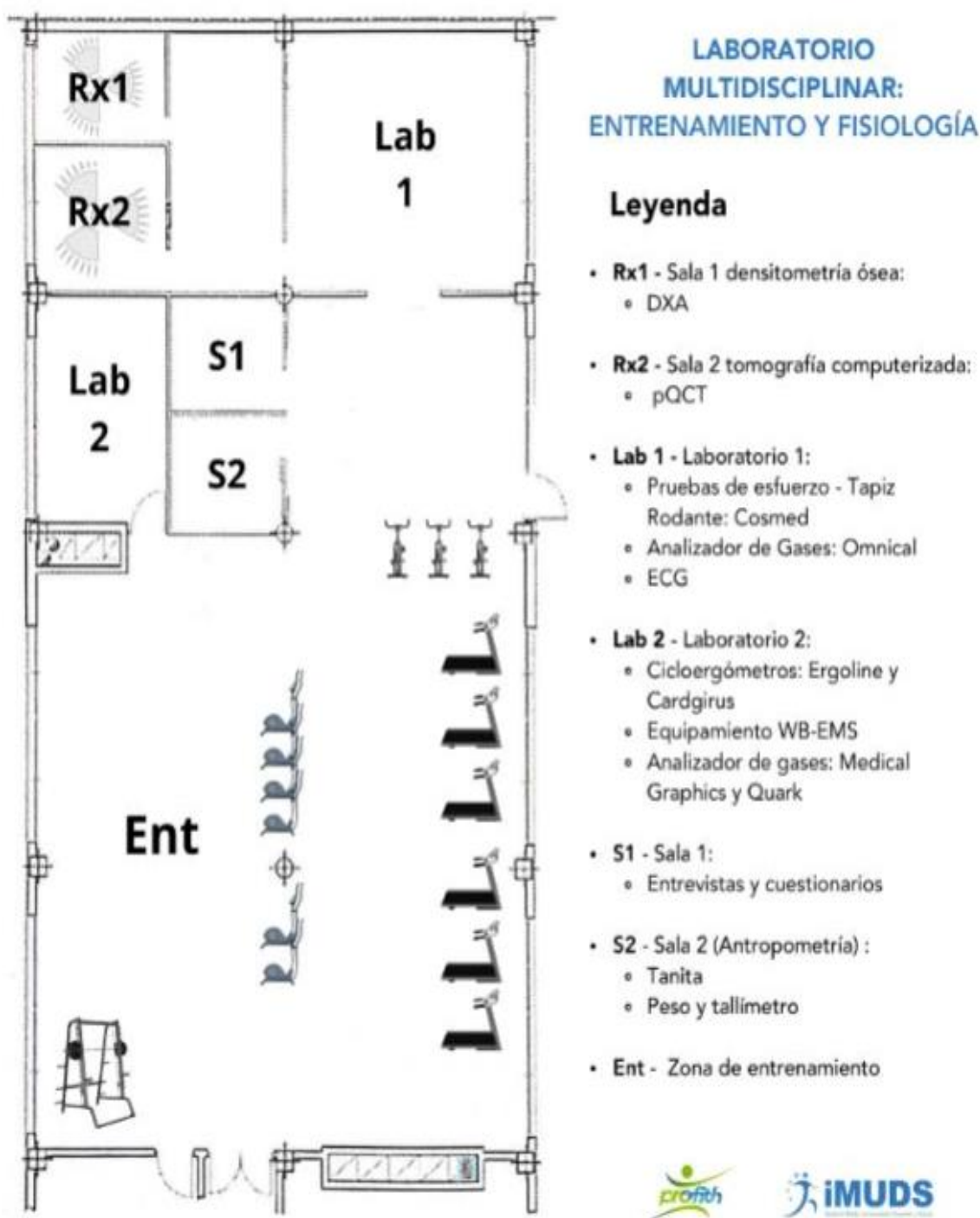


Figure 5. Names and places of the Lab in floor 2.



5. Annexes

- Annex A. 2.1 Standard Messages