

Manual of Procedures FLADEX Project

MOP Chapter 2: Logistics



Promoting Fitness & Health
through Physical Activity



UNIVERSIDAD
DE GRANADA

Chapter 2: Logistics

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1. Introduction

The main objective of this chapter is to present in a summarized form the general logistics of the flADex project, a counterbalanced crossover trial that will include 20 older adults aged 68 to 83 with non-pathological brain amyloid status (<12 centiloid) and APOE e4 noncarriers. Here you can find an index of the chapters that describe each of the protocols that will be carried out in the flADex project, the evaluation schedule, and the organization of each of the visits. In addition, the access protocols to the facilities and the contact information of the staff are detailed.

2. Index of chapters

- **Chapter 1.** Ethics committee and insurance
- **Chapter 2.** Logistics
 - 2.1. Familiarization
- **Chapter 3.** Recruitment, eligibility and screening
- **Chapter 4.** Randomization and data management
 - 4.1. Randomization
 - 4.2. Data management
- **Chapter 5.** Cognitive assessments and questionnaires
 - 5.1. Cognitive assessments
 - 5.2. Questionnaires
- **Chapter 6.** Blood samples
- **Chapter 7.** Magnetic Resonance Imaging (MRI) assessment
- **Chapter 8.** Exercise intervention

3. Organization

Each participant will be included in all study conditions in a randomized order: (i) moderate aerobic exercise (between 60-70 of the Maximal Heart Rate (HR_{max}); (ii) resistance exercise (4-6 Moderate intensity of Rate of Perceived Exertion) and (iii) control resting condition. Each condition, lasting 30 minutes, will be performed once. Each participant will have 4 visits (1 familiarization visit and 3 condition visits). The organization of the project is described in the following sections.

3.1. Visits organization

The FIADeX project will consist of 3 waves: the first and second waves will include 9 participants each, and the third wave will include 2 participants. Each wave will span 4 weeks, with week 1 dedicated to the familiarization visit, and weeks 2, 3, and 4 for the condition visits. Each day of the condition visits will involve 3 participants (“Part1” to “Part20” in orange boxes) for the intervention. **Figure 1** illustrates the overall organization of the entire project.

2024	SEPT-OCT 2024											
	WEEK 1			WEEK 2			WEEK 3			WEEK 4		
<	Monday 23	WeD 25	Thurs 26	Monday 30	WeD 2	Thurs 3	Monday 7	WeD 9	Thurs 10	Monday 14	WeD 16	Thurs 17
Part1				V1			V2			V3		
Part2												
Part3												
Part4												
Part5	Phone call	FAM V0			V1			V2			V3	
Part6												
Part7						V1			V2			V3
Part8												
Part9												
2024	OCT-NOV 2024											
	WEEK 1			WEEK 2			WEEK 3			WEEK 4		
Participant	Monday 21	WeD 23	Thurs 24	Monday 28	WeD 30	Thurs 31	Monday 4	WeD 6	Thurs 7	Monday 11	WeD 13	Thurs 14
Part10				V1			V2			V3		
Part11												
Part12												
Part13												
Part14	Phone call	FAM (V0)			V1			V2			V3	
Part15												
Part16						V1			V2			V3
Part17												
Part18												
2024	NOV-DIC 2024											
	WEEK 1			WEEK 2			WEEK 3			WEEK 4		
Participant	Monday 18	WeD 20	Thurs 21	Monday 25	WeD 27	Thurs 28	Monday 2	WeD 4	Thurs 5	Monday 9	WeD 11	Thurs 12
Part19						V1			V2			V3
Part20												
	Phone call	FAM (V0)										

Figure 1. Organization of visits for the three waves.

3.2. Organization during familiarization visit

The familiarization visit, in week 1 of each wave, will take place at iMUDS (Instituto Mixto Universitario Deporte y Salud). In summary, the following labs will be used: (i) Floor 0: round table (teaching room) and gym; and (ii) Floor 1: room 34, Lab1, Rx2, S1 and S2. **Figure 2** shows the sites that are going to be used during the familiarization visit.

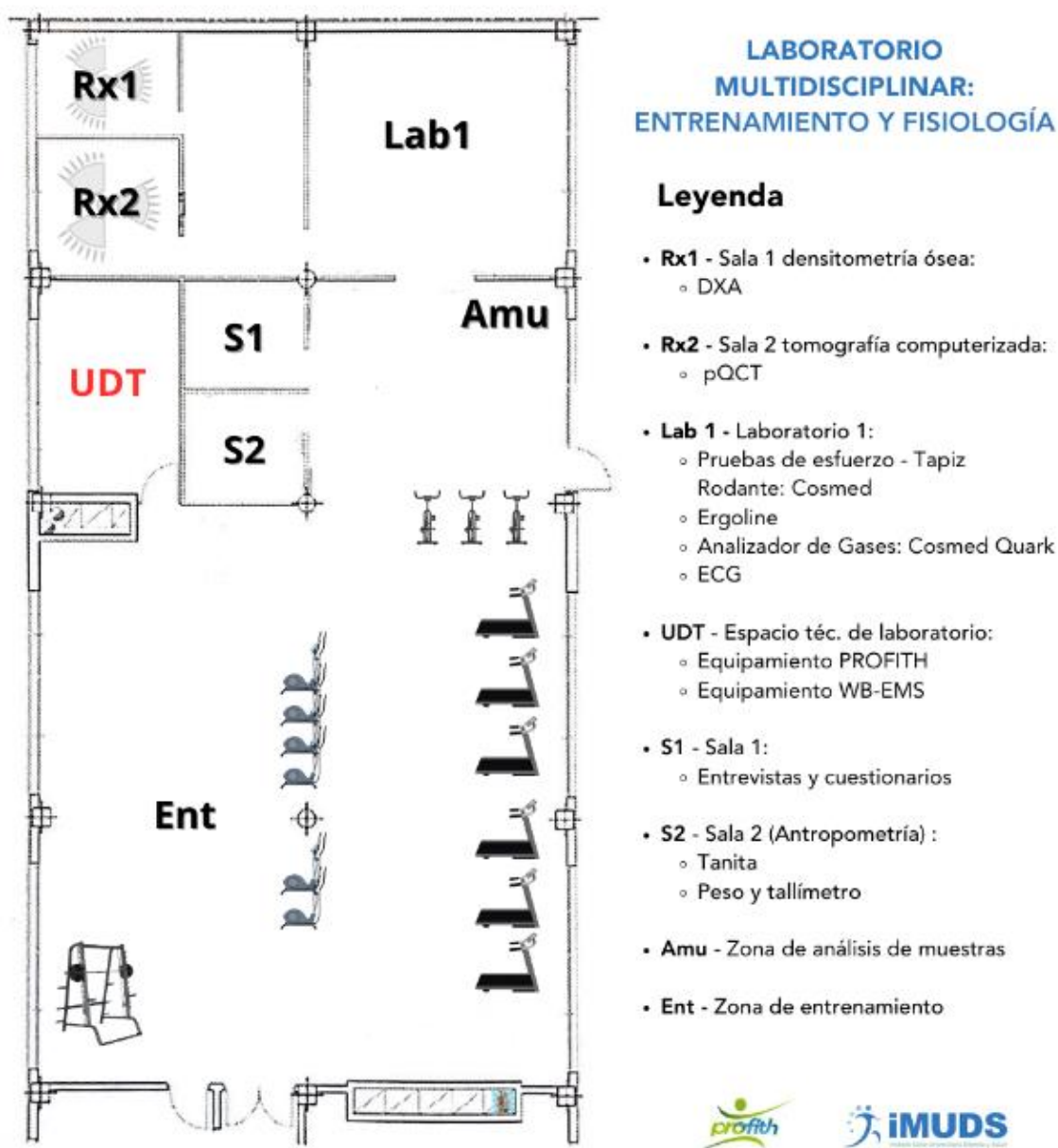


Figure 2. Sites at iMUDS for familiarization visit.

Figure 3 illustrates the organization and sites to be visited during the familiarization sessions (example for three participants and three trainers). The number of participants attending each familiarization day will vary by wave, depending on their availability. Initially, 12 participants will attend for the first wave of the project, followed by 6 participants for the second wave and 2 participants for the third wave. The timing of the familiarization will depend on the number of participants for each familiarization day, but the structure will remain consistent, commencing immediately after the previous participant finish the familiarization. Each trainer will accommodate a maximum of 4 participants per familiarization day.

For more information regarding familiarization visit check the protocol “2.1. FAMILIARIZATION”.

	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	MoCA	34	Informed Consent and Project Information	Round Table					
	35 → 40	Resting heart rate + blood pressure								
	40 → 45	Medical information and medicaments	Lab1			JAVI S. / Tablet 3 & Polar 10				
	45 → 50	MRI Quest								
	50 → 55	Blood Questionnaire + PA quest		MoCA	34	Arrival of the participant	SITE			
	55 → 60	Anthropometry (weight, height and hip height)	S2	Resting heart rate + blood pressure	Informed Consent and Project Information	Round Table				
0 → 5	GET READY FOR CONDITION	GYM floor 0	Medical information and medicaments	S1						
5 → 10	Condition A + Feeling scale		MRI Quest				MoCA	34		
10 → 15	Condition A + RPE		Blood Questionnaire + PA quest							
15 → 20	Condition B		Anthropometry (weight, height and hip height)	S2	Resting heart rate + blood pressure					
20 → 25	Condition B + RPE		GET READY FOR CONDITION	GYM floor 0	Medical information and medicaments	Rx2				
25 → 30	Leaving of the participant		Condition A + Feeling scale		MRI Quest					
30 → 35		Condition A + RPE	Blood Questionnaire + PA quest		Anthropometry (weight, height and hip height)		S2			
35 → 40		Condition B								
40 → 45		Condition B + RPE								
45 → 50		Leaving of the participant			Condition A + Feeling scale		GYM floor 0			
50 → 55				Condition A + RPE						
55 → 60				Condition B						
10h	0 → 5					Condition B + RPE				
	5 → 10					Leaving of the participant				

different procedures to be performed during the visit. '1001' refers to the first participant of the day, '1002' to the second, and '1003' to the third. The sites we will use at CIMCYC will be: Laboratory 11 in floor 1 (cabins 102, 104, 106, 108, 112 and 115), Laboratory 4 in floor 2 and MRI scan in floor 0.

Time	Mins	1001	1002	1003
8h	0 → 5			
	5 → 10	Arrival or the participant (FLOOR 0, small cabin)		
	10 → 15	Explanation of the protocol & site		
	15 → 20	Reminder of the condition + POMS quest		
	20 → 25	PRE quests + blood pressure		
	25 → 30	MRI info (participant go into the MRI)		
	30 → 35	MRI		
	35 → 40	MRI	Arrival or the participant (FLOOR 0, small cabin)	
	40 → 45	MRI	Explanation of the protocol & site	
	45 → 50	MRI	Reminder of the condition + POMS quest	
	50 → 55	Go to Lab11 by lift (FLOOR 1)	PRE quests + blood pressure	
	55 → 60	Cognitive tests PRE	MRI info (participant go into the MRI)	
9h	0 → 5	Cognitive tests PRE	MRI	
	5 → 10	Cognitive tests PRE	MRI	Arrival or the participant (FLOOR 0, small cabin)
	10 → 15	BLOOD draw PRE	MRI	Explanation of the protocol & site
	15 → 20	GET READY FOR CONDITION	MRI	Reminder of the condition + POMS quest
	20 → 25	Condition + Feeling scale	Go to Lab11 by lift (FLOOR 1)	PRE quests + blood pressure
	25 → 30	Condition + RPE	Cognitive tests PRE	MRI info (participant go into the MRI)
	30 → 35	Condition	Cognitive tests PRE	MRI
	35 → 40	Condition + RPE	Cognitive tests PRE	MRI
	40 → 45	Condition	BLOOD draw PRE	MRI
	45 → 50	Condition + RPE + Feeling scale + CHANGE CLOTHES	GET READY FOR CONDITION	MRI
	50 → 55	Blood draw POST T1 (0 min after condition)	Condition + Feeling scale	Go to Lab11 by lift (FLOOR 1)
	55 → 60	PACES + Blood pressure (in MRI)	Condition + RPE	Cognitive tests PRE
10h	0 → 5	Go to MRI by lift (FLOOR 0)	Condition	Cognitive tests PRE
	5 → 10	Prepare MRI POST	Condition + RPE	Cognitive tests PRE
	10 → 15	MRI	Condition	BLOOD draw PRE
	15 → 20	MRI	Condition + RPE + Feeling scale + CHANGE CLOTHES	GET READY FOR CONDITION
	20 → 25	MRI	Blood draw POST T1 (0 min after condition)	Condition + Feeling scale
	25 → 30	MRI	PACES + Blood pressure (in MRI)	Condition + RPE
	30 → 35	MRI	Go to MRI by lift (FLOOR 0)	Condition
	35 → 40	Go to Lab11 by lift (FLOOR 1)	Prepare MRI POST	Condition + RPE
	40 → 45	Blood draw POST T2 (50 min after condition)	MRI	Condition
	45 → 50	Cognitive tests POST	MRI	Condition + RPE + Feeling scale + CHANGE CLOTHES
	50 → 55	Cognitive tests POST	MRI	Blood draw POST T1 (0 min after condition)
	55 → 60	Cognitive tests POST	MRI	PACES + Blood pressure (in MRI)
11h	0 → 5	Blood draw POST T3 (70 min after condition)	MRI	Go to MRI by lift (FLOOR 0)
	5 → 10	POMS quest	Go to Lab11 by lift (FLOOR 1)	Prepare MRI POST
	10 → 15	BREAKFAST	Blood draw POST T2 (50 min after condition)	MRI
	15 → 20	BREAKFAST	Cognitive tests POST	MRI
	20 → 25		Cognitive tests POST	MRI
	25 → 30		Cognitive tests POST	MRI
	30 → 35		Blood draw POST T3 (70 min after condition)	MRI
	35 → 40		POMS quest	Go to Lab11 by lift (FLOOR 1)
	40 → 45		BREAKFAST	Blood draw POST T2 (50 min after condition)
	45 → 50		BREAKFAST	Cognitive tests POST
	50 → 55			Cognitive tests POST
	55 → 60			Cognitive tests POST
12h	0 → 5			Blood draw POST T3 (70 min after condition)
	5 → 10			POMS quest
	10 → 15			BREAKFAST
	15 → 20			BREAKFAST

Figure 4. Condition visits organization.

The staff in charge of the condition visits will be as follows:

- Project manager: Isabel Martin-Fuentes
- Trainers for the conditions: Beatriz Fernández, Javier Fernández and Javier Martínez.
- MRI: technician José Manuel; researcher in charge: Isabel Martín.
- Cognitive assessments: Andrea Coca.
- Blood draws: 1. Alejandro Vega Córdoba
2. Cristina Fernández Mancilla
3. María José Sánchez Polo
4. Ignacio López -Lendinez Ruiz
5. Elena Vilchez Luzon
- Blood management and processing: Marcos Olvera, Emilio Barranco and José David Marín.

The staff in charge of other tasks:

- Responsible of visit conditions, familiarization visit, calls to participants and reminders for visits: Beatriz Fernández.
- Responsible of assessments/intervention and MRI scans: Isabel Martín.
- Responsible of MRI quality control review: Andrea Coca (MPRAGE sequence), Lucía Sánchez (pCASL sequence).
- Responsible of cognitive assessments: Andrea Coca.
- Responsible of blood samples and management of blood material: Marcos Olvera.
- Responsible 1 of REDCap platform review: Javier Martínez.
- Responsible 2 of REDCap platform review: Isabel Martín.
- Management of breakfast: Javier Fernández.

3.4. Previous conditions

Each visit must adhere to specific prior conditions to ensure rigorous standardization and minimize any potential bias in participants' performance during the evaluations. These conditions will include guidelines on food intake the day before and on the day of the evaluations, as well as the amount of physical exercise performed and the hours of rest. The same recommendations will apply to all three visit conditions. A total of 3 annexes outlining these prior conditions will be provided via WhatsApp to the participants to facilitate access to this information:

- For first participant in each visit condition: Annex 2.1. Prev_cond_part_1.docx
- For second participant in each visit condition: Annex 2.2. Prev_cond_part_2.docx
- For third participant in each visit condition: Annex 2.3. Prev_cond_part_3.docx

4. Calendar – chronogram

Figure 5 presents a general calendar of the flADeX study. It provides a visual representation of all the phases the flADeX projects will go through, from the start of the ethics committee request to the completion of the assessments/intervention.

The assessments/intervention were scheduled to take place in three waves, between the end of September and the end of December.

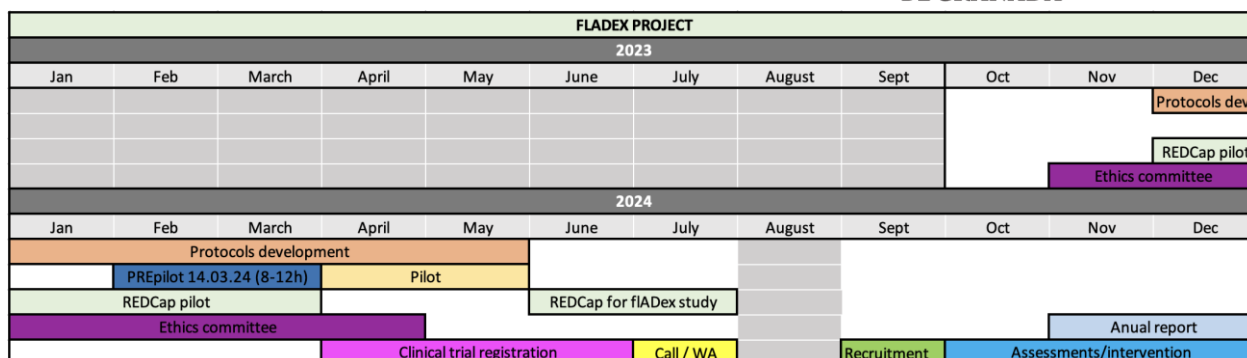


Figure 5. Overall flADeX project schedule.

5. Protocol of access and booking

The project will be conducted at two different centers, each of which will have a specific access protocol for researchers involved in the flADeX project:

5.1. iMUDS

This will be the site for the familiarization visit in week 0 of each wave. Reservations must be made before the beginning of the project. To access common areas, the Principal Investigator (PI) of the project, Irene Esteban Cornejo, must request access for the relevant staff by emailing the center's director, Jonatan Ruiz (ruizj@ugr.es, cc'ing the reception staff), specifying the following information:

ACCESS AUTHORIZATION to iMUDS for the following researcher:

- Responsible party:
 - Name; Surname, ID: xxx
- Accompanying persons:
 - Name; Surname, ID: xxx
- AUTHORIZED AREAS:
 - Meeting room at iMUDS.
- SCHEDULE AND HOURS:
 - Day of the week, day-month-202X, time slot (e.g., 16:00-20:00).

After that, the researcher in charge, Javier Sánchez, will have to book the specified sites in google calendar with the label "Fladex_34_Lab1 _Rx2_S1_S2".

5.2. CIMCYC (Centro de Investigación, Mente, Cerebro y Comportamiento):

This center will host all the assessments and intervention (MRI scans, blood draws, conditions, cognitive tests...) It is very important to book all the facilities in advance, as soon as the schedule is known. Within the CIMCYC the facilities that we will use are as follows:

5.2.1. Laboratory 11, floor 1: to perform the experimental conditions (102, 104 & 115), blood draws and blood pipetting (cabins 106 & 108), and the cognitive tests (cabin 112).

First, PI, Irene Esteban Cornejo should send an email to the director of Laboratory 11, Antonio Candido Ortiz (acandido@ugr.es) to request the use of the facilities. In this email, Andrés Catena (acatena@ugr.es), collaborator of the flADeX project should be copied (cc).

Once the request is approved, the reservation for the sites must be made through the Google Calendar “LAB 11 (CIMCYC),” specifying “Fladex: 106 (8:30h-12:10h) / 108 (10:00h-13:00h) / 102 and 104 (9:20h-11:00h) / 112 (8:55h-12:00h) / 115 (9:20h-11:00h)” and using the provided credentials:

ID: fladex@ugr.es

The team must also post a schedule on all the doors of Laboratory 11, indicating the locations to be used, along with the corresponding dates and times.

The project manager (Isabel Martín) must maintain constant communication with the staff working in Laboratory 11 to stay updated on the organization and proper use of the facilities.

5.2.2. Laboratory 4, floor 2: to perform the blood processing in the centrifuge device.

Researchers in charge of the blood processing (Marcos Olvera and Emilio Baranco) must contact the staff of the Laboratory 4 (Stella Algarra López, xxxx) to manage the blood processing.

5.2.3. MRI scan, floor 0: to welcome the participants and perform the MRI procedure.

The reservation for the MRI scan at the CIMCYC can be made through: <https://cic.ugr.es/acceso.php>; User type: UGR Users; xxxx.

1. To do this, a ‘service request’ must be made (see Figure 6), stating that the MRI is being reserved for the flADeX Project. After this, a code will be generated to confirm the reservation.



Figure 6. CIC Service Request.

2. To complete the reservation, follow the steps specified in Figure 7 (1. Select month and year; 2. Select day; 3. Choose one or more time slots; 4. Click the ‘add slot(s)’ button; and 5. Click the ‘submit request’ button).

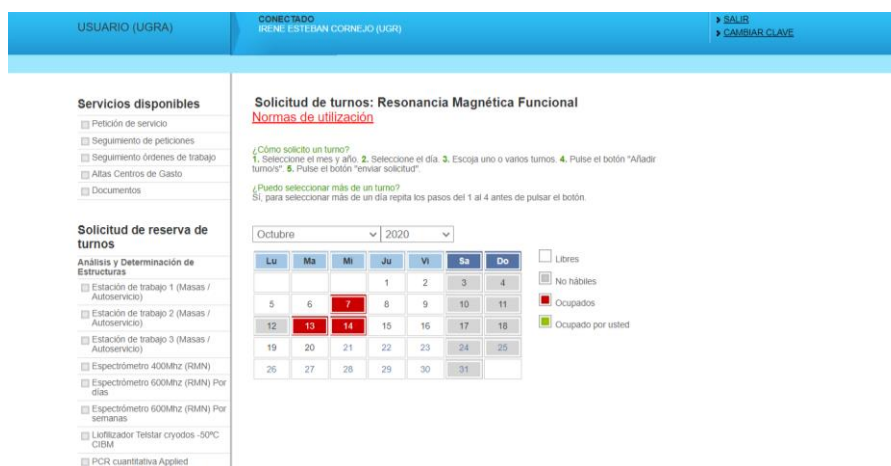


Figure 7. MRI Reservation, CIC.

*Additionally, we are using the facilities of the Faculty of Pharmacy (located near the CIMCYC) for the disposal of biological waste from blood draws. The researchers in charge of blood processing (Marcos Olvera and Emilio Barranco) should contact the faculty staff for this purpose (Ángel, xxxx). They must take the containers whenever needed, go to the site at the Faculty of Pharmacy and exchange them for a clean one.

6. Economic management

6.1. Invoices

The procedure for purchasing materials through the flADex project's expense account is very important to follow, as failing to adhere to the established steps will prevent these purchases from being made.

1. The first step is to request a proforma invoice or quote from the company for the items we are interested in purchasing. The buyer's information that must be included is as follows:
University of Granada, Address: CUESTA DEL HOSPICIO, S/N - 18012 - GRANADA - (GRANADA) - SPAIN
VAT ESQ1818002F
2. If the purchase exceeds €3000, it will be necessary to request three proformas from different companies to process the payment through the university.
3. Once the proformas are obtained, the Principal Investigator (PI), Irene Esteban Cornejo, must send them to the administrative manager, Elena/Jose, via email at edufisi@ugr.es.
4. After the proforma is approved by the university's internal services, a 'Cómprame' (Purchase Order) will be generated and sent to the company. Once this happens, the company can upload the invoice using this 'Cómprame.'
5. Finally, the PI must validate the invoice, and the purchase will be completed."

6.2. Payment to participants

Participants will receive some "gifts" as a token of gratitude for their participation in the project:

- A T-shirt with the logo of the flADex project.
- A compensation of €30 for volunteering to participate.

Participants will need to provide their bank account number and a photocopy of their DNI during the familiarization day. Beatriz Fernández will be in charge to provide this information to the department administration after each wave of the project. For this purpose, some documents must be completed ("Annex 2.4. SUJETOS EXPERIMENTALES-Modelo pago sujeto.docx" and "Annex 2.5. SUJETOS EXPERIMENTALES-Modelo Memoria IP.docx", and).

These documents will then be sent to the administration of the department of the Faculty of Sports Science (edufisi@ugr.es) for processing.

7. Prints

For the necessary photocopies required to conduct the visits of the flADeX project, there is an account under this project (flADeX-Irene Esteban Cornejo) at the copy shop of the Faculty of Medicine, located on the ground floor of the main building (to the right of the reception, at the end of the hallway on the left). Therefore, an email should be sent to gracofaxmedicina@gmail.com with the documents to be printed, specifying that they should be charged to the account of Irene Esteban – flADeX project. Once we receive confirmation of the printing, the documents can be picked up at the copy shop.

8. Potential setbacks

8.1. Participants drop out during the project

We may face different situations:

1. The participant regrets volunteering to participate in the project before starting, but after the phone screening. Actions:
 - In this situation, the researcher in charge (Beatriz Fernández) must record this information in the phone screening form in REDCap, explaining the reason for the dropout. Another participant from the list will then be contacted.
2. The participant, after passing the phone screening, is unable to perform the familiarization session for any reason (inability to perform any of the conditions, detection of any exclusion criteria...). Actions:
 - We are performing the familiarization visit for some extra participants as backup list just in case any adverse situation occurs. In this situation, we must first inform the participant that is not eligible for the project, and then contact another participant from the backup list to check whether is available to join that wave.
 - If for any reason there are no more participants in the backup list who have complete the familiarization session and with availability for that wave, we will aim to conduct the familiarization session for a new participant from the phone list within the same week (week 1). This new participant will then be able to begin visit 1 of the project the following week (week 2) along with the rest of the participants in that wave.
3. The participant regrets volunteering to participate in the project after starting and after any visit has been completed. Actions:
 - The trainer in charge of that condition visit must record that information in the “Quest Pre Condition” form in REDCap. In the ítem “Participant assist to the visit” we must select “no” and provide the reason in the corresponding text box.
 - The researcher in charge (Beatriz Fernández) will contact another participant from the list to be incorporated in the last wave.

8.2. Adverse event report

If a participant experiences an adverse event during the execution of any of the conditions or during the assessments, this information will be recorded in the REDCap database in the “Adverse Event Report” form, selecting the options that best describe the adverse event and providing a detailed explanation of the event.

Then, the adverse event will be discussed within the work team of the project to determine the appropriate course of action for that participant.

8.3. Death report

In the unfortunate event that a study participant passes away while participating in the study, necessary steps must be taken to discontinue contact with the participant. This information will be documented in the REDCap database in the “Adverse Events Records” form, selecting the respective option in the question titled: “**Led the adverse event to any of this situation?**”.

9. Annexes

- Annex 2.1. Prev_cond_part_1.docx
- Annex 2.2. Prev_cond_part_2.docx
- Annex 2.3. Prev_cond_part_3.docx
- Annex 2.4. SUJETOS EXPERIMENTALES-Modelo pago sujeto.docx
- Annex 2.5. SUJETOS EXPERIMENTALES-Modelo Memoria IP.docx