

Judo for intellectual disability project

Submission date 13/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2024	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 11/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Scientific evidence supports that physical activity and adequate nutrition can enhance the quality of life of individuals with intellectual disabilities (ID). The aim of this study is to assess the effects of a sports program based on judo, together with actions aimed at improving nutritional habits, for adolescents with intellectual disabilities.

Who can participate?

Adolescents between 14 and 22 years old with a mild to moderate degree of intellectual disability

What does the study involve?

One group will be exclusively made up of participants with ID, while another will be integrated into the regular classes of a judo club together with participants without ID. The control group will consist of adolescents with ID who do not participate in extracurricular sports activities. The judo sessions take place in a large and well-ventilated space with a 120 m² tatami made of high-density foam. Each participant wears a judogi, which includes a jacket, pants and belt. Sessions last 60 minutes and are led by two black belt teachers, supported by four volunteer instructors. The sessions are divided into three parts: warm-up, main judo exercise and cool down. They include general movements and landing techniques, simplified judo-specific movements and sets, ground control and throwing techniques, and repetitions of basic technical movements. The instruction method follows a principle of gradual progression, allowing participants to progress at their own pace through guided imitation and modeling of techniques. At the same time, initiatives to improve nutritional habits will be carried out jointly in the family environment and during judo sessions. At the end of each judo session, it will be established that each participant consumes fresh fruit, requiring the collaboration of families to facilitate this action. Subsequently, in the family environment, each occasion in which fruit or vegetables are consumed must be documented through photographs, which will be uploaded to an exclusive mobile application for participants, family members, researchers and teachers. Gamified rewards will be established to encourage the consumption of healthy foods. Finally, the results will be compared in the period before and after the intervention.

What are the possible benefits and risks of participating?

The practice of judo is expected to improve quality of life, physical condition and nutritional habits. There is no risk of negative effects.

Where is the study run from?
Ramón Llull University (Spain)

When is the study starting and how long is it expected to run for?
September 2023 to December 2026

Who is funding the study?
European Education and Culture Executive Agency

Who is the main contact?
Dr Jose Morales, josema@blanquerna.url.edu

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Longitudinal study of the effects of a sports program based on judo for adolescents with intellectual disabilities

Acronym

Study objectives

Based on the formulated objectives, the following hypotheses are proposed, taking into account those situations in which statistical significance can be obtained ($P < 0.05$): The group of adolescents with ID who participate in the judo program will present better results in the indicators of physical condition, nutritional habits, social interaction and quality of life. A secondary hypothesis that is formulated is based on the fact that the group that participates in regular judo sessions with adolescents without ID will present better results than the group that exclusively attends the sessions with subjects with ID in the evaluated indicators.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/02/2024, Research Ethics Committee of the Ramon Llull University (Claravall Street, 1, 3, District de Sarrià-Sant Gervasi, Barcelona, 08022, Spain; +34 (0)936 02 22 00; rbabington@rektorat.url.edu), ref: CER URL_2023_2024_011

Study design

Simple crossover quasi-experimental with random groups and non-probabilistic convenience sampling

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Adolescents with intellectual disabilities

Interventions

Participation in a judo-based sports program for 2 days per week during a school year

The design of the study is a simple crossover, quasi-experimental with random groups and non-probabilistic convenience sampling. The independent variable (group) will have three levels: a) a group with isolated ID, b) an inclusive group of subjects with ID plus participants without ID, and c) a control group composed of subjects who do not practice any extracurricular physical activity and come from special education centers and schools. In order to comply with ethical recommendations, two intervention periods will be established so that participants who commit according to their availability can participate in an intervention period, attending regular judo sessions with adolescents without disabilities and another intervention period attending judo sessions exclusively with subjects with intellectual disabilities.

The judo sessions take place in a large and well-ventilated space with a 120 m² tatami made of high-density foam. Each participant wears a judogi, which includes a jacket, pants and belt. Sessions last 60 minutes and are led by two black belt teachers, supported by four volunteer instructors. The sessions are divided into three parts: warm-up, main judo exercise and cool down. They include general movements and landing techniques, simplified judo-specific movements and sets, ground control and throwing techniques, and repetitions of basic technical

movements. The instruction method follows a principle of gradual progression, allowing participants to progress at their own pace through guided imitation and modeling of techniques.

At the same time, initiatives to improve nutritional habits will be carried out jointly in the family environment and during judo sessions. At the end of each judo session, it will be established that each participant consumes fresh fruit, requiring the collaboration of families to facilitate this action. Subsequently, in the family environment, each occasion in which fruit or vegetables are consumed must be documented through photographs, which will be uploaded to an exclusive mobile application for participants, family members, researchers and teachers. Gamified rewards will be established to encourage the consumption of healthy foods. Finally, the results will be compared in the period before and after the intervention.

Intervention Type

Behavioural

Primary outcome(s)

1. Physical fitness evaluated with the ALPHA-FITNESS battery
2. Quality of life in adolescents evaluated with the KIDSLIFE scale
3. Nutritional habits evaluated using the KIDMED questionnaire. An app will be created to monitor and record the consumption of healthy foods, in which they can compare and encourage themselves with the rest of the participants.
4. Satisfaction with the program evaluated using the Physical Activity Enjoyment Scale (PACES)

All evaluations will be carried out at the beginning and end of the intervention

Key secondary outcome(s)

A secondary measure that is evaluated is the comparison of the results according to the group, since the participants will be carried out in two modalities: an isolated group (where all participants have ID) and an inclusive group (where the group is made up of adolescents. with and without ID). All evaluations will be carried out at the beginning and end of the intervention.

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Adolescents (of both sexes) between 14 and 22 years old
2. A degree of severity of ID between light and moderate according to the support intensity scale for children and adolescents (SIS-C) by Verdugo et al. (2014), making it clear that it is adaptive behavior and not IQ that will determine inclusion in the program

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

14 years

Upper age limit

22 years

Sex

All

Total final enrolment

110

Key exclusion criteria

1. Presenting a severity of ID greater than mild and moderate according to the SIS-CI scale
2. Being less than 14 years old or more than 22 years old
3. Being incapable of performing any of the tests
4. Being incapable of carrying out moderate-vigorous physical activity
5. Not committing to participate actively and regularly in the training sessions of the experimental groups
6. For the members of the group control, who participate in some extracurricular activity based on sports or physical activity

Date of first enrolment

06/02/2024

Date of final enrolment

30/09/2025

Locations**Countries of recruitment**

Greece

Ireland

Italy

Portugal

Spain

Switzerland

Study participating centre

University of Genoa

Via Balbi, 5

Genova

Italy

16126

Study participating centre
Universitat Ramon Llull Fundacio
Claravall Street, 1
Barcelona
Spain
08022

Study participating centre
Judo Assist Ireland
Corravalley
Ardcroney
Nenagh Tipperary
Ireland
067

Study participating centre
Sport Evolution Alliance CRL
Rua Joao Luis De Moura 22, 1
Porto Salvo
Portugal
2740-071

Study participating centre
Real Federación Española de Judo y Deportes Asociados
Ferraz Street, 16
Madrid
Spain
28008

Study participating centre
Interdisciplinary Network of Special and Intercultural Education INCLUDE
KEAS
Thessaloniki
Greece
54638

Study participating centre

SO Europe Eurasia Foundation

42 Mount Street
Upper 2nd Floor
Dublin 2
Ireland
D02 DV52

Study participating centre**Swiss Adaptive Judo**

Zechhaldenstrasse 1
Rebstein
Switzerland
9445

Sponsor information**Organisation**

Ramon Llull University

ROR

<https://ror.org/04p9k2z50>

Funder(s)**Funder type**

Government

Funder Name

European Education and Culture Executive Agency

Alternative Name(s)

European Education & Culture Executive Agency, Education, Audiovisual and Culture Executive Agency, Agence exécutive européenne pour l'éducation et la culture, Europäische Exekutivagentur für Bildung und Kultur, EACEA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

During the first month of the project, a Data Management Plan (PGD) will be carried out that will establish how the data will be managed during the duration of the project and its continuity, however, it will be reviewed and modified if needed throughout the project. of the development and execution of the project. To carry it out, CORA EINA DMP will be used (an adapted version based on the model created by the Center for Digital Curation), a tool that guarantees that data management complies with the FAIR principles (Findable, Accessible, Interoperable and Reusable). The obtaining, processing, conservation, communication and transfer of data will be done in accordance with the provisions of the General Data Protection Regulation of the European Union and Organic Law 3/2018, of December 5, on data protection and guarantees of digital rights all data obtained will be analyzed and used only for the scientific objectives of the study.

The primary data will be collected through registration sheets and preserved in the following way: pseudonymized (coded). Pseudonymization is the processing of personal data in such a way that they cannot be attributed to a data subject without the use of additional information. Therefore, the participants will be pseudonymized, leaving the identification codes only in the hands of the PIs and the field research team. The regulations that regulate the processing of personal data give participants the right to access their data, object, correct it, cancel it, limit its processing, restrict or request its deletion. They may also request a copy of it or for it to be sent to a third party (right of portability). The data will be stored in CSV, xlsx or txt formats in a virtual folder at Blanquerna-Ramon Llull University (B-URL), with limited access to researchers.

With the aim of offering open access and giving visibility to the data obtained in the project, once completed (approximately 6 months), the main blocks of the study will be deposited, stored, shared, disseminated and preserved in the data publication repository. in open trust with which the URL (CORA Repositori de Dades de Recerca) participates, a specific repository for data from Catalan universities and CERCA centers. These are published in open access, following the FAIR principles and taking into account ethical and legal aspects, if applicable, through data sets (datasets) made up of the file or files of the research data, an identifier, a description of the formats used, descriptive metadata of the data, the readme file and, if necessary, other context documentation. Said metadata will be indexed in Google Dataset Search, DataCite Search, OpenAIRE and Mendeley Data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/06/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes