Talcahuano, May 20, 2026

Research Project Title:

"Effectiveness of Artificial Intelligence- and Computer Vision-Assisted Telerehabilitation, With and Without Resistance Training, on Disease Impact and Physical Function in People With Fibromyalgia: A Randomized Controlled Trial (FibroIA 2.0)"

Abstract

Fibromyalgia is a highly prevalent primary chronic pain condition in Chile, characterized by widespread musculoskeletal pain, impaired physical function, and reduced quality of life. Therapeutic exercise is considered a first-line non-pharmacological intervention; however, barriers related to access, adherence, and long-term maintenance of its benefits remain. Artificial intelligence (AI)- and computer vision-assisted telerehabilitation may help overcome these limitations, although evidence in individuals with fibromyalgia remains limited.

The primary objective of this study is to compare the effectiveness of AI- and computer vision-assisted therapeutic exercise programs, with and without resistance training, versus usual care, on disease impact and physical function in individuals with fibromyalgia.

A three-arm parallel-group randomized controlled superiority trial with a 1:1:1 allocation ratio, 3-month follow-up, and intention-to-treat analysis will be conducted. The intervention groups will consist of: (1) AI-assisted mobility and stretching exercises plus usual care; (2) AI-assisted combined mobility, stretching, and resistance training exercises plus usual care; and (3) a control group receiving usual care only. Interventions will be delivered through the Rehbody telerehabilitation platform, accessible via commonly used electronic devices.

The study involves minimal risk to participants, does not require human or financial resources from primary healthcare facilities, uses interventions recommended by clinical guidelines, and ensures informed consent, data confidentiality, and the right to withdraw voluntarily without affecting usual healthcare.

ClinicalTrials.gov Identifier: NCTXXXXXXXX

Protocol Version: 3.0

PROBLEM STATEMENT

Fibromyalgia (FM) is a primary chronic pain condition currently recognized in the 11th revision of the International Classification of Diseases (ICD-11). In Chile, its prevalence is estimated at approximately 3.3% of the general population, a figure consistent with worldwide prevalence estimates.

Despite its high prevalence, FM remains a condition of uncertain etiology and complex clinical management. It is characterized by persistent widespread musculoskeletal pain accompanied by fatigue, sleep disturbances, cognitive difficulties, impaired physical function, and varying degrees of disability, among other symptoms, all of which significantly affect the quality of life of those living with the condition.

The complexity of FM is also reflected in the lack of consensus regarding its treatment. Moderate-certainty evidence indicates that clinicians hold divergent views on whether FM should primarily be understood as a biomedical disorder or as a condition of psychosocial nature. Within this context, healthcare professionals tend to prioritize pain relief as the primary treatment goal. However, this approach is particularly challenging because FM has no known cure, and its symptoms may persist for extended periods, even up to 15 years after disease onset.

From a functional perspective, individuals with FM have been shown to exhibit reduced physical performance, as demonstrated by functional testing, as well as higher levels of disability compared with healthy individuals, largely as a consequence of prolonged exposure to chronic pain. Additionally, this population has been found to engage in higher levels of sedentary behavior, with increases of up to 36.14 minutes per day compared with healthy controls, a pattern associated with adverse metabolic consequences and an increased risk of mental health problems.

In clinical practice, the management of FM includes both pharmacological and non-pharmacological interventions. However, non-pharmacological strategies constitute the cornerstone of treatment, among which therapeutic exercise, in its various forms, is recommended as a first-line intervention, supported by a strong recommendation based on scientific evidence.

JUSTIFICATION AND USE OF RESULTS

Law No. 21.531 on Fibromyalgia and Non-Oncological Chronic Pain is currently in force in Chile and was published in the Official Gazette on February 10, 2023. This law seeks to improve the quality of life of individuals living with these conditions and establishes the right of people with fibromyalgia to receive timely and preferential healthcare, access to treatment, physical and psychological therapies, and information regarding their condition, among other rights. Regarding research, Article 9 states that intersectoral research in basic sciences, clinical aspects, and therapeutic management of the disease shall be promoted and encouraged. It also provides opportunities for both conventional and complementary medicine projects that comply with the high standards established by the fundamental principles of human research, with the aim of contributing to the diagnosis and treatment of fibromyalgia, in accordance with Article 4(b) of Law No. 21.105.

The results of this study may serve as an empirical basis to inform and improve decision-making at the local level, contributing to the development of more effective and responsive rehabilitation programs in the future. Furthermore, the findings may be used to guide rehabilitation management strategies at regional and national levels, ensuring that interventions and resource allocation are aligned with the actual needs of individuals with fibromyalgia and with the technical guidelines proposed by the Chilean Ministry of Health.

THEORETICAL BACKGROUND

Exercise-based therapy (EBT) has been shown to be an effective intervention for managing fibromyalgia (FM) symptoms, including reductions in pain, anxiety, and overall disease impact, as well as improvements in both physical and mental quality of life. In this regard, a systematic review with meta-analysis identified that various exercise modalities, such as circuit-based programs integrating aerobic, strength, endurance, and flexibility components, as well as movement-based practices (e.g., yoga, tai chi, and Pilates), are effective for managing symptoms associated with this condition.

However, recent evidence suggests that not all exercise modalities produce the same clinical effects. In particular, a systematic review concluded that resistance training is the only intervention that has demonstrated significant and clinically meaningful improvements in both the short and long term among individuals with FM. These findings have important clinical implications, as they suggest that resistance training may represent a more effective and feasible approach for pain management compared with other modalities, such as aquatic therapy.

Regarding exercise dosage, evidence indicates that EBT achieves the greatest benefits when delivered with a total volume of 21 to 40 sessions, a frequency of three sessions per week, and a duration of 31 to 60 minutes per session. Furthermore, regular participation in moderate-intensity physical activity over an extended period of up to nine years has been associated with positive long-term effects on functional capacity, pain intensity, disease impact, and quality of life in women with fibromyalgia. These benefits may contribute to reducing the need for pharmacological treatment and promoting more favorable clinical outcomes. Nevertheless, the beneficial effects of these interventions tend to diminish over time, highlighting the need to develop and evaluate strategies aimed at maintaining therapeutic benefits in the long term.

In response to these challenges, artificial intelligence (AI)-assisted exercise prescription and telerehabilitation interventions have emerged as innovative alternatives for addressing the limitations of usual care models. Available evidence indicates that AI-guided exercise prescription in physiotherapy has demonstrated effectiveness across a variety of clinical settings, including low back pain, post-stroke rehabilitation, and cardiovascular rehabilitation. In these contexts, randomized controlled trials and meta-analyses have evaluated AI-based systems capable of providing real-time feedback, personalized exercise programs, and remote monitoring of patient performance. However, there remains a notable lack of studies evaluating the effectiveness of these interventions in individuals with FM, limiting the generalizability of these findings to this specific population.

OBJECTIVES

General Objective

To compare the effects of artificial intelligence- and computer vision-assisted therapeutic exercise programs, with and without resistance training, versus usual care on fibromyalgia impact and physical function in individuals with fibromyalgia.

Specific Objectives

1. To evaluate the effects of an artificial intelligence- and computer vision-assisted mobility and stretching exercise program, compared with usual care, on fibromyalgia impact and physical function in individuals with fibromyalgia.
2. To evaluate the effects of an artificial intelligence- and computer vision-assisted combined mobility, stretching, and resistance training exercise program, compared with usual care, on fibromyalgia impact and physical function in individuals with fibromyalgia.
3. To compare the effects of artificial intelligence- and computer vision-assisted therapeutic exercise programs versus usual care on fibromyalgia impact and physical function in individuals with fibromyalgia.
4. To compare the effects of a combined mobility, stretching, and resistance training program versus a mobility and stretching program on fibromyalgia impact and physical function in individuals with fibromyalgia.
5. To evaluate pain catastrophizing and exercise adherence as secondary outcomes in individuals with fibromyalgia.

RESEARCH HYPOTHESES

Primary Hypothesis

Participants receiving artificial intelligence- and computer vision-assisted telerehabilitation will demonstrate a significantly greater reduction in disease impact after 12 weeks compared with participants receiving usual care.

Secondary Hypothesis

Participants receiving the combined exercise program (mobility plus resistance training) will demonstrate greater improvements in physical function and pain outcomes compared with those receiving the mobility and stretching program.

Null Hypothesis

There will be no significant differences in disease impact or physical function between individuals with fibromyalgia receiving artificial intelligence- and computer vision-assisted telerehabilitation and those receiving usual care.

METHODOLOGY

Operational Definition of Variables

Primary Variables

1. Fibromyalgia Impact: Refers to the negative impact of fibromyalgia on domains related to physical functioning, pain, fatigue, sleep disturbances, memory, hypersensitivity, and other symptoms. It will be assessed using the Spanish-validated version of the Revised Fibromyalgia Impact Questionnaire (FIQ-R).

2. Physical Function: Refers to an individual's actual and objectively measurable ability to perform physical activities and carry out everyday tasks essential for independent living. This domain is based on objective assessments obtained through standardized tests that quantify functional performance. In this study, physical function will be assessed using the 30-Second Sit-to-Stand Test (30s-STS), recorded as the number of repetitions completed.

Secondary Variables

3. Pain Catastrophizing: An exaggerated, negative, and ruminative cognitive-emotional response to actual or anticipated pain that magnifies perceived threat and involves feelings of helplessness. It will be assessed using the 4-item Pain Catastrophizing Scale (PCS-4).

4. Exercise Adherence: Exercise adherence refers to an individual's commitment and consistency in maintaining a long-term exercise program by aligning their behavior with prescribed recommendations regarding attendance, intensity, and exercise technique. It involves the integration of exercise into daily routines and is facilitated by motivation, enjoyment, and social support. It will be assessed using the Exercise Adherence Rating Scale (EARS).

5. Sociodemographic and clinical variables: These correspond to the personal and social characteristics of the participants.

    - Age: Measured in years.
    - Gender: Male, female, or other.
    - Marital Status: Single, married, divorced, widowed, or other.
    - Occupation: Main occupation or primary work activity.
    - Educational level.
    - Comorbidities: Other coexisting medical conditions.
    - Access to technology.
    - Pharmacological treatment: Analgesics, antidepressants, anticonvulsants (type, dose, frequency)
    - Previous exercise experience**.**

Study Design

A three-arm parallel-group randomized controlled trial with a 1:1:1 allocation ratio, superiority design, 3-month follow-up, and intention-to-treat analysis will be conducted. Participants will be randomly assigned to one of the three study groups. The study protocol has been developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines, ensuring that all critical aspects of the design, conduct, and reporting of the clinical trial are adequately addressed.

Study Population, Sample Selection and Size, Unit of Analysis, and Unit of Observation

Study Population

The study population will consist of adults aged 18 years or older, of any sex/gender, with a medical diagnosis of fibromyalgia, who are receiving care within the healthcare network under the jurisdiction of the Talcahuano Health Service and meet the eligibility criteria established in the study protocol.

Sample Selection

Participants will be recruited from the target population. All eligible individuals who meet the inclusion and exclusion criteria and provide written informed consent will be invited to participate during the recruitment period or until the required sample size has been reached.

Following enrollment, participants will be randomly assigned to one of three study groups: (1) an artificial intelligence- and computer vision-assisted mobility and stretching exercise program; (2) an artificial intelligence- and computer vision-assisted combined mobility, stretching, and resistance training exercise program; or (3) a control group receiving usual care.

Randomization Procedure

The randomization sequence will be generated using computer software and variable permuted block sizes to ensure balanced allocation across study groups. The sequence will be generated by an independent researcher who will not be involved in participant recruitment or group allocation.

Allocation concealment will be ensured through the use of sequentially numbered, sealed, opaque envelopes, which will be opened only at the time of participant assignment.

Unit of Analysis and Unit of Observation

The unit of analysis and the unit of observation will be the individual participant diagnosed with fibromyalgia. All outcome assessments will be performed at the individual level at the time points specified in the study protocol.

Sample Size

The sample size was calculated through an a priori power analysis using G*Power software (version 3.1.9.7). For this randomized controlled trial, a fixed-effects Analysis of Covariance (ANCOVA) model was selected to compare three independent groups (two experimental groups and one control group), using the baseline measurement of the primary outcome as a covariate.

Calculation Parameters

The following parameters were specified for the sample size calculation:

- Significance level (α): 0.05
- Statistical power (1−β): 0.80
- Number of groups (k): 3
- Number of covariates: 1
- Effect size (f): 0.43 (considered a large effect)
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Calculation Formula

To estimate the effect size (f) from the proportion of explained variance (η^2), the following relationship was used:

$$f = \sqrt{\frac{\eta^2}{1 - \eta^2}}$$

Where **f** represents the effect size and **η^2** represents the proportion of variance explained by the group factor.

The total sample size (**N**) was estimated based on the standard relationship used in analysis of variance models:

$$N = \frac{(Z_{1-\alpha} + Z_{1-\beta})^2}{f^2} \times (k - 1)$$

*(Note: G*Power software adjusts this relationship for the ANCOVA model, taking into account that the inclusion of a covariate correlated with the dependent variable reduces error variance, thereby improving statistical efficiency.)**

Technical Justification and Results

The selection of an effect size of f = 0.43 was based on the findings of a precursor study in which neuroscience education and exercise interventions reported partial eta-squared (ηp^2) values of 0.438 for disease impact (FIQ-R) and 0.685 for pain intensity (VAS), both substantially exceeding the threshold for a large effect ($\eta p^2 = 0.14$).

Based on these criteria, a sample size of 60 participants (20 per study arm) was determined to be sufficient to detect clinically meaningful differences. To preserve statistical power in the presence of potential loss to follow-up, an Intention-to-Treat (ITT) analysis will be performed.

Additionally, using a conservative estimate that assumes a 15% attrition rate, the sample size may be increased to 66 participants (22 per group) to maintain the required statistical power throughout the 12-week intervention period.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults aged 18 years or older, of any sex/gender, with a documented medical diagnosis of fibromyalgia established in primary or secondary healthcare settings according to the American College of Rheumatology (ACR) criteria.
- Individuals able to understand and complete the self-report questionnaires used in the study.
- Individuals with access to a compatible electronic device (smartphone, tablet, or computer) and an internet connection required for participation in the telerehabilitation intervention.
- Individuals with basic digital literacy skills, defined as the ability to use electronic devices and interact with commonly used applications.
- Individuals who provide written informed consent to participate in the study.

Exclusion Criteria

- Current participation in another structured therapeutic exercise program, whether supervised or unsupervised.
- Moderate to severe functional dependence in activities of daily living, defined as a score <60 on the Barthel Index.
- Absolute contraindications to therapeutic exercise, including hypertensive crisis (≥170/110 mmHg), dyspnea at rest, resting tachycardia, or severe glycemic abnormalities (blood glucose >250 mg/dL or <90 mg/dL in individuals receiving insulin therapy).
- Severe uncontrolled pain, defined as a score ≥8 on the Numeric Pain Rating Scale (NPRS) at rest.
- Medical or neurological conditions that significantly limit the safe performance of physical exercise, as determined by clinical assessment.
- Recent changes in fibromyalgia-specific pharmacological treatment within the previous 4 weeks, to ensure clinical stability throughout the intervention.

Proposed Intervention

The study will be conducted in the following phases:

1. Recruitment Phase

This phase consists of identifying and selecting participants who meet the eligibility criteria. Potential participants within the jurisdiction of the Talcahuano Health Service will be contacted remotely, including both members of fibromyalgia patient associations and individuals with fibromyalgia who are not affiliated with such organizations but have been referred by rehabilitation teams from primary and secondary healthcare settings. Potential candidates will then be screened to verify compliance with the established inclusion and exclusion criteria.

2. Randomization Phase

Following enrollment, participants will be randomly allocated to one of the three study groups using a validated and publicly available randomization software program, such as Randomization.com. This procedure will ensure balanced group allocation, minimize selection bias, and support the internal validity of the study.

3. Pilot Phase (see Appendix 1)

This two-week adaptation phase is designed to familiarize participants with the RehBody telerehabilitation platform, which integrates artificial intelligence and computer vision technologies to guide, monitor, and personalize the performance of therapeutic exercises. Exercises will be performed using commonly available electronic devices, including smartphones, tablets, or computers, facilitating accessibility and ease of implementation.

Each participant will receive individualized login credentials (username and password) to access the platform. No sensitive personal information or banking information will be required. Training, technical support, and participant guidance will be provided remotely throughout this phase.

4. Intervention Phase

During this 12-week phase, participants will complete the exercise protocol delivered through the RehBody platform (see Appendix 1).

1. Group 1: AI-Assisted Mobility and Stretching Program
2. Participants assigned to Group 1 will perform a mobility and stretching exercise program exclusively through the RehBody platform while continuing to receive their usual care.
3. Group 2: AI-Assisted Combined Exercise Program
4. Participants assigned to Group 2 will perform a combined exercise program consisting of mobility exercises, stretching exercises, and resistance training, delivered through the RehBody platform in addition to usual care.
5. Group 3: Control Group (Usual Care Only)

Participants assigned to the control group will continue receiving the usual care prescribed by their treating physician. All concomitant interventions, including medications, physiotherapy, and other therapies, will be documented throughout the study period.

5. Assessment Phase

Outcome assessments will be conducted at multiple time points throughout the study, including pre-intervention, post-intervention, intermediate monitoring assessments, and follow-up evaluations. All assessments will be individualized and conducted via Zoom videoconferencing, allowing assessors to directly observe the correct performance of tests and study procedures.

The assessment schedule will include the following time points:

1. Baseline Assessment: Conducted before the start of the intervention to establish baseline measurements.

2. Intermediate Assessments: Conducted at Weeks 4 and 8 to monitor participant progress, promote adherence, and reduce the risk of attrition.

3. Post-Intervention Assessment: Conducted at the completion of the 12-week intervention period to evaluate treatment outcomes.

4. Follow-Up Assessment: Conducted 3 months after completion of the intervention to assess the persistence of treatment effects and the durability of clinical outcomes.

In addition, participants will receive weekly remote follow-up throughout the study period to monitor adherence to the exercise program, address questions or concerns, and minimize dropout during the intervention.

Procedures for Data Collection, Instruments, and Data Quality Control Methods

Data Collection

Due to the nature of the intervention, blinding of participants and treating therapists will not be feasible. However, outcome assessors and statistical analysts will remain blinded to group allocation throughout the study.

Outcome measurements will be performed by a research assistant to minimize observer bias. Online questionnaires will be administered using Google Forms.

Data will be stored in a secure database with restricted access and automatic backup procedures. The database will include detailed information on all primary and secondary variables previously described. Importantly, no personally identifiable or sensitive information will be stored. Instead, each participant will be assigned a unique identification code to ensure anonymity and confidentiality.

Instruments for Primary Outcomes

1. Revised Fibromyalgia Impact Questionnaire (FIQ-R) (See Appendix 2)

The FIQ-R is a 21-item self-report instrument that assesses physical function, overall impact, and fibromyalgia-related symptoms. The Spanish version adapted to Chilean language and culture demonstrates excellent internal consistency ($\alpha = 0.91$), adequate test–retest reliability (ICC = 0.90), and convergent validity through significant positive correlations with pain intensity (NPRS), pain interference (BPI), and physical symptom severity (PHQ-15), as well as the expected negative correlation with health-related quality of life measured by the SF-12.

The total score ranges from 0 to 100, with higher scores indicating greater disease impact. The function domain score is divided by three, the overall impact domain is added directly, and the symptom domain score is divided by two. The estimated administration time is 1.3 minutes. Reported minimal detectable change (MDC) values vary according to the study and population analyzed but generally range between 15.16 and 21.49 points.

2. Remote 30-Second Sit-to-Stand Test (30s-STS)

The 30s-STS assesses lower-limb strength through a physical performance measure. It demonstrates good to excellent test–retest reliability (ICC: 0.85–0.91) and a minimal detectable change ranging from 2.14 to 2.69 repetitions, supported by moderate-quality evidence. Furthermore, it has shown adequate known-groups validity for distinguishing individuals with and without fibromyalgia.

This test has been shown to correlate with handgrip strength, muscle mass, overall physical performance, balance, functional capacity, and mobility- and quality of life-related symptoms.

The test consists of asking participants to perform as many sit-to-stand repetitions as possible within 30 seconds without using their arms for support, while the assessor records the total number

of repetitions using a handheld stopwatch (Cuyul-Vásquez et al., 2021). The 30s-STS has demonstrated validity and reliability for remote administration in telehealth settings (Bowman et al., 2023) and has also been validated, with reference values established, for the Chilean population. The MDC reported in the literature for this population is 3 repetitions.

Instruments for Secondary Outcomes

3. 4-Item Pain Catastrophizing Scale (PCS-4) (See Appendix 3)

The PCS-4 is a shortened version of the original 13-item Pain Catastrophizing Scale. It has been validated in Spanish and in the Chilean population and, like the original version, is designed to assess catastrophizing in individuals with musculoskeletal pain.

The scale has a unidimensional structure and high internal consistency ($\alpha = 0.84$; $\omega = 0.84$). In the Chilean population, mean scores of 7 points (SD = 3.9) and a standard error of measurement of 1.56 have been reported. Evidence of validity has been demonstrated through associations with pain intensity, pain interference, and kinesiophobia. Furthermore, the PCS-4 has shown strict invariance across sex and strong invariance across groups defined by pain chronicity and educational level.

The questionnaire is self-administered. Each item is scored on a Likert scale ranging from 0 ("not at all") to 4 ("all the time"). Total scores are obtained by summing item responses, yielding a range from 0 to 16, with higher scores indicating greater levels of pain catastrophizing.

4. Exercise Adherence Scale (EARS) (See Appendix 4)

The Exercise Adherence Scale (EARS) is an instrument designed to assess adherence to home-based therapeutic exercise programs. It consists of three sections: Section A (optional exercise recommendations), Section B (the primary section comprising six items that assess adherence behavior), and Section C (optional barriers and facilitators). In research settings, Section B is primarily used, and its total score (0–24) is obtained by summing responses across the six items.

Because the instrument has not been specifically validated in the Chilean population, it will be used in this study as a secondary adherence measure to complement the interpretation of clinical outcomes. It will be administered at baseline, immediately post-intervention, and at the 3-month follow-up assessment.

The Spanish version has demonstrated excellent psychometric properties, including high internal consistency ($\alpha = 0.93$) and excellent test–retest reliability (ICC = 0.95). Regarding construct validity, weak correlations have been observed with pain intensity (VAS; $r = -0.29$) and disability (Roland-Morris Questionnaire; $r = 0.00$), supporting the interpretation that the scale measures an independent construct, namely adherence behavior rather than pain or disability. Factor analysis has further confirmed that the Spanish version maintains semantic, conceptual, linguistic, content, and operational equivalence with the original instrument.

In addition, the EARS has demonstrated adequate responsiveness, evidenced by significant effect sizes capable of detecting changes in adherence over time. In terms of feasibility, the average administration time is approximately 219 seconds, which is considered acceptable in clinical settings. Finally, no ceiling or floor effects have been reported, supporting its ability to discriminate between different levels of exercise adherence.

Data Quality Control

Procedures will be implemented to ensure data quality prior to statistical analysis. These procedures will include verification of data entry accuracy, management of missing data, and assessment of outliers. Specific strategies for handling missing data will include techniques such as multiple imputation or sensitivity analyses, depending on the amount and pattern of missing data observed.

These procedures and analytical techniques will ensure that the study findings are robust, reliable, and valid, providing results that are both accurate and generalizable within the context of the study.

Procedures to Ensure Ethical Standards in Research Involving Human Participants

Informed Consent

The informed consent process will be conducted through a tripartite procedure, strictly in person, while ensuring participant privacy at all times within a consultation room located in the rehabilitation unit of CESFAM San Vicente, in accordance with Article 11 of Chilean Law No. 20.120.

The process will involve three parties: the Principal Investigator, the participant, and the Director of CESFAM San Vicente or a delegated representative acting as an independent witness. The procedure consists of three consecutive stages:

- Invitation and Information: The Principal Investigator will explain the study objectives, procedures, potential risks, and expected benefits to individuals diagnosed with fibromyalgia who are being invited to participate.
- Verification of Voluntariness: The independent witness will verify that the participant fully understands the voluntary nature of participation and retains the right to withdraw from the study at any time without any consequences for their healthcare or future treatment.
- Completion and Tripartite Signature: Once the participant's competence and voluntary willingness to participate have been confirmed, the informed consent document will be signed in duplicate. One original copy will be provided to the participant and the other retained by the research team. The participant, the Principal Investigator, and the independent witness will each sign both copies.

Once informed consent has been formally completed through the tripartite signature process, the original copies retained by the research team will be stored physically within the rehabilitation unit of CESFAM San Vicente. This institutional setting provides a controlled environment that complies with Chilean Law No. 20.584 on Patients' Rights and Duties and Law No. 19.628 on the Protection of Private Life.

To ensure maximum confidentiality, all consent forms will be organized and stored using the unique numerical identification code assigned to each participant, thereby maintaining separation between personal identity and the clinical data analyzed during the study. Access to this physical repository will be strictly restricted to the Principal Investigator and secured under lock and key, with institutional safeguards in place to prevent loss, deterioration, or unauthorized use of information.

This procedure ensures the integrity, confidentiality, and traceability of the original records and facilitates on-site monitoring and auditing activities by the Scientific Ethics Committee of the Talcahuano Health Service.

Confidentiality

All collected data will be stored and managed in accordance with the research data management guidelines established by the Scientific Ethics Committee of the Talcahuano Health Service. All study procedures will be conducted in compliance with the Declaration of Helsinki and applicable Chilean regulations, including the Patients' Rights and Duties Act (Law No. 20.584) and the Personal Data Protection Act (Law No. 19.628). This process involves the removal of any personal information (e.g., name, national identification number, address, telephone number) that could directly or indirectly identify an individual, ensuring that all data are anonymized prior to analysis.

Regarding the use of artificial intelligence and computer vision systems, digital data collected during exercise sessions will be handled confidentially and anonymized through the assignment of unique numerical identification codes that prevent the direct identification of participants. No identifiable images or sensitive personal data will be stored by the research team.

Adverse Event Management

A continuous monitoring system will be implemented throughout the clinical trial to identify and manage any adverse events that may occur. An adverse event will be defined as any significant exacerbation of pain, musculoskeletal injury, or medical event requiring healthcare attention. Potential adverse events associated with the intervention may include muscle soreness, fatigue, or other exercise-related symptoms.

Participants will be monitored throughout the study through weekly assessments, including direct participant reports and remote monitoring conducted by two research assistants serving as the study monitoring committee. In the event of a significant adverse event, the Director of CESFAM San Vicente, or their designated representative, will determine whether the participant should be temporarily or permanently withdrawn from the study.

All adverse events will be thoroughly documented and reported to the Scientific Ethics Committee. If a serious or recurring risk is identified, modification or suspension of the study will be considered to ensure participant safety.

Although the study is considered minimal risk, a contingency fund has been allocated to cover any costs associated with emergency medical care or serious musculoskeletal complications directly attributable to the intervention. This measure guarantees that no financial burden will be incurred by participants or by the public healthcare system.

RESULTS ANALYSIS PLAN

Software for Data Analysis

Statistical analyses will be conducted using JASP version 0.95.4.0, a free and open-source statistical software package developed by the University of Amsterdam that allows complex data analyses through a user-friendly and intuitive interface.

The primary analysis will be performed according to the Intention-to-Treat (ITT) principle. Missing data will be addressed using multiple imputation if the proportion of missing values exceeds 5%.

Data Analysis Methods According to Variable Type

Descriptive Analysis (Sample Characterization)

In accordance with the general and specific objectives of the study, descriptive analyses will be conducted to characterize the study population at baseline. Sociodemographic and baseline clinical variables will be summarized using measures of central tendency and dispersion (mean and standard deviation, or median and interquartile range, depending on data distribution), as well as frequencies and proportions for categorical variables. This analysis will allow characterization of the sample and assessment of baseline comparability among study groups.

Within-Group Analysis

To evaluate the effect of each intervention within each group, pre- and post-intervention measurements will be compared. Normality assumptions will be assessed using the Kolmogorov–Smirnov test. Model assumptions will be evaluated through residual inspection and tests of homogeneity of variance. Depending on the results, paired Student's *t*-tests will be applied, or, when normality assumptions are not met, equivalent non-parametric tests (Wilcoxon signed-rank test) will be used.

Between-Group Analysis

To compare changes in clinical outcomes among the three study groups, Analysis of Covariance (ANCOVA) will be employed. Models will be adjusted for baseline values of the dependent variables and clinically relevant covariates to control for potential confounding factors. Homogeneity of variances will be assessed using Levene's test. When statistically significant differences are identified, post-hoc pairwise comparisons with Bonferroni correction will be performed.

Significance Level and Effect Size

Statistical significance will be established at $p < 0.05$. In addition, effect sizes will be calculated to complement the clinical interpretation of the findings. Partial eta squared (ηp^2) will be reported for ANCOVA models, whereas Cohen's *d* will be calculated for within-group comparisons and interpreted according to conventional thresholds.

As a complement to the analysis of continuous variables, Relative Risk (RR) estimates will be incorporated through the strategic dichotomization of key outcomes to facilitate interpretation of clinical relevance and monitoring of study safety. First, a "clinical responder" rate will be defined for the primary outcome (FIQ-R), considering a clinically meaningful reduction in the total score as a

successful outcome. This approach will allow comparison of the probability of improvement between the AI-assisted intervention groups and the usual care group.

Additionally, RR will serve as a key measure for evaluating intervention safety by comparing the incidence of adverse events across the three study arms. Finally, for the physical function outcome (30-Second Sit-to-Stand Test), RR will be calculated for achieving age- and sex-specific normative functional performance thresholds.

All relative risk estimates will be presented together with their corresponding 95% confidence intervals, providing an intuitive measure of effect magnitude to support clinical decision-making.

TIMELINE

MONTHS

Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Literature Review and Study Planning	■	■																										
Scientific Ethics Committee Approval			■	■	■																							
ClinicalTrials.gov Registration						■																						
Participant Recruitment							■	■	■																			
Randomization										■																		
Pre-Intervention Assessment											■																	
Pilot Testing												■																
Intervention													■	■	■													
Post-Intervention Assessment																■												
Data Analysis																	■	■										
Dissemination of Results																			■	■	■							
Follow-up Assessment																						■	■	■				
Follow-up Data Analysis																									■			
Dissemination of Follow-up Results																										■	■	■

BUDGET

This study does not receive external funding and has no institutional budget allocated for its implementation. The investigators declare that they have no conflicts of interest with Rehbody. All operational costs associated with the study will be covered through the investigators' own resources. Specifically, access to the Rehbody platform will be financed by the Principal Investigator, while the statistical analysis software will be provided by one of the external investigators. Any costs related to scientific publication will be assumed by the lead author.

Additionally, the Principal Investigator will maintain a contingency fund using personal resources to cover any expenses arising from emergency medical care or serious musculoskeletal complications directly attributable to the intervention, thereby ensuring no financial burden for participants or for the public healthcare system.

The implementation of the study will not require the use of healthcare personnel, facilities, or working hours from primary healthcare centers. Therefore, the study will not interfere with the routine operation of the healthcare network.

APPENDIX 1: PROPOSED INTERVENTION

	Exercise Dosage	**List of AI-Assisted Exercises Delivered Through the Rehbody Platform**
Pilot Intervention (Platform Familiarization Phase)	Frequency: 2 sessions per week Number of Exercises: 4 Sets and Repetitions: 2 sets of 10–15 repetitions per exercise, depending on the exercise. Rest Interval: 20–60 seconds between sets. Duration: 2 weeks to familiarize participants with the platform.	1. Standing Shoulder Flexion Mobility 2. Seated Right Knee Extension 3. Seated Left Knee Extension 4. Wrist Mobility Exercise Estimated Session Duration: 5–10 minutes
Group 1: Mobility and Stretching Exercise Program	Frequency: 2 sessions per week Intensity: 4–6 on the Borg Rating of Perceived Exertion Scale (0–10). Number of Exercises: 7 Sets and Repetitions: • Mobility exercises: 2 sets of 10–15 repetitions. • Stretching exercises: 4 repetitions per exercise. Rest Interval: 20–60 seconds between sets. Total Duration: 12 weeks.	Mobility Exercises (10–15 minutes) 1. Marching in Place 2. Standing Shoulder Flexion Without Weight 3. Standing Left Ankle Full Plantarflexion–Dorsiflexion 4. Standing Right Ankle Full Plantarflexion–Dorsiflexion 5. Wrist Mobility Exercise Stretching Exercises (5 minutes) 6. Seated Cervical Flexion Stretch 7. Prayer Stretch in Kneeling Position
Group 2: Resistance Training + Mobility and Stretching Exercise Program	Frequency: 2 sessions per week Intensity: 4–6 on the Borg Rating of Perceived Exertion Scale (0–10). Number of Exercises: 11 Sets and Repetitions: • Mobility exercises: 2 sets of 10–15 repetitions. • Stretching exercises: 4 repetitions per exercise. • Resistance training exercises: 10–12 repetitions per exercise. Rest Interval: 20–60 seconds between sets. Total Duration: 12 weeks.	Mobility Exercises (10–15 minutes) 1. Marching in Place 2. Standing Shoulder Flexion Without Weight 3. Standing Left Ankle Full Plantarflexion–Dorsiflexion 4. Standing Right Ankle Full Plantarflexion–Dorsiflexion 5. Wrist Mobility Exercise Resistance Training Exercises (15–20 minutes) 6. Weighted Deadlift 7. Chair Squats 8. Dumbbell Lateral Shoulder Raise 9. Bilateral Bent-Over Dumbbell Row Stretching Exercises (5 minutes) 10. Seated Cervical Flexion Stretch 11. Prayer Stretch in Kneeling Position
Group 3: Usual Care (Control Group)	Participants allocated to the control group will continue receiving the usual care prescribed by their treating physician. Usual care may include pharmacological management, medical follow-up, physical therapy, or other healthcare interventions deemed appropriate according to routine clinical practice. All concomitant interventions, including medications, physical therapy, and any additional treatments received during the study period, will be recorded and monitored.	

INFORMED CONSENT

Folio N°

Study Title:	Effectiveness of Artificial Intelligence- and Computer Vision-Assisted Telerehabilitation, With and Without Resistance Training, on Disease Impact and Physical Function in People With Fibromyalgia: A Randomized Controlled Trial (FibroIA 2.0)
Version:	1.0
Principal Investigator:	Romualdo Ordóñez Vega, Physiotherapist
E-mail	Kine.ordonez@gmail.com
Contact Telephone:	+56 9 82256426
Sponsor:	CESFAM San Vicente

PART I: Information

1. Introduction

Dear Participant:

You are being invited to participate in the following study:

"Effectiveness of Artificial Intelligence- and Computer Vision-Assisted Telerehabilitation, With and Without Resistance Training, on Disease Impact and Physical Function in People With Fibromyalgia: A Randomized Controlled Trial (FibroIA 2.0)".

2. Purpose of the Study

The purpose of this research is to compare the effects of therapeutic exercise programs assisted by artificial intelligence and computer vision, with and without resistance training, versus usual care on disease impact and physical function in individuals with fibromyalgia during 2026.

This study will be conducted remotely through a telerehabilitation program.

3. Selection of Participants

Participants in this study will be users belonging to the jurisdiction of the Talcahuano Health Service.

4. What Your Participation Involves

Your participation will include assessments of variables related to disease impact, physical function, pain catastrophizing, and exercise adherence, as well as participation in a therapeutic exercise program delivered through artificial intelligence- and computer vision-assisted telerehabilitation.

5. Duration

Your participation in the artificial intelligence- and computer vision-guided therapeutic exercise intervention will last 12 weeks and will consist of two sessions per week, with a total duration of approximately 60–80 minutes per session.

6. Voluntary Participation

Your participation is entirely voluntary. You have the right to decide whether or not to participate in this study. If at any time you no longer wish to continue, you may withdraw without providing a reason. Your decision will not result in any consequences or affect your usual healthcare services in any way. If you choose to withdraw from the study, the data collected from you will not be used in the study.

7. Risks

Participation in this study is considered to involve minimal risk to your health. However, individuals who are not accustomed to regular exercise may experience mild fatigue or delayed-

onset muscle soreness, particularly during the first sessions.

8. Benefits

The results of this study are expected to provide scientific evidence regarding the effectiveness of artificial intelligence- and computer vision-assisted telerehabilitation programs for individuals with fibromyalgia, contributing to the development of new rehabilitation strategies and generating a collective benefit.

Participants may also experience individual benefits by gaining access to a supervised therapeutic exercise program that may help improve physical function, reduce pain, and enhance quality of life. Furthermore, the intervention may promote greater adherence to exercise and encourage self-management of fibromyalgia through active rehabilitation strategies.

9. Costs or Incentives Related to Participation

Participation in this study will not involve any costs to you, either now or in the future. You will not receive any financial compensation or incentive for participating.

10. Confidentiality

The data collected in this study will be safeguarded by the Principal Investigator, Romualdo Ordóñez Vega, and retained for five years in both physical (paper) and electronic formats. After this period, the data will be permanently destroyed.

Electronic data will be stored on the Principal Investigator's computer, which is protected by password-restricted access, secure operating system controls, and dedicated exclusively to research purposes. Access will be limited to the Principal Investigator.

To ensure confidentiality and anonymity, all participant information will be coded using a unique identification number. No personally identifiable sensitive information will be included in the study database.

11. Use and Publication of Findings

All information obtained during this study will remain confidential. Data will be coded using a participant identification number and anonymized.

The results of this research may be published in scientific journals or used in future research projects. Under no circumstances will information be used in a manner that allows personal identification or for purposes unrelated to the objectives of this study.

The study findings will also be shared with healthcare administrators and participants through a formal results presentation session.

12. Participant Rights

You are free to participate in this study and may withdraw at any time without penalty, liability, sanctions, or loss of benefits.

Questions or concerns regarding your participation may be directed to the Principal Investigator:
Romualdo Luciano Ordóñez Vega
Email: kine.ordonez@gmail.com Telephone: +56 9 82256426

If you wish to obtain information about the study results after completion of the research, you may request them by contacting the Principal Investigator using the email address provided above.

This study has been approved by the Scientific Ethics Committee of the Talcahuano Health Service.

If you have questions regarding your rights as a participant or wish to report any concerns or irregularities, you may contact the Chair of the Accredited Scientific Ethics Committee of the Talcahuano Health Service: Dr. Patricia Marcela Cortés Jofré
Telephone: +56 41 2722254 Email: ricardo.rios@redsalud.gob.cl

PART II:

INFORMED CONSENT FORM

I have been invited to participate in the study entitled: “Effectiveness of Artificial Intelligence- and Computer Vision-Assisted Telerehabilitation, With and Without Resistance Training, on Disease Impact and Physical Function in People With Fibromyalgia: A Randomized Controlled Trial (FibroIA 2.0)”.

I understand that my participation will involve assessments related to the impact of fibromyalgia, pain, physical function, and quality of life, as well as participation in a therapeutic exercise program delivered through artificial intelligence- and computer vision-assisted telerehabilitation. Participants will complete a 12-week intervention and will undergo assessments at baseline, post-intervention (Week 13), and 3 months after completion of the intervention (Week 25), with sessions delivered through a digital platform that uses artificial intelligence to provide feedback on exercise performance. I also understand that I may be randomly assigned to one of the study groups and that assessments will be conducted before and after the intervention, as well as during follow-up evaluations.

I have read and/or had read to me the information contained in this consent document.

I have had sufficient time to ask questions, and all my questions have been answered clearly.

I have no further questions regarding my participation.

I freely and voluntarily agree to participate in this study, and I understand that I have the right to withdraw at any time without penalty, liability, sanctions, or loss of benefits.

Date (26/05/2026)

_____	_____
Participant Name	Participante Signature
_____	_____
Romualdo Ordóñez Vega Principal Investigator	Signature Principal Investigator
_____	_____
Claudio Morales Hidalgo Director, CESFAM San Vicente	Signature (Witness/Minister of Faith):

Prepared by CEC_SST.