

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of pulmonary rehabilitation in adult patients with cystic fibrosis - a clinical intervention

#### Protocol summary

##### Study aim

The purpose of this study was to evaluate the impact of pulmonary rehabilitation on the general health of patients with CF that are already in treatment with CF transmembrane conductance regulator (CFTR) modulators

##### Design

An interventional study of 28 patients who performed pulmonary rehabilitation for 3 weeks

##### Settings and conduct

The study was performed at a single pulmonary rehabilitation center in Timisoara, Romania. Patients received for 3 weeks pulmonary rehabilitation

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were patients confirmed with CF after medical consultation, age > 18 years, sweat test (iontophoresis), genetic testing, and non-smokers. Furthermore, it was imperative to ascertain the current therapy status involving CFTR modulators. Exclusion criteria were: age < 18 years, exacerbations in the last month, patients with active smoking status, and other lung diseases than CF.

##### Intervention groups

The intervention group received for 21 days, daily training sessions that lasted between 30 and 40 minutes and included diaphragmatic breathing, pursed-lip breathing, strength and endurance training for both the upper and lower extremities, respiratory muscle training, and clearance techniques

##### Main outcome variables

The quality of life assessed with the CFQ-R questionnaire improved significantly.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231115060065N2**

Registration date: **2023-12-05, 1402/09/14**

Registration timing: **retrospective**

Last update: **2023-12-05, 1402/09/14**

Update count: **0**

##### Registration date

2023-12-05, 1402/09/14

##### Registrant information

###### Name

Alexandru Florian Crişan

###### Name of organization / entity

University of Medicine and Pharmacy Victor Babes  
Timisoara

###### Country

Romania

###### Phone

+40 765 525 688

###### Email address

crisan@umft.ro

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-30, 1402/03/09

##### Expected recruitment end date

2023-11-12, 1402/08/21

##### Actual recruitment start date

2023-06-02, 1402/03/12

##### Actual recruitment end date

2023-11-12, 1402/08/21

##### Trial completion date

2023-11-12, 1402/08/21

##### Scientific title

Effects of pulmonary rehabilitation in adult patients with cystic fibrosis - a clinical intervention

##### Public title

Pulmonary rehabilitation in patients with cystic fibrosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients confirmed with cystic fibrosis after medical consultation Age > 18 years Non-smokers status

**Exclusion criteria:**

Age < 18 years Exacerbations in the last month Other lung diseases than cystic fibrosis

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

Actual sample size reached: **28**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Comisia de Etică a Spitalului de Boli Infectioase si Pneumoftiziologie Victor Babes Timisoara

**Street address**

Gheorghe Adam nr. 13

**City**

Timisoara

**Postal code**

300310

**Approval date**

2023-05-30, 1402/03/09

**Ethics committee reference number**

4989

**Health conditions studied**

1

**Description of health condition studied**

Cystic fibrosis

**ICD-10 code**

E84

**ICD-10 code description**

Cystic fibrosis

**Primary outcomes**

1

**Description**

CFQ-R questionnaire domains will improve

**Timepoint**

Before intervention and 3 weeks after intervention.

**Method of measurement**

CFQ-R.

**Secondary outcomes**

1

**Description**

Physical capacity will improve

**Timepoint**

before intervention and 3 weeks after intervention

**Method of measurement**

6MWT

2

**Description**

Respiratory muscle strength will improve

**Timepoint**

before intervention and 3 weeks after intervention

**Method of measurement**

MIP/MEP

**Intervention groups**

1

**Description**

Intervention group: received for 21 days, daily training sessions that lasted between 30 and 40 minutes and included diaphragmatic breathing, pursed-lip breathing, strength and endurance training for both the upper and lower extremities, respiratory muscle training, and clearance techniques

**Category**

Rehabilitation

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Clinical Hospital of Infectious Diseases and Pulmonology, Victor Babes Timisoara, Romania

**Full name of responsible person**

Pescaru Camelia Corina

**Street address**

Gheorghe Adam nr. 13

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+40 722 818 228

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pescaru.camelia@umft.ro

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Medicine and Pharmacy Victor Babes  
Timisoara

**Full name of responsible person**

Pescaru Camelia Corina

**Street address**

Eftimie Murgu

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University of Medicine and Pharmacy Victor Babes  
Timisoara

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

University of Medicine and Pharmacy Victor Babes  
Timisoara

**Full name of responsible person**

Pesacaru Camelia Corina

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Timisoara

**Full name of responsible person**

Pescaru Camelia Corina

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pneumology

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Not available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available