# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The impact of urinary incontinence rehabilitation intervention on self esteem and quality of life in women with neurogenic bladder in Rofeideh Rehabilitation Hospital

## Protocol summary

**Study aim**

The impact of Urinary incontinence rehabilitation Intervention on self esteem and quality of life in women with neurogenic bladder

**Design**

Quasi experimental study with available samples by one group method before and after with a sample size of 35 people

**Settings and conduct**

1) Development and approval of interventions 2) Sampling of 35 women with neurogenic bladder hospitalized in multiple sclerosis and spinal cord injuries and strokes of Rofeideh Rehabilitation Hospital 3) Explain the goals and fill out the informed and pre test consent form 4) Perform a 2 dimensional intervention including clean intermittent catheterization, behavioral therapy In 12 sessions of 30 minutes in six weeks, which are 7 sessions in the first week and then weekly 5) Post test

**Participants/Inclusion and exclusion criteria**

Inclusion: Clean intermittent catheterization Literacy body mass index ؛ Non inclusion: Cervical spinal cord injuries Alcohol and drug Acute depressive disorder Drugs affecting urinary incontinence Diuretics Active urinary tract infection Gynecological surgeries Being pregnant History of cesarean section or normal delivery in the last 6 months Pelvic floor muscle prolapse

**Intervention groups**

1) Development and approval of interventions 2) Sampling of 35 women with neurogenic bladder hospitalized in multiple sclerosis wards and spinal cord injuries and strokes of Rofeideh Rehabilitation Hospital by available sampling method based on inclusion and exclusion criteria within a period of one month 3) Explain the goals and fill out the informed and pretest consent form 4) Perform a 2 dimensional intervention including clean intermittent catheterization, behavioral therapy (determining the time of urination, delaying urination and adjusting diet and medication) in 12 sessions in six weeks 5)Post test

**Main outcome variables**

Improving quality of life and self esteem in urinary incontinence

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211011052729N1**
Registration date: **2021-12-16, 1400/09/25**
Registration timing: **retrospective**

Last update: **2021-12-16, 1400/09/25**
Update count: **0**

**Registration date**

2021-12-16, 1400/09/25

**Registrant information**

**Name**
Asieh Soghrati
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-02-03, 1399/11/15

**Expected recruitment end date**

2021-03-20, 1399/12/30

**Actual recruitment start date**
2021-02-03, 1399/11/15
**Actual recruitment end date**
2021-03-20, 1399/12/30
**Trial completion date**
2021-03-20, 1399/12/30

**Scientific title**
The impact of urinary incontinence rehabilitation intervention on self esteem and quality of life in women with neurogenic bladder in Rofeideh Rehabilitation Hospital

**Public title**
The impact of urinary incontinence rehabilitation intervention on self esteem and quality of life in women with neurogenic bladder
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Clean Intermittent catheterization according to the doctor's instructions Literacy Having a body mass index of less than 30 kg per m2
**Exclusion criteria:**
Cervical spinal cord injuries ( C1 to C7) Alcohol and drugs Acute depression Taking medications that affect urinary incontinence or changing its prescription during the month before the study Taking diuretics to lower blood pressure Active urinary tract infection according to the patient's test results History of gynecological surgeries Being pregnant No history of cesarean section or normal delivery in the last 6 months Pelvic floor muscle prolapse
**Age**
From **18 years** old to **60 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **35**
Actual sample size reached: **30**
**Randomization (investigator's opinion)**
N/A
**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**
University of Social Welfare and Rehabilitation Sciences
**Street address**
Evin Blvd, Daneshjoo Ave.,Koodakyar Street, University of Social Welfare and Rehabilitation Sciences, Tehran,Iran
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**Province**
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**Postal code**
1985713871
**Approval date**
2020-12-22, 1399/10/02
**Ethics committee reference number**
IR.USWR.REC.1399.259

## Health conditions studied

**1**

**Description of health condition studied**
Urinary incontinence and neurogenic bladder
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Self esteem
**Timepoint**
Before the intervention and 6 weeks after starting the urinary incontinence rehabilitation program
**Method of measurement**
Rosenberg self esteem questionnaire

## Secondary outcomes

**1**

**Description**
Urinary Incontinence Quality of Life Questionnaire
**Timepoint**
Before the intervention and 6 weeks after starting the urinary incontinence rehabilitation program
**Method of measurement**
Urinary Incontinence Quality of Life Questionnaire

## Intervention groups

**1**

**Description**

Method of intervention: Urinary incontinence rehabilitation interventions in patients with neurogenic bladder were developed using literature review and then validated. In this way, after compiling the dimensions of urinary incontinence rehabilitation interventions in this study, using a review of the existing texts in this field, the program was compiled by 10 rehabilitation specialists, including physicians specializing in physical medicine and rehabilitation, and urologists, nutritionists. , Physiotherapist, occupational therapist and head nurses and faculty members of the nursing department with experience in rehabilitation nursing, correction, approval and accreditation. Rehabilitation intervention based on the mentioned texts and validation, including 2 dimensions of clean intermittent catheterization, behavioral therapy (determining the time of urination, delaying urination and diet and medication) in 12 sessions of 30 minutes in six weeks Which is 7 sessions in the first week and then in the second, third, fourth, fifth and sixth weeks of a week. The time of this study is from the second half of February 2021 to the end of March 2021 and the evaluation of the program in The time periods of the first week of the first session, as a pre-test (filling in the questionnaires for the first time by the clients before the intervention) and the sixth week of the twelfth session, as a post-test (filling the questionnaires for the second time by the clients after the intervention) Took. After approving the proposal and obtaining the code of ethics, sampling was done by the method available in the departments of neurology, spinal cord injury, stroke of Rofeideh Rehabilitation Hospital and was performed within a period of one month and patients with inclusion criteria were included in the study. The objectives of the study were explained to the samples and the informed consent form was completed by the patients. Neurology, spinal cord injury, stroke were completed and quality of life in urinary incontinence and self-esteem were measured before the intervention. Urinary incontinence rehabilitation interventions in a two-dimensional intervention, in 7 30-minute sessions over 1 week Individual in-person and out-of-group training due to the prevalence of Covid-19 disease was taught and at the same time an educational booklet was provided to patients. Urinary incontinence To evaluate the correct implementation of urinary incontinence rehabilitation interventions, one session was held every week. Consultation, training and follow-up of the intervention was done by telephone with the researcher. If necessary, referrals were made to medical centers. At the end of the intervention and follow-up, 6 weeks after the last training session, post-test was performed and patients again completed the research questionnaires. Educational pamphlets and urinary incontinence rehabilitation interventions were provided to hospital wards for ethics. Session 1 (Week 1): Explain the intervention and its purpose, obtaining consent from clients, pre-test, filling out questionnaires for the first time by clients / Session 2 (Week 1): Anatomy and physiology training, urinary system and how it works Session 3 (Week 1): Familiarity with neurogenic bladder and its symptoms / Session 4 (Week 1): Training of urinary incontinence rehabilitation interventions (clean intermittent catheterization) by the researcher for clients, providing all training files through the group Virtual / Session 5 (first week): Behavior therapy (setting a specific time for urination according to the urination schedule, delaying the urination time as much as possible according to the urination schedule), providing all the training files through Virtual group / Session 6 (first week): Behavior therapy (diet), providing all the training files through the virtual group / Session 7 (first week): Tracking exercises, reviewing how clients do exercises and troubleshooting By sending video and video call online, answering clients' questions / Eighth session (second week): Examining how clients do exercises And troubleshooting by sending video and video call online, answering clients 'questions / Session 9 (third week): following up on exercises, reviewing how clients perform exercises and fixing problems by sending video and video calling online, answering clients' questions / Session 10 (Week 4): Follow up the exercises, check how the exercises are done by the clients and fix the problems by sending a video and online video call, answer the questions of the clients / Session 11 (Week 5): Follow the exercises, check how to do the exercises By clients and troubleshooting by sending video and video call online, answering clients 'questions / Twelfth session (sixth week): the last session answering clients' questions, post-test, refilling questionnaires for the second time by clients, their satisfaction with the performance This intervention, feedback

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

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**Full name of responsible person**

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## Sponsors / Funding sources

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
nothing

**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**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
Only part of the data such as information about the main outcome or the like can be shared.
**When the data will become available and for how long**
6 months after the results are published
**To whom data/document is available**
Academic people and scientific institutions
**Under which criteria data/document could be used**
Ethical, legal and scientific licenses
**From where data/document is obtainable**
Referred to the University of Social Welfare and Rehabilitation Sciences, Department of Nursing, Associate Professor of Nursing Dr. Narges Arsalani (Corresponding Author) Or send an email to the address nargesarsalani@gmail.com
**What processes are involved for a request to access data/document**
Ethical, legal and scientific licenses of university Going to university of social welfare and rehabilitation sciences
**Comments**