

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of defecation experiences in elderly people living in nursing homes and their caregivers with a two-part basin equipped with a patient washing and automatic disinfection system

Protocol summary

Study aim

Determining and comparing the experiences of urination and defecation in the elderly living in nursing homes when using the existing sanitary defecation basin in comparison with the two-part defecation .

Design

A crossover clinical trial without blinding on 30 elderly people and their caregivers.

Settings and conduct

This study is a cross-sectional clinical trial study that will be conducted on 30 elderly people (men and women) in nursing homes in the east of Tehran province (including Damavand and their caregivers (paramedics and the service personnel responsible for disposal care). Selection of the elderly from among the centers available and based on the inclusion criteria, which include the willingness of the elderly and their caregivers to participate in the study, living in a nursing home for at least 6 months, recommending the use of a bed in bed due to mobility problems, or the elderly not being discharged to any There will be a reason in the next 3 months. Exclusion criteria include the discharge, transfer or death of the elderly from the nursing home before the completion of the study period, the unwillingness of the elderly or their caregivers to continue participating in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: willingness to participate in the study by the elderly and their caregivers, living in a nursing home for at least 6 months, recommending the use of a bed in bed due to mobility problems or..., non-discharge of the elderly for any reason within 3 months the future..

Intervention groups

This trial is a cross-over trial in which subjects first use a standard sanitary pad for one week and then a two-part sanitary pad for one week.

Main outcome variables

Excretion experiences in the elderly and their caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110621006854N6**

Registration date: **2023-03-12, 1401/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-12, 1401/12/21**

Update count: **0**

Registration date

2023-03-12, 1401/12/21

Registrant information

Name

Elham Ebrahimi

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

Phone

+98 22 1522 3903

Email address

ebrahimi_308@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-07-27, 1402/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of defecation experiences in elderly people living in nursing homes and their caregivers with a two-part basin equipped with a patient washing and automatic disinfection system

Public title

Comparing the experiences of the elder people in using two types of basins (available in the market and new basins) during urination and defecation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria that include willingness to participate in the study by the elderly and their caregivers, living in a nursing home for at least 6 months, recommending the use of a bed in bed due to mobility problems or..., non-discharge of the elderly for any reason within 3 months the future

Exclusion criteria:**Age**

From **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Joint Ethics Committee of the Faculty of Nursing, Midwifery and Rehabilitation of Tehran Unvers

Street address

Nursing and midwifery college of Tehran University of

Medical Sciences, Tohid square,Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2023-01-03, 1401/10/13

Ethics committee reference number

IR.TUMS.FNM.REC.1401.148

Health conditions studied**1****Description of health condition studied**

It doesn't include any diseases

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Discharge experiences of the elderly and their caregivers

Timepoint

Experiences at the end of a week of using a normal and a two-part basin

Method of measurement

Standard questionnaire of excretion experiences

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention and control group (cross-over experiment): using a normal toilet bowl for one week, and then as a control, using a two-part bowl for one week.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Care centers for the elderly

Full name of responsible person

Elham Ebrahimi

Street address

End of Imam Khomeini boulevard, Iranian nursing homean, Bumehen,Tehran, Iran.

City

Tehran
Province
Tehran
Postal code
1655147196
Phone
+98 912 646 4211
Email
ebrahimi_308@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Ebrahimi
Street address
Nursing and Midwifery College of Tehran University of
Medical Sciences, Tohid Square, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 912 646 4211
Email
ebrahimi_308@yahoo.com
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
10
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Ebrahimi
Position
Assistant Professor
Latest degree
Ph.D.

Other areas of specialty/work

Midwifery
Street address
Nursing and Midwifery College of Tehran University of
Medical Sciences, Tohid Square, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 912 646 4211
Email
ebrahimi_308@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Ebrahimi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nursing and Midwifery College of Tehran University of
Medical Sciences, Tohid Square, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 912 646 4211
Email
Ebrahimi_308@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Ebrahimi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nursing and Midwifery College of Tehran University of
Medical Sciences, Tohid Square, Tehran, Iran.
City
Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 912 646 4211

Email

Ebrahimi_308@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available