Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
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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 Univers
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

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Sponsors / Funding sources

1

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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
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
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Elham Ebrahimi
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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