Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

The Impact of Videotape on The Self-efficacy and Quality ofLlife in Tracheostomy Patients

Protocol summary

Summary

The aim of this single blinded study،survey the Iimpact of Videotape on Quality of life and Self efficacy in Tracheostomy Patient which Hospitalized in Amir Alam and Imam Khomeini Institute in Tehran. after obtaining written informed consent to Participate in the study, Participants set into two groups based on random block 5 ,the total number of samples is 80 and considering the loss, 45 People calculate for each group.inclusion criteria include: age above 20 years, Self-care ability, No history of mental problems, Lack of work and education in Health Centers. Exclusion criteria include absence of a willingness to cooperation ,exacerbate the situation and unable to cooperation.two group after received routine education from Medical Staff complete sf-36 and self efficacy Questionnaire. In the Intervention group, in addition to the regular training received from the Medical Staff, one tutorial CD with audio and video features, created by the Researcher, was given to the Patients.The CD content was teaching an introduction to Tracheostomy care, showing the Daily care a Tracheostomy Patients need including bathing, shaving, suction, replacing the bandage around Tracheostomy, cleaning Tracheostomy Tube, the Tracheostomy site infection symptoms, how to communicate with Others and presence in public. The Intervention group could watch the movie with no restrictions in terms of the number of times.2 month lather again two groups complete the Questionnaire and Data compare and analysis.

General information

Acronym

not

IRCT registration information

IRCT registration number: **IRCT2015110224434N1**
Registration date: **2015-11-22, 1394/09/01**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-11-22, 1394/09/01

Registrant information

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Salam Vatandost
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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences-Research Deputy of University and Research, Deputy of Nursing and Midwifery Faculty

Expected recruitment start date

2015-10-28, 1394/08/06

Expected recruitment end date

2016-02-27, 1394/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Videotape on The Self-efficacy and Quality ofLlife in Tracheostomy Patients

Public title

The Impact of Videotape on The Self-efficacy and Quality

of Llife in Tracheostomy Patients

Purpose

Supportive

Inclusion/Exclusion criteria

(Participants:The Participants were Patients with Tracheostomy in the ENT Ward of Amir Alam Hospital and the Imam Khomeini Institute of Cancer in Tehran) (Inclusion Criteria Included: Patients over 20 years old؛ self-care ability؛ cooperative ability؛ not having a history of mental illness؛ full awareness of the time, place and the Person at the time of training؛ completing the Questionnaires؛ access to facilities for watching training videos, lack of experience or training in Health Centers and the ability to communicate in Persian language). (Exclusion Criteria:unwillingness to continue cooperation for any reason؛ deterioration of the Person’s condition and inability to complete the Questionnaire؛ lack of possibility to coordinate an appointment in order to complete the Questionnaire after the Intervention).

Age

From **20 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan Kniversity of Medical Sciencies

Street address

Pasdaran Street, Kurdistan Kniversity of Medical Sciencies,Sanandaj, Iran

City

Sanandaj

Postal code

Approval date

2014-11-02, 1393/08/11

Ethics committee reference number

muk.rec.1394227

Health conditions studied

1

Description of health condition studied

Tracheostomy

ICD-10 code

Z93.0

ICD-10 code description

Tracheostomy status

Primary outcomes

1

Description

self-efficacy

Timepoint

discharge and 2 month lather

Method of measurement

sherer self efficay quistionary

2

Description

quality of life

Timepoint

discharge and 2 month lather

Method of measurement

sf-36 quistionary

Secondary outcomes

1

Description

no

Timepoint

no

Method of measurement

no

Intervention groups

1

Description

Control group: routine education from medical staff

Category

Behavior

2

Description

Intervention: routine education from medical staff and Videos teaching how to take care of the tracheostomy for use in home for two months

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Alam Hospital

Full name of responsible person
Salam Vatandost, Masterof Sciences in Critical Care Nursing

Street address
Kurdistan University of Medical Siences, Pasdaran Street, Sanandaj,Kurdistan, Iran

City
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2

Recruitment center

Name of recruitment center
Cancer Institute of Imam Khomeini

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdistan University of Medical Sciencies

Full name of responsible person
Ebrahim Ghaderi

Street address
Kurdistan University of Medical Sciencies-Research Center

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Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kurdistan University of Medical Sciencies

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty