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Educational intervention in primary caregivers of dependent persons on the prevention of dependency-related skin lesions

Submission date
19/04/2024

Recruitment status
No longer recruiting

Registration date
11/05/2024

Overall study status
Completed

Last Edited
25/03/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The situation of dependency increases the risk of dependency-related skin lesions (lesiones cutáneas relacionadas con la dependencia; CRLD). Likewise, people included in homecare programs have shown a national prevalence of CRDLs of 6.11%, with a home origin of 83.3%. The figure of the Primary Care nurse is very important in the care of dependency and chronicity, facilitating the empowerment of users for self-care and that of caregivers for the care of others. The nurse historically educates, prepares and trains the patient and caregivers through health education which is included in the portfolio of primary care services. Health education decreases the risk of suffering from CRLD. This study aims to assess how well an educational program, using a nursing group support system, helps prevent skin lesions in dependent individuals at the Arnedo Health Center.

Who can participate?
People at risk for dependency-related skin lesions and their caregivers in the population at risk at the Arnedo Health Center

What does the study involve?
The main objective of this study is to analyze the effectiveness of an educational program based on a nursing group educational support system for caregivers in the prevention of skin lesions related to dependence in terms of reducing the appearance of these lesions. Participants will be checked for CRLD appearance, knowledge index, quality of life, and caregiver burden at 0, 1, 3, and 6 months post-session.

What are the possible benefits and risks of participating?
Avoidance of the appearance of skin lesions related to dependence in persons at risk, benefiting in other terms such as the improvement of the caregiver's level of knowledge, quality of life or emotional overload of the caregiver.

There are no objective risks of participation in the study.

Where is the study run from?
The municipality of Arnedo Health Center, province of La Rioja, Spain

When is the study starting and how long is it expected to run for?
September 2020 to April 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Rebeca Garrido García, rebe_garri@hotmail.com; rgarridog@riojasalud.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IDRGG01

Study information

Scientific Title
- P: People at risk for dependency-related skin lesions and their primary caregivers.
- I: Training of caregivers of people at risk of suffering from dependency-related skin lesions (CRLD) through an educational nursing program in the prevention of these lesions based on a nursing group educational support system within the framework of care for chronicity and dependency. Direct intervention that involves an indirect intervention in people at risk of suffering CRLD.
- C: Caregivers of persons at risk for CRLD receive standardized individual advice from their referring nurse.
- O: Reduce the occurrence of dependency-related skin lesions in dependent persons.

Acronym

CRLD

Study objectives
The participation of primary caregivers of patients at risk for dependency-related skin lesions in a group educational intervention on their prevention will decrease the occurrence of (lesiones cutáneas relacionadas con la dependencia; CRLD) by 25% compared to patients receiving only standardized individual counseling.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/02/2021, La Rioja Drug Research Ethics Committee (Pl. San Pedro, 3, 26006 Logroño, La Rioja, Logroño, 26006, Spain; 941 27 88 67; secretaria.ceic@riojasalud.es), ref: PI489

Study design
Simple blinded multicenter randomized clinical trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life

Health condition(s) or problem(s) studied
Prevention of skin lesions related to dependence

Interventions
This study will analyze the effectiveness of an educational program based on a nursing group educational support system for caregivers in the prevention of skin lesions related to dependence in terms of reducing the appearance of these lesions in the at-risk population of the Arnedo Health Center.

Intervention group: Interventions will be carried out in weekly group training sessions. The control of the appearance of dependency-related skin lesions (lesiones cutáneas relacionadas con la dependencia; CRLD), knowledge index, health-related quality of life, and caregiver overload will be assessed at 0, 1, 3 and 6 months after having received the sessions. Before starting the intervention, the validated questionnaires/instruments will be delivered as participants are recruited for the study, and these questionnaires will be used to measure the variables under study (test phase). The recruitment and completion of the questionnaires will last two months, closing the entry of new participants if the sample size has been reached.

Detailed standardized individual counseling will be provided in the control group activity. Randomization will be carried out in a simple manner so that each patient has the same probability of being in one or the other intervention group by generating random numbers using the Excel program. A list will be created with an alphanumeric code of each person participating in the study and these will be randomly placed in the control or intervention group. One or two of the investigators, different from the people who recruit, intervene and assess the research participants, will be in charge of generating the list and including the assigned random identification number in a sealed envelope.

Intervention Type
Mixed

Primary outcome(s)
Effectiveness assessed via the incidence of injuries, and appearance of skin lesions (i.e., pressure and/or shear injuries, skin lesions associated with moisture, friction injuries, skin tears and a mixture of combined injuries) related to dependence by a referring nurse or the principal investigator measured using the collected data at 0, 1, 3 and 6 months

Key secondary outcome(s))
Current key secondary outcome(s) as of 25/03/2026:

The following secondary outcome measures will be assessed at 0, 1, 3 and 6 months:
1. Knowledge of dependence-related skin lesions in caregivers of persons at risk for CRLD measured using the Questionnaire of knowledge of family caregivers about prevention of pressure ulcer and dependence-related skin lesions (COCU-LCRD-23) in Spanish
2. Health-related quality of life (HRQoL) of caregivers of persons at risk for CRLD measured using the EuroQol EQ-5D-5L HRQoL questionnaire
3. Emotional overload of caregivers of persons at risk for CRLD measured using the Zarit Burden Interview assessing caregiving burden

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Previous key secondary outcome(s):

The following secondary outcome measures will be assessed at 0, 1, 3 and 6 months:
1. Knowledge of dependence-related skin lesions in caregivers of persons at risk for CRLD measured using the Questionnaire of knowledge of family caregivers about prevention of pressure ulcer and dependence-related skin lesions (COCU-LCRD-23) in Spanish
2. Health-related quality of life (HRQoL) of caregivers of persons at risk for CRLD measured using the EuroQol EQ-5D-5L HRQoL questionnaire
3. Emotional overload of caregivers of persons at risk for CRLD measured using the Zarit Burden Interview assessing caregiving burden
4. Post-intervention costs of caring for people at risk of developing dependence-related skin lesions measured using pricing data stipulated by Riojano Health Service for nursing consultation, nursing home and cure material
5. Cost-utility analysis (CUA) of a health education intervention for the prevention of dependence-related skin lesions measured using data recorded in medical records

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Patients at risk of developing CRLD according to the Braden scale for the prediction of pressure ulcer risk available in Selene AP (Selene®).
2. Primary caregiver identified
3. Sufficient knowledge in terms of understanding, reading and writing correctly in Spanish
4. The caregiver has received standardized CRLD prevention training provided by their referring nurse or research team

Participant type(s)
Carer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Occasional or secondary caregivers who are not primary caregivers, i.e., who do not assume full responsibility for the caregiving task
2. Caregivers who do not speak Spanish
3. Caregivers who present cognitive impairment or learning difficulties
4. Caregivers who are not sufficiently independent for basic activities of daily living (ABVD) and have a Barthel index ≤ 60

Date of first enrolment
01/12/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Spain

Study participating centre
Centro de Salud de Arnedo
Av de Benidorm, 57, 26580 Arnedo, La Rioja
Arnedo
Spain
26580

Sponsor information

Organisation
University of Valencia

ROR
https://ror.org/043nxc105

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated and/or analyzed will be published as a complement to the publication of results.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			26/04/2024	No	Yes