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A Randomised Trial of a Psychoeducational Intervention to Improve Home Care Safety for Informal Caregivers

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Abstract

Background: Informal caregivers play a crucial role in medication safety and daily care at home, yet they often lack training and support. Caregiving errors in home settings remain under-recognised and can compromise patient safety.

Objective: To evaluate the effectiveness of a psychoeducational intervention in reducing caregiving and medication-related errors among informal caregivers.

Methods: A randomised controlled psychoeducational intervention was conducted in Spain with 141 informal caregivers of highly dependent individuals on multiple medications. Participants were randomly assigned to an intervention group (N=71) or control group (N=70). The intervention included two participatory sessions combining theoretical content and practical training on safe care and medication management. Outcomes included self-reported errors, video-based error recognition, and emotional burden of caregiving tasks. Data were collected at baseline, post-intervention, and three-month follow-up.

Results: The experimental group showed a significant reduction in self-reported errors (from 0.84 to 0.34 errors per caregiver; $p < 0.001$), while errors increased in the control group. The odds of reporting no errors post-intervention were significantly higher in the intervention group (OR = 4.05). Error recognition improved in 67.6% of participants (Cohen's d = 0.55). Emotional burden declined significantly, and perceived caregiving competence remained high, with nearly all participants reporting improved task performance and satisfaction.

Conclusions: A brief psychoeducational intervention can enhance home care safety and caregiver confidence. Supporting informal caregivers is key to preventing avoidable harm and ensuring safer care for individuals with chronic and complex conditions.

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Key Words: Housing (MeSH), informal caregivers, medication errors (MeSH), caring errors, patient safety (MeSH), psychoeducational intervention, Health Education (MeSH).

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Conflict of interest. Authors declare that there are not any financial or non-financial interests that are directly or indirectly related to the present work to disclose.

Authors contributions. JJM, IC, and MG contributed to the conceptualisation of the study. EGH, ASG, VRN, VM, PB, and AA were responsible for data collection and contributed to the development of the intervention. CPE conducted the statistical analyses. All authors contributed to the interpretation of the data. JJM and EGH drafted the initial version of the manuscript. All authors reviewed and approved the final version.

Data availability. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Introduction

Spain, alongside Italy and Japan [1], leads the list of countries with the highest ageing populations. This demographic ageing leads to an increase in non-communicable diseases, which in turn increases the demand for healthcare services and the consumption of healthcare resources [2]. By 2030, it is expected that chronic diseases will double their current incidence among people over 65 years of age [3]. Consequently, the number of patients with multiple chronic conditions, increased fragility, and complexity is growing.

Multimorbidity and polypharmacy pose a higher risk of medication-related adverse events [4]. Medication errors (MEs) refer to any preventable incident that may cause inappropriate medication to use or harm to the patient while the medication is under the control of healthcare professionals, as well as the patient or their informal caregivers [5,6].

Individuals with chronic conditions experience a progressive loss of autonomy and an increasing need for support to address physical and emotional symptoms, manage their treatment, communicate with healthcare professionals, and, in more complex cases, perform daily tasks [7]. Women, reflecting persistent gender inequalities, predominantly assume the role of caregivers for chronically ill, multimorbid, and polypharmacy patients, and often feel a greater sense of responsibility for providing care at home [8]. Among informal caregivers, women are common, and in most cases, they are daughters, daughters-in-law, or spouses of the person they care for. Around 60% of informal caregivers have basic education, and, typically, they have not received training to manage and administer medication and apply home care procedures [9].

Research on family caregivers has increased in recent years. Most studies have focused on analysing the emotional and social burden resulting from the care of dependent individuals [10–13]. A growing body of research has also addressed the needs and challenges they face regarding medication management, despite being one of their main tasks and having a considerable impact on the health status of the person they care for [14–18]. More than half of caregivers take responsibility for administering 5 or more prescribed medications per day, and nearly 20% administer 10 or more [19]. Health literacy, health beliefs, and the information they have about

the therapeutic regimen to follow are key to the safe use of medication at home [20]. Although two out of three caregivers admit to having problems managing medications, recent evidence suggests that rigorously tested caregiver-centred interventions aimed at reducing medication-related errors in the home setting remain limited [21]. However, it is worth noting that around 5% of MEs require new treatment or hospitalisation [22]. Most MEs cause concern to the patient and their families, consume healthcare resources (new consultations), and create insecurity during treatment, which leads to further errors.

Evidence suggests that self-efficacy is associated with better task performance, greater confidence, and more adaptive coping efforts [23]. This construct may be particularly relevant in home care, where informal caregivers often undertake complex responsibilities with limited training and support. Examining self-efficacy in this context may help to better understand factors that influence safer caregiving practices and the protection of care recipients [24]. Health locus of control has also been used in health psychology and medication-adherence research to examine whether individuals attribute health-related outcomes mainly to their own actions, to other people, or to external circumstances [25,26]. In home caregiving, this construct may help to interpret whether caregivers perceive safe care and error prevention as dependent on their own ability to learn and monitor routines or as mainly determined by environmental constraints and lack of support.

This study tested the effectiveness of a psychoeducational intervention aimed at informal caregivers to achieve safer medication use at home. This study is aligned with the WHO's challenge to achieve Medication Without Harm [27] and focuses on informal caregivers as key partners in home care safety, but whose intervention is decisive in-patient safety: caregivers.

Methods

An experimental two-arm design (experimental vs. control) was used, with assessments conducted at baseline (pre-intervention), immediately after the intervention (post-intervention), and three months later (follow-up). Group assignment was performed through simple randomisation. In this study, an informal caregiver's error was defined as any preventable event related to action or omission in medication or care performed by caregivers at home, whether it resulted in harm to the patient [6]. A dependent patient was a person with reduced functional autonomy due to age, chronic illness, disability, or cognitive impairment who requires assistance or supervision to perform basic activities of daily living and health-related care tasks.

The structure and reporting of this study were guided by relevant items from the CONSORT 2025 statement [28].

Ethics

The project received approval from the Ethics Committee of Sant Joan d'Alacant University Hospital on December 22, 2021 (project code: 21/063) and was registered at ClinicalTrials.gov (ref. NCT05247801, February 18th, 2022, https://clinicaltrials.gov/search?term=NCT05247801). The research was performed in accordance with Spanish national regulations regarding research involving human participants and was performed in accordance with the Helsinki Declaration (updated in October 2024).

Patient or public involvement

No patients directly participated in this study. The research focused on informal caregivers of dependent individuals. Participants in the intervention group contributed insights that informed the refinement of the educational materials. Additionally, the videos used in the follow-up assessment featured real informal caregivers, which enhanced the realism and relevance of the content.

Changes to trial protocol

Two modifications were made to the original protocol prior to participant recruitment and data analysis. First, the planned sample size was recalculated based on updated estimates of the expected frequency of caregiving and medication-related errors, in order to ensure sufficient statistical power. Second, the follow-up period was shortened from six to three months to reduce the risk of recall bias and improve the accuracy of reported errors. Both changes were introduced to enhance the methodological rigour and validity of the study findings and were implemented before participant recruitment and before outcome data analysis.

Trial setting

The study was conducted in collaboration with healthcare institutions located in three Spanish regions: Andalusia, Madrid, and the Valencian Community. These sites provided access to informal caregivers of highly dependent individuals and supported participant recruitment and intervention delivery.

Participants

A total of 142 caregivers of complex, taking seven or more medications daily, and dependent patients were invited to participate. Eligible caregivers were responsible for older adults' patients for at least six months per year. Care recipients were required to be receiving support at one of the collaborating institutions.

Caregivers were excluded if they cared for institutionalised patients for at least three months per year, had formal healthcare training, or had filed a liability claim within the past five years.

Sample size

The sample (71 in each group) was calculated to detect clinically meaningful differences in error rates between groups, based on the frequency of 70% of MEs reported in a previous study [29], with a 95% confidence level, 80% statistical power and an expected dropout rate of 15%.

Recruitment

Participants were recruited in collaboration with the partner centres involved in the study. Caregivers were approached during regular medical consultations while accompanying the care recipient, through caregiver schools, and via caregiver associations or foundations. Additionally, a snowball sampling approach was used within the collaborating institutions, with enrolled caregivers helping to identify other potentially eligible caregivers who were also receiving assistance in those same settings. In all cases, lists of caregivers who agreed to participate were compiled. At this stage of recruitment, recruiters were unsure whether participants would be assigned to the control or the intervention group. From these lists, participants meeting the inclusion criteria were selected and then randomly assigned based on

drawing lots to either the intervention or control group using simple randomisation. This procedure was carried out independently by two members of the research team (CPE and PB) to ensure allocation concealment and avoid selection bias. Group allocation took place after informed consent was obtained, and participants were not informed of their group assignment to reduce bias.

Blinding

Group allocation was concealed until the point of assignment and communicated to participants by an independent researcher who was not involved in outcome assessment. To minimise bias, outcome assessors were blinded to group assignment. However, due to the behavioural nature of the intervention, blinding of participants was not feasible.

Interventions

Participants in the control group received the usual information and training procedures routinely provided by the participating centres.

Participants in the intervention group received a structured psychoeducational intervention, whose contents were defined through iterative refinements and based on prior research assessing caregivers' reported needs in the home setting [29]. The intervention aimed to increase self-efficacy and health literacy and included audiovisual materials and printed support resources.

The experimental intervention consisted of two presential sessions, each approximately one and a half hours in duration, delivered over the course of two separate weeks. Group sizes ranged from a minimum of 8 to a maximum of 12 participants. The sessions were structured in a dynamic and participatory format. The design and content of the intervention were informed by a prior qualitative study and a survey conducted with informal caregivers, which explored their experiences, training needs, and common challenges in providing care at home [29,30].

The psychoeducational intervention developed in this study integrated key components aimed at strengthening informal caregivers' ability to provide safe and effective care at home. The content was structured in two participatory sessions combining theoretical learning and practical skills training. Risk management of home caregiving events was a central theme, with a focus on identifying and addressing potentially unsafe conditions in the home. Theoretical content included how to recognise high-risk situations (e.g., improper storage of medications, distractions during care tasks, or lack of coordination among family members). Practical exercises encouraged participants to map caregiving routines and detect critical points where errors might occur. Understanding common causes of medication safety incidents was facilitated through exploration of real-life scenarios, including improper medication timing, omissions, duplications, or the use of expired medicines. Caregivers were guided to reflect on how low health literacy, environmental distractions, poor communication, or overconfidence might lead to such incidents. Behavioural problem management was introduced through facilitated discussions on common caregiving challenges and practical problem-solving. This component was directly linked to medication safety, as these challenges can increase the risk of errors, including missed doses, incorrect administration, or non-adherence to prescribed regimens. Caregivers shared the most frequent difficulties they encountered -such as communication breakdowns or resistance from care recipients- and discussed strategies for anticipating and managing these situations. To address

this, caregivers were trained in communication, behavioural, and emotional management strategies, such as using clear and simple language, adapting instructions to the cognitive and sensory abilities of the care recipient, breaking down tasks into manageable steps, responding calmly to resistance, and supporting emotional well-being to enhance engagement and cooperation. The second session included practical training in blood pressure monitoring and CPR, reinforcing the caregiver's role in monitoring health status and responding to critical situations. Self-care skills were addressed through activities aimed at improving caregivers' physical and emotional well-being. Caregivers reflected on their caregiving routines, learned basic self-care strategies, and received guidance on maintaining physical and emotional resilience. The intervention emphasised observing behavioural cues, identifying triggers, and adapting care routines accordingly. Finally, coping with unintentional errors at home was addressed both explicitly and implicitly. The intervention promoted a just and non-punitive perspective toward mistakes, encouraging caregivers to recognise errors, understand their origin, and take steps to prevent recurrence. Open-ended discussions normalised feelings of guilt or fear and emphasised the importance of seeking help and learning from errors as part of a safe home care culture. The session structure is outlined in Table S1 (Supplementary materials).

The intervention was conducted by a multidisciplinary team comprising a nurse, a pharmacist, a psychologist, and a biologist. To ensure consistency and minimise variability associated with individual facilitation styles, all professionals received prior training and reached consensus on the educational content to be delivered.

Measures

This study used two primary outcome measures: self-reported caregiving and medication-related errors and error recognition.

The self-reported errors measure captured the frequency, type, and consequences of caregiving and medication-related errors. Data were collected at two time points (pre-intervention, and three-month later post-intervention), allowing the analysis of both retrospective and prospective trends. Self-reported medication error measures have been used in previous studies on medication safety in home and community settings, particularly when continuous direct observation is not feasible [29,31,32]. In this study, the measure captured errors perceived and recalled by caregivers during routine home care, including omissions, wrong timing, dose-related errors, and care provision errors, together with their immediate consequences. The three-month recall period was used to reduce recall burden.

The video-based error detection ability assessed participants' ability to identify potential errors in caregiving scenarios. It involved video-based simulations of common home caregiving situations in which participants were asked to detect and describe any mistakes observed. This was administered pre- and three-month later post-intervention to evaluate changes in error awareness. It was applied only to the experimental group, as the task itself could influence learning and act as an active component of the intervention.

Type of medication error (e.g., underdosing, overdosing, omission, wrong timing) and caregiving error (e.g., forgetting dietary requirements, falls during bathing, back injuries during transfer) reported by participants. Consequences of those errors were

also recorded and categorised as: none, scare only, mild discomfort, or harm requiring medical consultation.

Specific precautions were taken to support the validity and feasibility of the study measures. Questionnaire items were designed and reviewed to ensure clarity and comprehension, while the video-based error recognition exercise was standardized to ensure that scenarios were understandable and that error identification was feasible and interpretable across participants.

Emotional burden of caregiving tasks measured using the short version of the Zarit Burden Interview (7-items) [33].

Potential limitations imposed by the care recipient's physical and social environment were self-assessed by participants on a scale from 0 (completely limited) to 10 (not limited at all), using the six-item COM-B questionnaire [34]. This questionnaire captures key behavioural determinants of safe caregiving at home, namely whether caregivers perceived themselves as sufficiently capable, supported by their environment, and motivated to maintain safe care and medication routines.

Error expectation captured whether caregivers believe they have made no errors, minor intercepted errors, or significant errors with consequences. These measures help assess caregivers' awareness, confidence, and sense of responsibility before and after the intervention. Emotional burden, perceived limitations, and error expectation were included as secondary exploratory measures because the intervention aimed not only to improve technical knowledge, but also to reduce emotional strain, strengthen perceived capability and opportunity to provide safe care, and increase caregivers' awareness of possible errors. These variables therefore provided complementary information on plausible psychosocial and behavioural mechanisms through which the intervention could influence safer caregiving practices.

Locus of control refers to caregivers' beliefs about the source of caregiving quality (internal ability vs. external conditions) and their perceived likelihood of having made unintentional errors. A high perceived control reflects confidence in one's ability to provide care effectively, while attributing quality solely to environmental limitations indicates an external locus of control.

Perceived improvement in caregiving ability, evaluated through an adapted version of the IEXPAC questionnaire for informal caregivers [30]. This instrument assessed the extent to which the intervention supported safe, effective, and person-centred caregiving, including decision-making and caregiver autonomy.

Satisfaction with the intervention, assessed using items aligned with Kirkpatrick's reaction level [35], covering perceived usefulness, clarity, relevance, and overall value of the intervention.

Data collection

Baseline

Sociodemographic data were gathered through a baseline survey, which was used to confirm eligibility and describe participant characteristics in both control and experimental groups. The survey also collected information on the care recipient's health status and the caregiver-reported emotional burden.

During the pre-intervention phase, data were collected on the number and type of self-reported caregiving and medication-related errors that had occurred over the

past three months, including a description of their consequences (self-reported errors measure). The locus of control, perceived limitations imposed by the care recipient's physical and social environment, and emotional burden of caregiving tasks were also measured in both groups.

The participants in the experimental group also viewed video scenarios illustrating common caregiving tasks and were asked to identify the potential errors depicted (video-based error detection ability) (Annex 1, Supplementary materials).

After the experimental intervention

In the post-intervention phase (immediately after the intervention), emotional burden, perceived limitations imposed by the care recipient's physical and social environment, and error expectations were assessed in the experimental group only. They were also asked about their opinion regarding the intervention and their self-perception as caregivers.

Three months later

In the follow-up phase, after completion of the intervention, self-reported caregiving and medication-related errors that occurred during the previous three months were assessed. This phase also included items to assess the type and consequence of preventable errors, emotional burden of caregiving tasks, and others aimed at evaluating participants' immediate experience and perceived value of the experimental intervention.

Participants of the experimental group in the follow-up viewed the same video scenarios regarding common caregiving tasks used in the pre-intervention. They identified potential errors depicted (video-based error detection ability). They were also asked to reflect on how the intervention had influenced their caregiving ability and the overall quality of care they provided. Finally, they rated the usefulness of the information received and their overall satisfaction with the intervention.

Data analysis

For statistical analyses, participants who did not meet the minimum threshold of one hour per day of participation during the intervention, as well as those who did not complete the 3-month follow-up, were excluded.

A descriptive analysis was conducted to characterise the participants, distinguishing between the control and intervention groups. The total number of reported errors was described for each study phase (pre- and post-intervention, and follow-up).

To assess differences between the control and intervention groups across study phases, a repeated-measures ANOVA was used to compare the total number of reported errors by group and time point. Additionally, a separate logistic regression model was conducted to examine the impact of the intervention on error admission (dichotomous variable admits/does not admit having made errors).

Within-group comparisons were performed using paired-sample tests: Student's t-test for related samples or, when normality assumptions were not met, the non-parametric Wilcoxon signed-rank test. For dichotomous variables, such as error admission, McNemar's test was used. Improvement in error admission between groups was assessed using Fisher's exact test.

To identify factors associated with the occurrence of errors, a multivariate logistic regression was performed using a stepwise selection method, with calculation of odds ratios (OR) and 95% confidence intervals (95% CI).

In the intervention group, a paired t-test was applied to evaluate improvement in error detection through video-based scenarios, and the effect size was estimated using Cohen's d.

Changes in emotional burden over time were analysed using the Friedman test, complemented by pairwise comparisons with the Wilcoxon test. Finally, a Z-test for proportions was used to compare the percentage change in caregivers reporting no emotional burden between the pre- and follow-up phases in both groups.

Sensitivity analyses were conducted to assess the potential impact of attrition by comparing baseline characteristics between participants included in the final analysis and those excluded due to missing follow-up data. Analyses were also performed separately within each study group, and a multivariate logistic regression model was used to identify factors associated with follow-up completion.

Results

A total of 141 informal caregivers participated in the study, with 70 assigned to the control group and 71 to the intervention group. Participant recruitment began in June 2023 and was completed in December 2024. The mean age of participants was 53.3 years (SD 12.4), and the majority were women (107; 75.9%). Most caregivers (97; 68.8%) were relatives of the person they cared for (Table 1). Additionally, 66 individuals (46.8%) received financial support to cover their needs as dependent persons. Slightly more than half of the care recipients required daily assistance with personal hygiene (99; 70.2%) (Table 2).

Table 1. Description of the stratified participant sample.

	Control Group (N=70)		Experimental Group (N=71)	
Informal caregivers profile	N	%	N	%
Sex				
Male	18	25.7	15	21.1
Female	51	72.6	56	78.9
Non-binary	1	1.4	0	0.0
Age (M ± SD)	55.8 ± 11.6		50.9 ± 12.8	
Are you a relative of the person you care for?				
Yes	66	94.3	31	43.7
No	4	5.7	40	56.3
Is caregiving your main occupation?				
Yes	26	37.1	42	59.2
No	44	62.9	29	40.8
How many hours per day do you dedicate to caregiving? (M ± SD)	13.3 ± 8.8		10.2 ± 9.9	
Do you receive financial compensation for your caregiving work?				
Yes	7	10.0	28	39.4
No	63	90.0	42	59.2
No response	0	0.0	1	1.4

Have you received any training related to your caregiving work?				
None	60	85.7	32	45.1
Up to 20 h	4	5.7	3	4.2
21h – 40 h	1	1.4	0	0.0
More than 40 h	5	7.1	36	50.7
Years of experience as a caregiver (M ± SD)	7.2 ± 11.1			6.7 ± 10.7
Do you live with the person you care for?				
Yes	52	74.3	33	46.5
No	18	25.7	38	53.5
Have you always cared for the same person(s)?				
Yes	55	78.6	32	45.1%
No	15	21.4	39	54.9
Is Spanish your primary language?				
Yes	67	95.7	69	97.2
No	3	4.3	2	2.8

Table 2. Description of care recipients supported by participants.

	Control Group (N=70)		Experimental Group (N=71)	
Recipients profile				
Age of the person you care for (M ± SD)	75.6 ± 14.1		76.5 ± 18.8	
Sex of the person you care for				
Male	35	50.0	18	25.4
Female	35	50.0	53	74.6
Daily medications taken	7.7 ± 4.0		4.7 ± 3.0	
Uses dispensing devices for medication management				
Yes	41	58.6	29	40.8
No	29	41.4	42	59.2
Primary condition				
Alzheimer’s disease	20	27.0	16	22.5
Stroke	16	21.6	8	11.3
Cancer	15	20.3	11	15.5
COPD	9	12.2	1	1.4
Cardiovascular disease	7	9.5	11	15.5
Reduced mobility	5	6.8	5	7
Diabetes	1	1.4	9	12.7
Blindness	1	1.4	3	4.2
Other	0	0	7	9.9
Does the person have a recognised degree of dependency?				
Yes	23	32.9	43	60.6
No	47	67.1	28	39.4
Recipients requiring daily assistance with everyday activities				
Eating	17	24.3	14	19.7

Washing	53	75.7	56	78.9
Dressing	27	38.6	29	40.8
Grooming	47	67.1	52	73.2
Bowel control	25	35.7	25	35.2
Bladder control	27	38.6	17	23.9
Using the toilet	25	35.7	21	29.6
Transfer (bed/chair)	18	25.7	7	9.9
Ambulation	20	28.6	15	21.1
Stair climbing	34	48.6	26	36.6

Medication and Care Provision Self-reported Errors

In the control group, the number of self-reported caregiving and medication-related errors increased from 46 in the pre-intervention phase (mean: 0.66 ± 1.51) to 77 in the follow-up phase (mean: 1.10 ± 1.51). In contrast, the experimental group reported 60 errors before the intervention (mean: 0.84 ± 1.80), which decreased to 24 in the follow-up (mean: 0.34 ± 0.90) (Table 3). A significant interaction effect between group and time was found using repeated-measures ANOVA, $F = 10.76$, $p = 0.001$, indicating that changes in error frequency differed significantly between the two groups. These findings were supported by a logistic regression analysis: in the control group, the odds of reporting errors increased significantly from pre- to follow-up-intervention (OR = 2.08, 95% CI: 1.01–4.36, $p = 0.048$), whereas the experimental group showed a significant reduction in error probability (group-by-time interaction: OR = 0.28, 95% CI: 0.09–0.80, $p = 0.019$). No significant baseline differences (pre-intervention measures) were observed between groups (OR = 1.22, $p = 0.600$).

Table 3. Total number of self-reported caregiving errors.

	Control Group (N=70)		Experimental Group (N=71)	
	PRE	Follow-up	PRE	Follow-up
Medication errors	31	23	31	11
Care provision errors	15	57	29	13
Total errors self-reported	46	77	60	24
Repeated-measures ANOVA	Sum of Squares	Mean Squares	F	P-value
Group x Pre vs. Post/Follow-up	15.90	15.902	10.76	0.001

Comparison of Error Types and Consequences Between Groups

In the control group, the most commonly reported medication error both pre-intervention and at three months later intervention (follow-up) was omission (14, 45.2% and 9, 42.9%, respectively), followed by confusion (6, 19.4%) in the pre-intervention phase and wrong timing (6, 28.6%) at follow-up. Regarding caregiving errors, the most frequent was a fall during bathing due to missing supports, reported in 6 cases (42.9%) at the pre-intervention phase and 8 cases (34.8%) at follow-up. Meanwhile, in the experimental group, the most commonly reported errors during the baseline were missed doses (10, 32.3%) and failure to administer medication at the scheduled time (9, 29.0%). At follow-up, the most frequently reported error was again

missed doses (5, 45.5%). The full breakdown of medication error types is presented in Table S2 (Supplementary Material).

Most of the errors reported by participants in the control group had no consequences (9, 56.3%) or caused only a scare (6, 37.5%) at baseline. At follow-up, nearly all (10, 90.9%) had no consequences, with just one case (9.1%) involving a scare. For caregiving errors, 5 cases (62.5%) had no consequences and 3 (37.5%) caused mild discomfort pre-intervention, while at follow-up, most resulted in either a scare (9, 42.9%) or mild discomfort (7, 33.3%), with only 5 (23.8%) having no consequences. In the case of the experimental group, during the pre-intervention phase, the majority of reported errors had no consequences (10, 76.9%), and only one case (7.7%) required treatment. At follow-up, just one case involved mild symptoms, while the rest had no consequences beyond a scare. Detailed data are provided in Table S3 (Supplementary Material).

Increased Recognition of Errors

The improvement in the admission of caregiving and medication-related errors in the follow-up was significantly greater in the experimental group (19.7%) compared to the control group (5.7%) ($p = 0.021$), according to Fisher's exact test. The odds of improvement—defined as reporting errors three months after the intervention and not reporting them afterwards—were four times higher in the experimental group (OR = 4.05), suggesting that the intervention had a meaningful effect on awareness of safe practices (Table S4, Supplementary materials).

Probability of Committing an Error

Within the experimental group, being a family caregiver was significantly associated with a higher likelihood of reporting caregiving or medication-related errors. Specifically, family caregivers had more than three times the odds of committing an error compared to non-family caregivers (OR = 3.64, p-value = 0.006). In contrast, having received specific training was significantly associated with a reduced likelihood of errors (OR = 0.42, p-value = 0.028), suggesting a protective effect of training even within the context of the intervention. These findings highlight the persistent influence of caregiver profile and prior training on safety outcomes, despite participation in the psychoeducational program (Table S5, Supplementary Materials).

Error Recognition Through Video-Based Scenarios

In the experimental group, out of 71 caregivers, 48 participants (67.6%) improved their ability to detect errors three months after the intervention (follow-up phase), indicating a substantial enhancement in their observational skills. In contrast, 12 participants (16.9%) showed no change, and 11 participants (15.5%) detected fewer errors than in the initial assessment. This improvement in error recognition was statistically significant (p-value < 0.001), with a moderate effect size (Cohen's d= 0.55, 95% CI: 0.33 – 0.78), suggesting the intervention had a meaningful impact on participants' ability to identify risky practices in home caregiving (Table 4).

Table 4. Changes in error detection based on video scenarios at the follow-up phase (experimental group N=71).

Change in video-based error detection ability	N	%
Detected more errors (pre-follow-up comparisons)	48	67.6
No change in the number of errors detected	12	16.9

Change in video-based error detection ability	N	%
Detected fewer errors Follow-up	11	15.5
Total	71	100

Emotional Burden of Caregiving Tasks

Caregivers in the control group did not show a significant reduction in emotional burden over time. The proportion reporting no emotional burden remained unchanged post-intervention (45.7%) but declined to 34.3% at follow-up. Although reports of frequent burden ("often" or "almost always") decreased, a notable increase in caregivers reporting low-level burden ("rarely") was observed at follow-up (51.4%), suggesting a shift from higher to milder -but persistent- strain in the absence of targeted support.

Caregivers in the experimental group reported a significant reduction in the emotional burden associated with caregiving tasks following the intervention. The percentage of participants who reported never experiencing emotional burden increased from 56.3% at baseline to 60.6% post-intervention, and further to 63.4% at the three-month follow-up. In parallel, the proportion of participants reporting frequent emotional strain decreased over time. A Friedman test confirmed a significant overall change in emotional burden across the three time points, $\chi^2 = 34.70$, $p < 0.001$. Pairwise Wilcoxon signed-rank tests revealed statistically significant reductions between: Pre- and post-intervention (W= 0.00, p-value = 0.0003), post-intervention and follow-up (W= 0.00, p-value = 0.0016), and Pre-intervention and follow-up (W = 0.00, p-value < 0.0001) (Table 5).

A statistically significant difference was detected in the percentage change of caregivers reporting no emotional burden between baseline and follow-up in the evolution of the groups (Z = 5.709, p-value < 0.001). While the control group experienced a 24.9% decrease, the experimental group showed a 12.6% increase in caregivers stating they did not feel emotionally exhausted at follow-up compared to baseline.

Table 5. Emotional burden of caregiving tasks.

Control group (N=70)			
Emotional Burden	Pre (N, %)	Post (N, %)	Follow-up (N, %)
Never	32 (45.7)	32 (45.7)	24 (34.3)
Rarely	12 (17.1)	16 (22.9)	36 (51.4)
Sometimes	18 (25.7)	13 (18.6)	8 (11.4)
Often	5 (7.1)	6 (8.6)	0 (0.0)
Almost always	3 (4.3)	3 (4.3)	2 (2.9)
Experimental group (N=71)			
Emotional Burden	Pre (N, %)	Post (N, %)	Follow-up (N, %)
Never	40 (56.3)	43 (60.6)	45 (63.4)
Rarely	10 (14.1)	11 (15.5)	14 (19.7)
Sometimes	11 (15.5)	12 (16.9)	8 (11.3)
Often	7 (9.9)	3 (4.2)	4 (5.6)
Almost always	3 (4.2)	2 (2.8)	0 (0.0)

Self-perceived Daily Limitations

Throughout the three study phases, participants in the experimental group generally reported low levels of limitation imposed by the care recipient's physical and social environment. They reported stable and low limitations from the physical (M = 7.5–7.6) and social environment (M = 7.4–7.5) across all phases (Table S6, Supplementary Material).

Motivation

Motivation to achieve good results declined at follow-up (mean = 5.0), while perceived competence remained high (mean = 8.0–8.6). Caregivers consistently reported feeling physically and psychologically strong to perform their role. Full results are available in Table S6 (Supplementary Material).

Locus of Control and Error Expectation

In addition to emotional burden, caregivers' beliefs about the origin of caregiving quality (internal vs. external locus of control) and their perceived likelihood of having made unintentional errors were assessed. As shown in Table S7 (Supplementary Material), the proportion of participants who attributed the quality of their caregiving to their own ability to learn and cope remained high across all phases in both groups, though it declined slightly at follow-up in the experimental group. In contrast, attributing caregiving quality solely to external environmental conditions increased notably in the control group at follow-up, while it decreased slightly in the experimental group. After the intervention, more participants in the experimental group recognised having made minor, intercepted errors, which may reflect increased awareness and error monitoring.

Intervention Evaluation

Participants in the experimental group evaluated the intervention very positively (Table 6). The vast majority reported that their participation had improved their caregiving capacity. All participants found the sessions engaging and easy to follow and unanimously agreed that their task performance improved. Additionally, over 90% felt more capable and committed to enhancing the care recipient's well-being, and more than 87% perceived a positive impact on their own health and well-being—highlighting the strong perceived value of the intervention.

Table 6. Evaluation of the experimental intervention (follow-up phase, N=71).

Evaluation Items	Response	N	%
Did you find the sessions you participated in engaging?	Yes	71	100
	No	0	0.0
Did you learn something applicable to your caregiving role?	Yes	70	98.6
	No	1	1.4
Was it easy for you to participate in the study?	Yes	71	100
	No	0	0.0
Did the sessions reflect your daily caregiving experience?	Yes	66	93.0
	No	5	7.0

Has your performance of the tasks practised improved through participation in the study?	Yes	71	100
	No	0	0.0
I now feel more confident and capable of providing care, managing health problems, and coping with the situation of the person I care for	Not at all	0	0.0
	Hardly	0	0.0
	Sometimes	16	22.5
	Completely	55	77.5
I now follow the care and treatment plan better than before	Not at all	0	0.0
	Hardly	1	1.4
	Sometimes	10	14.1
	Completely	60	84.5
I now feel more capable of ensuring the well-being and quality of life of the person I care for, and I am committed to improving their welfare	Never	0	0.0
	Occasionally	0	0.0
	Usually	7	9.9
	Completely	64	90.1
I feel that participating in this project has benefited my own health and well-being	Never	0	0.0
	Occasionally	0	0.0
	Usually	9	12.7
	Completely	62	87.3

Sensitivity analysis

Attrition differed significantly between groups ($\chi^2 = 5.31$, $p = 0.021$), with a higher proportion of excluded participants in the control group. In the control group, 46 out of 116 participants (39.7%) were excluded due to missing follow-up data, compared to 22 out of 93 (23.7%) in the intervention group.

Given the unequal attrition between groups, sensitivity analyses were conducted separately within each group. Baseline characteristics were broadly comparable between included and excluded participants. No significant differences were observed in age, caregiving experience, or daily caregiving hours (Table S8, Supplementary Material).

Similarly, categorical variables such as sex, training level, caregiving as the main occupation, financial compensation, and baseline error reporting did not differ significantly between included and excluded participants (Table S9, Supplementary Material). A difference was observed in caregiver relationship within the control group, but this pattern was not replicated in the intervention group.

Multivariate analysis showed a non-significant trend towards higher follow-up completion (OR = 2.31, 95% CI: 0.90–5.95, $p = 0.082$), indicating higher retention in the intervention group, while no baseline characteristics were significant predictors (Table S10, Supplementary Material).

Overall, these findings suggest that, despite differential attrition between groups, it is unlikely to have substantially biased the main intervention effects.

Discussion

Main findings

This study suggests that a brief psychoeducational intervention can significantly reduce self-reported caregiving and medication-related errors among informal caregivers, improve their ability to recognise risks, and alleviate emotional burden. These findings align with previous research showing that targeted training enhances caregivers' competences, knowledge about diseases, and reduce the chance of emotional distress or psychological strain [36–41]. Unlike other studies focused on the mental health, resilience, or health literacy of informal caregivers, this study specifically addressed how to reduce unintentional errors when caring for a dependent recipient at home. This trial addresses a still underdeveloped area of intervention, extending the current evidence base on caregiver involvement in medication management and the support needs identified in prior studies and recent reviews. It is increasingly clear that family and informal caregivers play a central role in medication management, especially for people with long-term conditions, yet their contribution remains insufficiently recognised and supported by health services [16]. Although the WHO's Medication Without Harm strategy [27] is primarily aimed at institutional facilities, these findings suggest that it should also be extended to the home setting. Indeed, this study reinforces the need for a caregiver-centred perspective, particularly in a context where medication management is often hindered by fragmented services, poor communication, and limited opportunities for caregivers to engage effectively with the health system [18]. It also responds to evidence showing that patients and caregivers frequently experience medication discontinuity, communication barriers, and limited participation in decision-making, highlighting the need for more patient- and caregiver-centred strategies to improve safety [42].

The intervention group not only showed fewer errors but also improved in recognising unsafe practices, which may reflect better recall of the training content and increased awareness of common risks in routine caregiving tasks. Findings on perceived control and error expectation are also consistent with a possible intervention effect on caregiver self-efficacy. The greater recognition of minor intercepted errors suggests improved reflective monitoring and awareness of safe caregiving practices, although follow-up missing data warrant cautious interpretation. This reinforces the importance of integrating practical tools, such as video-based scenarios, into training programs, especially for non-professionals who learn better through observation and experiential learning. Interestingly, caregivers who had previously received any formal training reported fewer errors, supporting the idea that even minimal structured education can have a protective effect. Likewise, our finding that the number of medications increases error probability emphasises the need for specific strategies in polypharmacy contexts [29].

Interestingly, the increase in self-reported errors observed in the control group should be interpreted with caution. One possible explanation is a panel or measurement effect, whereby participation in the study and repeated assessment increased caregivers' awareness of routine mistakes, leading them to identify and report errors that they had previously overlooked or not classified as such. In addition, the absence of structured reinforcement or practical support in the control group may also have contributed to this pattern [43].

The decline in emotional burden observed over time highlights the value of interventions that not only improve technical knowledge but also address caregiver well-being. The reduction in emotional burden may have contributed to safer caregiving indirectly, by improving caregivers' perceived control, confidence, and ability to engage with recommended practices. However, this possible mechanism cannot be confirmed from the present data alone, and future research should examine whether changes in emotional burden mediate improvements in safety-related behaviours and error prevention. This is particularly relevant for women, who remain the predominant providers of informal care and face disproportionate emotional and physical strain. The consistent findings of high motivation and confidence after this type of interventions underscore the importance of psychological reinforcement in supporting sustained behavioural change [36–41].

Contrasting with Prior Research

Previous studies have identified several common MEs, including incorrect dosing, mixing medications, confusing drugs based on their colour or shape, misinterpreting administration instructions, taking expired medications, chewing drugs intended to be swallowed whole, swallowing medications meant to be chewed, or using drugs that have not been properly stored [44]. The risk of MEs increases when multiple caregivers alternate in providing care. The use of dosing devices or electronic alert systems has been shown to reduce the incidence of MEs by up to one-third [4,27].

The causes of MEs committed by informal caregivers have been associated with several factors, including limited health literacy, the complexity of therapeutic regimens, communication barriers with healthcare professionals, and inconsistent information provided by those professionals. Additional contributing factors include a lack of guidance regarding medication precautions, misinterpretation of instructions from physicians or pharmacists, the use of herbal or natural products without informing the healthcare specialist, frequent changes in physicians or contradictory messages from different professionals regarding the same condition, and being cared for by multiple teams with poor coordination. Other issues involve reliance on multiple caregivers, administering medication using devices that require direct involvement from either the patient or caregiver to correctly calculate the dose, lack of understanding of the purpose of the medication, and look-alike packaging of medications [44–46].

The main challenges that caregivers face in ensuring the safe use of medications for their family members have been systematically categorized by Alsaeed et al. [47] into six key domains. These include logistical issues related to the organization and scheduling of medications, such as acquisition, storage, and classification; procedures for medication administration and health literacy, involving accurate dosing, appropriate routes of administration, and the complexities of polypharmacy; the impact on the caregiver, including burden, anxiety, and limited access to instrumental support; the impact on the care recipient, such as reduced autonomy and poor adherence; the dynamics of the caregiver-care recipient relationship, particularly in terms of trust and acceptance of external medication management; and the interaction with formal healthcare systems, where issues such as accessibility, trust, and effective communication with healthcare professionals. Taken together, these domains suggest that medication safety at home depends not only on the availability of support tools, but also on caregivers having clear, tailored, and usable information that helps them understand what to do, when to do it, and how to

recognise risk situations. From this perspective, a plausible mechanism is that the intervention improved caregivers' practical understanding of medication use, including timing, administration, and recognition of common risk situations. This may be particularly important because caregivers often report unmet needs for clear and tailored information about medicines, and misunderstanding remains a common pathway to unsafe practice [29,48].

In Spain, it has been demonstrated that complex chronic patients often lack knowledge about the precautions necessary for the safe use of their medications, despite evidence that patient knowledge plays a key role in reducing MEs [49]. Changes in prescriptions -such as dosage adjustments or the introduction of new medications- represent particularly critical moments for ensuring safe drug use. These transitions are associated with increased risk, underscoring the importance of empowering patients with accurate and accessible information to support medication safety [49].

Available evidence suggests that a range of strategies has already been developed to support safer medication use at home, although their focus, intensity, and evaluation vary considerably [14,16]. Among the existing strategies, several stand out. First, information is provided through brochures, websites, and blogs aimed at preventing MEs. There is a growing number of online resources offering specific recommendations for safer medication use at home, such as verifying that the drug matches the physician's prescription, maintaining and regularly updating a medication list, storing medications in their original containers, and informing healthcare providers about any vitamins, supplements, or over-the-counter products being used [16]. Additionally, there is an increasing number of multi-component apps designed for caregivers, which provide advice on problem-solving strategies, communication skills, social support, and mindfulness [50]. However, these apps generally do not address medication management in the home, and only a few include a "pillbox" function [51]. Second, efforts have been made to change the appearance and packaging of medications to ensure that different drugs look distinct from one another, thereby reducing the risk of confusion [46]. Third, the redesign of dispensing devices has received increasing attention. In recent years, syringes, dosing cups, spoons, and inhalers have been redesigned to enhance usability and safety, with patient experience playing a central role in the development of acceptable and effective solutions [52,53]. Fourth, various patient activation campaigns have been launched to increase awareness and encourage patients to take a more proactive role in their own care [45]. These initiatives aim to empower patients -especially during prescription or dosage changes- to ask questions and maintain accurate medication records, particularly in cases where multiple caregivers are involved. Such campaigns reinforce the role of patients as a critical barrier against adverse drug events [54]. Fifth, new medication alarm and monitoring devices have been introduced. These devices, in their various forms, have been shown to reduce MEs [27], and they are increasingly being adapted for compatibility with smartphones and tablets [55]. Despite these advances, there are still relatively few interventions specifically aimed at training informal caregivers to improve medication safety at home, even though, in many households, they are the ones primarily responsible for administering medications.

Practical Implications

For educators and trainers of informal caregivers, the results emphasize the need to move beyond basic health literacy. Training programs should include practical content on medication safety, recognition of risky situations, and strategies for daily caregiving. Tools such as video-based error recognition can improve observational skills and awareness [56,57]. Educators should also stress the value of psychological safety, encouraging caregivers to acknowledge and discuss mistakes as learning opportunities rather than sources of blame [25].

For healthcare professionals, especially those in primary care, the findings suggest the importance of incorporating brief psychoeducational interventions into routine practice to support informal caregivers in managing medication and care tasks safely. Clinicians should proactively identify caregivers who may be at risk of committing unintentional errors and offer targeted support, while fostering open communication to detect signs of emotional burden or safety concerns early on. For middle management in hospital, care home services, primary care, and nursing care settings, such as team coordinators and quality leads, these findings point to the need for caregiver support to be formally integrated into patient safety strategies. Structured programs should be facilitated in collaboration with clinical and educational teams, and caregiver-reported safety incidents should be monitored as indicators of home care quality.

Informal caregivers themselves can benefit directly from this type of intervention, gaining tools to prevent common errors related to medication timing, dosage, and organization. Practical, scenario-based learning strengthens their sense of competence and emotional resilience, while promoting healthier self-care practices and better use of reliable sources to resolve doubts related to treatment and care.

Finally, for health authorities and policy makers, the study highlights the need to extend institutional patient safety strategies—such as the WHO's Medication Without Harm—to the home environment. Recognizing the strategic role of informal caregivers in the continuum of chronic care and investing in scalable, community-based interventions can reduce preventable harm, support caregiver well-being, and alleviate pressure on formal healthcare systems.

Strengths

This study adds to the emerging evidence on how structured training may support safer home caregiving. Its main strength lies in combining self-reported safety outcomes, error-recognition tasks, and psychosocial measures within a pragmatic intervention delivered in real-world caregiving contexts. While many previous interventions have primarily focused on improving caregivers' mental health or health literacy, this study contributes to a growing but still limited body of research addressing the prevention of unintentional errors in home caregiving. By integrating self-reported data, objective measures such as video-based error recognition, and psychosocial indicators, the study offers a multifaceted approach that strengthens the internal consistency and interpretative value of its findings. The intervention was brief, easy to implement, and showed sustained effects at three-month follow-up. High adherence and participant satisfaction further support its feasibility. Unlike more abstract or remote programs, this study delivered practical, context-specific training applicable to everyday caregiving.

Limitations

The primary outcome relied on self-reported caregiving of medication-related errors, which are vulnerable to recall bias, social desirability bias, and changes in willingness to disclose errors after training. Hawthorne and social desirability effects cannot be fully ruled out. The study did not include an objective external verification of reported errors. Although no statistically significant baseline differences were observed in the primary outcome, the control group reported somewhat fewer care provision errors at baseline than the intervention group. This pattern may reflect random baseline imbalance, which can occur in trials when outcomes are based on low-frequency self-reported events. This study does not allow for the assurance that no other MEs occurred beyond those identified through the surveys or reported during the pre- and follow-up-intervention assessments. It also does not capture the full range of consequences, particularly medium- or long-term outcomes, resulting from potential MEs. The results should not be generalized to other settings, such as institutionalized patients. Indeed, external validity should also be considered in light of the study context. The trial was conducted in Spain, where family involvement in long-term home care remains particularly strong. This context may limit direct transferability to health and social care systems with different levels of formal home-care provision, or caregiver support. However, the findings may offer valuable insights for developing practical strategies aimed at improving patient safety in the home care context.

Although participants were randomly assigned to groups, some demographic variables -such as previous caregiving training, age, and cohabitation with the care recipient- differed between groups. These differences, while expected in real-world settings, may have influenced the outcomes. The findings should be interpreted as evidence of reduced self-reported errors rather than definitive proof of reduced errors in all caregiving practices. Future studies should consider stratified randomization or adjust for covariates in the analysis.

Conclusions

This trial provides further evidence that brief psychoeducational interventions may improve safety-related outcomes in home caregiving. In this sample, the intervention was associated with a notable reduction in self-reported caregiving and medication-related errors, improved ability to recognize unsafe practices, and a meaningful decline in emotional burden. Moreover, the intervention appeared effective in reducing the frequency of certain types of MEs (e.g., confusion, wrong timing) and some caregiving errors (e.g., inadequate food texture, falls). Although back injury reports increased in the experimental group, this may reflect greater sensitivity and reporting accuracy following training. Overall, the types and consequences of errors differed meaningfully between groups, supporting the potential impact of the psychoeducational intervention on error detection and awareness. These findings underscore the potential of targeted training to promote both safer care and caregiver well-being in the domestic setting.

By focusing on a neglected yet high-risk group—informal caregivers responsible for complex, polymedicated patients—this study contributes to expanding the scope of patient safety beyond institutional settings. It also highlights the relevance of integrating theoretical and experiential learning, especially through practical exercises and scenario-based simulations, to foster critical awareness and confidence in caregiving routines. The results suggest that caregiver training should be recognized as a strategic component of safety and quality frameworks in health systems, particularly as chronic disease management continues to shift toward

home-based care. Public health authorities, professional educators, and primary care teams should consider implementing scalable and community-based interventions that address both the technical and emotional dimensions of informal caregiving.

Future research should explore the long-term impact of such interventions, their adaptability to diverse contexts, scalability, and integration with formal healthcare systems. The specific added value of video-based error recognition within caregiver training could be deeply explored. Comparative designs including groups with general training with and without video-based error recognition, as well as usual care, would help clarify its incremental effect on caregiver safety outcomes. Tailoring interventions to the literacy levels and lived experiences of caregivers remains a critical priority for ensuring safer home care. Particular attention should be given to the phenomenon of double victimization among informal caregivers -those who, in addition to bearing the burden of care, experience guilt or emotional distress when errors occur [58,59]. In parallel, policy efforts should aim to formally recognize the role of informal caregivers and provide them with the tools, knowledge, and emotional support necessary to reduce preventable harm and sustain the quality of care at home.

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