Title: Innovative Teaching Solutions to Improve the Outcomes of Home Caregivers
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Abstract

Justification. Caring multipathological and polymedicated patients at homes is inexorably growing in OCDE countries, with a greater risk of suffering diverse errors made by their carers. **Objective**. To promote the training of home caregivers using five different educational solutions compared against the natural intervention. **Method**. Prospective, parallel and mixed research study with two phases. *Candidates:* will be home-based caregivers caring either a person with multiple co-morbid conditions or polymedication or a person that have a permanent device implanted such as a Port-a-Cath. *First phase*: Expert groups joined together to design and plan potential educational solutions directed to caregivers based on the identification of medication and home care errors, their causes and consequences and risk factors that favor them. *Second phase*: Inter- and intrasubject single-factor experimental design (6 groups, 5 experimental groups and control, with pre-post- intervention and follow up measures), simple random assignment, to determine the effectiveness several educational solutions (n=420 participants). The study will be carried out in primary care centers and caregivers' associations in Valencian Community, Andalusia, Madrid, Murcia and Catalonia. **Expected results.** To identify critical elements for risk management in the home for caregivers. To find the most effective and optimal educational solution that also reduces the impact of gender bias in this activity.

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Overview and aim

The increase in the number of people with chronic diseases is a significant burden of care and consumption of health care resources all over the world. Most are elderly and, in some degree, dependent for their diary activities of a caregiver. Thanks to the work of people caring people at home, these people survive while preserving their well-being as much as possible. This work covers a range of activities from physical and emotional support for the promotion of autonomy to the management of their pharmacological treatment, in many cases applying more complex care. The sex bias generally prompts that the provision of care for dependent persons is carried out by women, which widens the already existing gender gap to the detriment of women.

Although care at home is more complex, demanding assume more than the basic tasks of hygiene and feeding, caregivers usually receive instructions from healthcare professionals during a while.

Attempts have been made to alleviate the lack of training in caregiving through caregiver schools, self-help groups, information in brochures, websites, equipment design, or caregiver apps with problem-solving tools. These approaches have in common that they situate a caregiver as a passive entity to whom they provide information and training on home care through traditional methods. Moreover, some sources of information such as videos, websites, blogs or podcasts are available but there is no quality control of these contents. Around medication, today we have: (1) Passive information in brochures, websites, and apps to help prevent errors; (2) Changes in medication packaging to differentiate medications; (3) Redesign of dispensing devices seeking ease and safety while caring for the patient experience; (4) Patient education campaigns, empowering patients about their medication; (5) Devices with medication alarms adapted to mobiles or tablets. However, we do not know to date whether active learning on how to appropriate treatment administration and reduce caregiving errors by caregivers at home would be the solution. Studies have been highlighted the frequency and type of medication errors at home. Less information is available about care errors made by these caregivers.

There are several ways of learning certain task. One can learn by listening about a procedure, following some written instructions, by watching a video or by being immerse in a virtual environment where learning actively a process is possible. Exploit the potential of immersive active learning technologies such as virtual reality (VR), augmented reality (AR) or 360 degrees video (360V) would allow caregiver placement at the center of his/her learning. 360V/ VR / AR are being successfully used for the training of healthcare professionals, as adjuvant treatment in clinical situations, or to break the isolation of people living institutionalized or alone. Nevertheless, 360V, VR and AR have hardly been used to provide caregivers with skills and self-confidence to deal with medication, caring tasks and errors in caregivers' role at home.

The project seeks to put people at the center of interventions while respecting their digital rights. The comparison between 360V, VR, RA, web-based information, written information and standard procedure, to determine which is the best way to train home caregivers in order to increase their technical competences and soft skills, including self-confidence, is the outcome this project would analyze. This study aims to explore the

experience and needs of caregivers (skilled and unskilled) of dependent and chronically ill patients and then to design and test the effectiveness of several interventions aimed at promoting safer medication use in the home.

Methods

Intervention design

This is a prospective, parallel, fully randomized (with simple random assignment of participants to one of six arms) experimental study to compare (inter-group and intra-subject PRE and POST measures) educational interventions aimed at training caregivers using typical scenarios during their work at home in order to reduce medication and caring errors and improve caregivers' motivations and self-efficacy.

Present protocol underwent the revision and approval of an Ethics Committee Board, obtaining the approval in December 2021 and January 2023 (CODES 21/063; 22/079 and 22/080). ClinicalTrial xxxxxxxx

Recruitment

Recruitment will be carried out in the collaborating centers through the programmes for complex chronic patients, schools for carers, and associations and foundations for carers and/or diseases causing dependency situations using the "snowball" technique.

Participants (caregivers) will be recruited during a regular consultation where they go to accompany the person they care for to the consultation, or in a clinical consultation of their own where they can comment that they are caring for a person at home. Recruitment will be carried out through systematic sampling according to the list of people seen in the consultation, using k=3. The collaborator will systematically select 1 out of every 3 patients cited in the consultation list. If the person refuses to be included in the study, the next person on the list will be invited and then k=3 will be applied.

Additionally, in the recruitment of caregivers, two aspects must be considered:

- *Qualification of the caregivers*
In the recruitment of caregivers, a balanced sample of qualified and unqualified caregivers will be sought, forcing, as far as possible, 50% qualified caregivers and 50% unqualified caregivers in both the control and experimental groups.
- *Gender*
When recruiting, the gender of the caregiver will also be considered, so that 30% male caregivers will have to be ensured, to ensure the presence of men in the study sample.

Inclusion/exclusion and recruitment criteria

Study participants are qualified or unqualified caregivers who oversee patients in one of two groups: 1) multi-pathological, polymedicated, dependent, and 2) devices and catheters (oncological, ostomy, etc.). To facilitate recruitment, each centre will be provided with templates adjusted to the participants and arms to which they are committed. The inclusion criteria for each group are detailed below.

Inclusion criteria for carers of multi-pathological, polymedicated and dependent patients

- Qualified or unqualified carers caring for multi-pathological patients (coexistence of two or more chronic conditions lasting one year or more, requiring continuous medical assistance or limiting daily activities), polymedicated (simultaneous daily treatment of 5 or more drugs) and Barthel equal or lower than 55.
- Carers who are in charge of this person for at least 6 months of the year.
- Residence in C. Valenciana, Andalusia, R. de Murcia, C. Madrid and Catalonia (in the home of the patient or relative).

Inclusion criteria for caregivers of patients with devices and catheters

- Qualified or unqualified caregivers in charge of patients with a fixed catheter who require care from another person.
- Carers who are in charge of that person for at least 6 months of the year.
- Residence in C. Valenciana, Andalucía, R. de Murcia, C. Madrid and Cataluña (in the patient's or relative's home).

Exclusion criteria

The exclusion criteria are common to both groups of carers:

- Caregivers of patients who had filed a patrimonial claim in the last 5 years.
- Carers of part-time residents in nursing homes.
- Carers with a health profession.
- Carers of dependent elderly people who do not meet the inclusion criteria.
- Carers with experience in using VR or AR for a similar purpose.
- Carers over 90 years of age.
- Carers with more than two dependents.
- Carers with problems of vertigo, tinnitus, motion sickness, epilepsy, seizures or similar symptoms, severe cardiac conditions or wearing a cardiac pacemaker or hearing aid.

Inclusion criteria for professionals

- Professionals with at least 5 years of experience working in hospitals, health centers and day-care centers.

Intervention design

Medication errors refer to any avoidable incident that may cause inappropriate use of medication, or harm to the patient, while the drug is under the control of the healthcare professional, patient, or caregivers. Care errors to describe any avoidable incident during care, grooming, mobilization that can cause or does cause harm to the patient and that, in our case, occurs in the home and is performed by caregivers.

Care can come from qualified or mostly unqualified people (family members or untrained carers) who take on complex tasks with little training. In this project we consider the limit of 20 hours of training to differentiate between qualified and unqualified carers.

The study includes two phases, a first phase of data collection and a second experimental phase. Some of the centers may not participate in one of these arms due to their idiosyncrasies. The same applies to the day-to-day situations listed in the document.

Phase 1. In this phase, already completed, information on knowledge, needs and differences in responsibility for the safe use of medication and dispensing of care among caregivers has been captured through nominal groups and an online survey disseminated via email to caregiver associations, which has allowed for the identification of errors, causes and consequences and risk factors that favor these errors. This information feeds into the design of situations for the experimental phase.

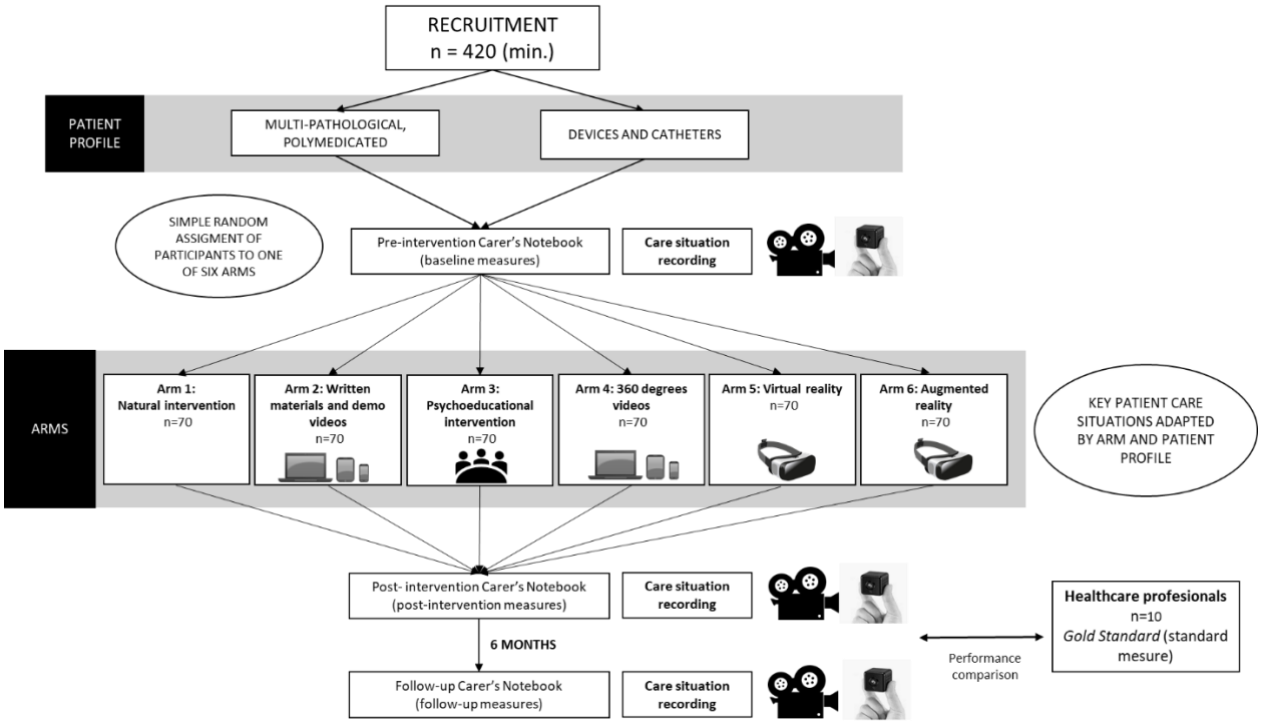
Phase 2. A true experimental design will be conducted to determine the effectiveness of different interventions, each of them reflected in an arm, to reduce errors during the care and administration of medication at home by caregivers.

To be able to determine which educational solutions are optimal, the study has the following arms:

- *Arm 1-Control group*: Natural intervention (actual provision of information and answering of questions). This arm will evaluate the natural learning during the action.
- *Arm 2-Experimental group 2:* Intervention with written materials and demonstration videos specifically designed for this study. This arm will evaluate the effect of a traditional, more passive form of learning, with little degree of interaction with the content.
- *Arm 3-Experimental group 3:* Psychoeducational intervention specifically designed for this study. With this specific intervention, participants will learn by sharing information with the session facilitator and other participants, which will facilitate a more active form of learning, with a higher degree of interaction than the previous arm.
- *Arm 4-Experimental group 4:* Intervention using immersion 360 degrees specifically designed for this study. Participants enrolled in this arm, by completing it, is assumed that will experience a form of learning more participatory and immersive than conventional videos, as they can interact with the content by changing the camera angle.
- *Arm 5-Experimental group 5:* Virtual Reality intervention specifically designed for this study. Using VR to learn procedures will encourage caregivers to learn in a fully immersive and participatory environment where they will have to interact with the virtual content, enhancing their learning experience.
  Arm 6-Experimental group 6: Augmented Reality Intervention specifically designed for this study. This intervention will increase participants' skills through active learning as they interact with real-world care situations while receiving simultaneous support from AR devices.

In each of the experimental groups, key patient care situations will be developed and the educational solutions for each of the arms will be adapted.

The process of this phase of the study is summarized in the following figure.



The evaluation of the effectiveness of each of the arms will be measured, among other ways, by recording two attempts to execute the care situation to be trained in the intervention. This recording will be made at three different times: at the baseline visit (pre-intervention), after the intervention (post-intervention) and 6 months after the end of the intervention (follow-up). The control group is an exception, as there is no specific intervention and therefore the post-intervention recording is omitted. Thus, in the case of the control group, only the pre-intervention and 6 months after the intervention will be recorded.

These recordings will be assessed by means of an objective checklist (rubric), which assesses the errors and learning on which the educational solutions have an impact. This task will be carried out by members of the research team.

Chronological development of the project

Screening visit:

Caregivers will be informed about the study, what their commitment is, what is needed from them and the requirements. Those who are interested and meet the inclusion and exclusion criteria (described in the section Inclusion/exclusion criteria and recruitment), will be asked to sign the consent form.

Subsequently, the centers will randomly assign participants to one of the study arms and construct the registration code for each caregiver, following the guidelines in the recruitment section (the caregiver's date of birth is required).

Start-up visit (Pre-intervention):

At this point, the carers will go to the medical centre to which they belong, where they will be recorded carrying out their simulated carer's work. The recording will be made using a device consisting of neutral glasses or a headband with a small camera to record comfortably. At the beginning of the recording, the caregiver's identification code must be shown. In the same session, at the end of the recording, the centres will explain to the participants that they must fill in a questionnaire with their data, the Pre-intervention Carer's Notebook, which can be accessed from a QR code/link that will be given to them at that moment.

Subsequently, the videos of the start-up sessions of each participant will be recorded and assessed by the research team with the help of staff from the centres following the rubric provided.

Intervention:

- *Intervention application (different sessions according to arm, arms 2 to 6 only).*

At this point, the corresponding intervention will be carried out for each participant. Depending on the arm to which he/she has been assigned, the procedure and duration of the intervention sessions will be different. The information for each intervention is explained in the following sections. It will follow the following scheme:

- *Arm 1 (Control group):* no specific intervention different from the natural one is performed so it will not be necessary to convene the participants of this group for this session.
- *Arms with intervention at home* (Arm 2 - Intervention with written materials and videos, Arm 4 - Intervention with 360º materials and Arm 6 - Intervention with augmented reality): the intervention is carried out by the caregiver alone at home, so it is useful to hold a training session at the centre to explain to the caregiver the task to be carried out at home.
- *Arms with intervention at the centre* (Arm 3 - psychoeducational intervention, Arm 5 - intervention with virtual reality): the stipulated sessions of each arm will be carried out in the rooms provided in the centres.

Post-intervention visit

Once each arm's own intervention has been received, participants will be called to participate in a new recording of the care work in the medical centre. As in the pre-intervention, at the beginning of the recording, the caregiver's identification code must be shown. At the end, a new link and QR with the Post-intervention Caregiver's Notebook will be shared with them so that they can fill it in online through the link. This flow will be for all arms except for the control arm (Arm 1), where no recording will be carried out and no post-intervention caregiver's notebook will be completed.

Again, the videos resulting from the recordings of this session should be analysed following the available rubric.

Follow-up visit (+6 months)

After 6 months (follow-up phase), participants will be recorded making two attempts at the care they were trained in. As in the previous recordings, at the beginning of the recording, the caregiver's identification code must be shown. At the end, they will be given a new QR and link to the Caregiver's Notebook Follow-up.

Gold Standard (professional group)

In addition to the participants in the control and experimental groups, the study will also include a group of 10 healthcare professionals, who will act as the Gold Standard group. This group will be recorded performing all the care situations to be trained to have a standard measure with which to compare the performance of the caregivers, once they have received the training.

Data analysis

Time of use will be recorded and correlation analyses will be performed to determine the size and direction of the effect on the outcomes. The difference between the measures considered above rated will be considered before and after (PRE and POST intervention (time 0) and FOLLOW UP (+6 months)) the experimental intervention sessions as outcome variables. The distribution of the data will be tested using the Kolmogorov-Smirnov test, the measures will be compared with an ANOVA test for normally distributed continuous variables, and the Kruskal-Wallis test if the distribution is not normal. Given the number of time-ordered and repeated variables per subject, they will be explored using a linear mixed effects model (LMM). Data will be stratified taking into account gender, age, recipient profile and time of use. P values <0.05 are considered to indicate statistically significant differences. Statistical analyses will be performed on R and SPSS. If the intervention is successful, the control group will be invited to receive the treatment of the experimental group on the same terms. The results of this project will be prepared for dissemination according to the contents of the "Standards for reporting qualitative research" (SRQR) guidelines for qualitative studies, the Consort checklist for randomized trials, and the CHEERS checklist for economic outcome evaluations.
Discussion sobre utilidad o lo que hacen otros estudios