VIDEO DISCHARGE INSTRUCTIONS IN PEDIATRIC GASTROENTERITIS: A RANDOMIZED, CONTROLLED TRIAL

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Introduction

Acute gastroenteritis is one of the most frequent reasons for pediatric emergency consultations over the year, creating an important healthcare spending (1) in a disease which is auto-limited and has a favourable course in the majority of cases.

In this context of high volume of patients, it is very important to define which information is given to patients' caregivers about management, evolution and prognosis in this disease. A good discharge education in these patients can help families to feel ready to care after the patient at home. However, a bad comprehension of the information given, or an inadequate set of discharge instructions can lead to a worse therapeutic adherence and problems with follow up of this patients (2). Discharge instructions in emergency departments are not always adequate and are frequently unadapted to caregivers' level of comprehension, as it has already been described in previous articles (2). Evidence says that, in many cases, this leads to higher rates of unnecessary subsequent visits to emergency departments (3), and worse perceived satisfaction (4)

Video discharge instructions (VDI) have been evaluated in various studies, both in adults (5) and in pediatric populations, in which the aim is to improve the knowledge of caregivers, the comprehension of the information and the caregivers' satisfaction (6) when adding this resource to the usual verbal recommendations. These studies have shown that the efficacy of these videos is higher when they are brief, since it keeps the attention of the viewers focused in the important part of the message. Also, it has been suggested that in the future these instructions could be added to usual clinical practice as another element of patient-physician communication and as a way of educating patients and caregivers 86,7)

Our study tries to evaluate if it is possible to improve the quality of the information given to caregivers by adding a set of video discharge instructions to the usual verbal information given at discharge in patients who are diagnosed of acute gastroenteritis in pediatric emergency departments. Our hypothesis is that associating video discharge instructions to usual verbal instructions, the comprehension will be better and the satisfaction with the information received will be higher).

The aims of this study are:

- The main aim is to compare the gained knowledge between a group of patients informed through the usual procedure and a group in which video discharge instructions are added.
- Secondary aims will be comparing between these two groups the level of satisfaction with the information received, and the rates of subsequent visits to emergency department and outpatient clinics.

Methods

The study is designed as an open-label, parallel, randomized trial which takes place between June 2019 and June 2020 in the pediatric emergency department (PED) of a third-level Spanish hospital which receives 58000 emergencies annually

Population of study will be patients attending the emergency department who are diagnosed of acute gastroenteritis. ESPGHAN criteria for AGE will be used: decreased stool consistency and/or increased evacuation frequency during a period <7 days, associated or not to fever or vomiting(6). Patients are eligible if they are accompanied by a usual caregiver; if two caregivers were present, they woul decide who would participate.

Inclusion criteria

- Age between 1 month and 16 years.
- Visit to emergency department accompanied by usual caregivers.
- Ability to fluently communicate in Spanish
- Diagnosed of acute gastroenteritis and discharged home

Exclusion criteria

- Severe dehydration
- Chronic comorbidities needing special instructions (neurologic, respiratory or cardiologic)
- Caregivers were not able to communicate in Spanish
- Patients finally admitted for hospitalization.

Sampling will be performed by enrolling a maximum of 3 patients every working shift (the first three who consult for diarrhea/vomiting and finally get AGE diagnosis). Enrollment will be performed by 4 different investigators of the study. The sample size is calculated to provide a statistical power of 80% at an alpha level of 5% to detect a two-tailed difference of 0.5 points between the two groups, difference which we consider clinically relevant. We calculated that with an estimated loss rate of 15% of patients between randomization and follow-up test, assuming a 1-point variance in test results based on previous studies[7], this statistical power would be reached by enrolling 75 patients in each group. Sample size has been calculated with STATA statistical software.

Patients will fill in an initial test evaluating their knowledge about acute gastroenteritis, prior to their discharge (test 1). They were then randomly assigned to the control or intervention group. In the first group of subjects (control group) caregivers will receive, after completing the test and prior to discharge, the usual verbal information and recommendations about AGE following the guidelines of the Spanish Society of Pediatric Emergencies In the second group (intervention group) patients will be shown a short 2-minute video providing the same information about AGE, in addition to verbal instructions. In both groups, instructions will be given by one of the main investigators in order to provide homogeneous and consistent information. Both sets of instructions explicitly include the information that had been previously asked in the test. All patients additionally received a discharge report which includes instructions concerning aftercare treatment.

After discharge, all caregivers will be contacted by telephone and were asked the same 5 questions from the initial test. The questionnaire must be completed by the same caregiver as in Step 1. This test also includes questions about subsequent visits to either emergency units or outpatient pediatric clinics, satisfaction with the information (caregivers were asked to evaluate information in a score 0-10) and a question about whether they perceive video instructions as potentially useful tool or not. All questions

will be asked to all patients independently of the group they are allocated to. The first telephonic contact will be established 72 hours after discharge. If investigators are not able to contact them at first, telephonic contact will be repeated every 1-2 days up to a total of 5 days before excluding them and considering them as lost in follow-up.

Simple, 1:1 randomization is performed using R software. Patients will be randomly assigned to a group by opening sequentially numbered paper envelopes which contain the group in which the patient would be allocated, ensuring thus allocation concealment. The trial will be open-label because of the characteristics of the interventions, which do not make masking possible.

The primary efficacy endpoint will be the difference between the score obtained in the initial test and the follow-up test. Secondary efficacy assessments include the number of caregivers who get a 5-point score in the follow-up test, the rate of return visits and caregivers' satisfaction

Ethic aspects and protection of participating subjects

The proposed intervention for this study is considered as 'no risk', as it does not affect the therapeutic approach given to patients, and as it is considered that the information given to caregivers at discharge will be, in both groups, at least as valid as the usual clinical practice. The intervention group will receive video-based information additionally to usual verbal instructions. We consider, thus, that the study does not pose any risk to enrolled patients.

Information to subjects. Informed consent

This study will be performed based on the principles and ethical rules which come from the last revision (Fortaleza, 2013) of Helsinki Declaration.

There will be no economic compensation given to the participants of the study. The investigators will make sure that the parents or tutors of the patients will be clearly and completely informed on the aim of the study, the possible risks and all aspects of the study in which they are voluntarily participating.

The information given about the study to the parents or tutors will be verbally given, explaining the different aspects of the protocol. A copy of an Information sheet will be handed in to caregivers, as well as a copy of informed consent, which will be read by the caregivers before being signed.

The study will be carried out as stated in this protocol. Before starting, the study will have to be approved by the Ethical Committee of the center (CEIM) which will revise this protocol and all changes subjected, as well as informed consent and the Information sheet.

The rights, safety and well being of the patients included in the study are the most important values in this study and will prevail before the interests of science and society. The investigators participating in this study are qualified because of their education, experience and formal training.

Data confidentiality.

The information included in the study will be guarded following the rules stated in Spanish “Ley Orgánica 3/2018, de 5 de diciembre, de protección de datos de carácter personal y garantía de lso derechos digitales y el reglamento General de Protección de Datos (Reglamento 2016/679)” and “Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica”.

The main investigators of the study are responsible for the information and will keep an updated registry of the included subjects linked to the assigned number for the study, to allow for follow up and coordination of the study. The data gathered for the study will be registered in a Microsoft Excel document, protecting the identity of the patients.

All modifications to this protocol will be explained to the ethical committee (CEIM) and will be stated when publishing the study. All modifications should be accepted by CEIM before being implemented, unless there is a direct and immediate danger for patients. If the modification is substantial, changes in the information sheet and the informed consent will be made.

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