Implementation and evaluation of a Transition to Discharge Program for the reduction of early readmission in a mental health inpatient unit.

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ABSTRACT

Background

Early readmission to psychiatric units poses a significant challenge for both patients with mental health issues and healthcare institutions. It hampers patient progress and prognosis, and the professional approach taken during discharge can greatly influence the recovery process. This paper proposes a multicomponent discharge transition intervention to mitigate the risk of early readmission to a Mental Health Hospitalization Unit (MHHU).

Methods

The intervention entails developing a measurement scale to assess patients' risk of early readmission, allowing for stratification into high, medium, and low-risk categories. Tailored intervention strategies will focus on ensuring adherence and continuity of care post-discharge, with a more comprehensive approach for high-risk patients. Additionally, a post-discharge psychotherapeutic group will be incorporated for high-risk cases to support recovery. The efficacy of the program will be analyzed by comparing the overall early readmission risk at the Regional Hospital of Malaga's MHHU with the previous year, using admission episodes from two other hospitals in the province as a control group where the intervention program is not implemented. The success of the post-discharge group psychotherapeutic intervention will be evaluated through pre-post assessments of recovery measures, functionality, subjective well-being, social support, and treatment satisfaction.

Discussion

This proposal aims to address the issue of early readmission to psychiatric units by enhancing predictability and understanding of intervention strategies to reduce readmission rates.

Trial registration

KEY WORDS

Early readmission, discharge intervention, psychiatric unit, continuity of care, psychotherapy group, recovery.

INTRODUCCIÓN

Discharge from hospital after admission to a Mental Health Inpatient Unit is a particularly sensitive time, which can place the individual in a situation of great vulnerability. The transition from admission to the patient's usual environment and the return to care in his or her unit of reference, mostly the Community Mental Health Unit (CMHU), represents a major challenge for both the individual and the health institutions, often compromising continuity of care and leading to repeated hospital admissions, a phenomenon known as the "revolving door" (1).

The rate of early readmissions in a short psychiatric hospitalization unit can be a negative indicator of quality of care, resulting in a deficient attention to the needs and peculiarities of users that has important repercussions for patients, their caregivers and the health system (2). A correct interpretation of the impact that early readmission can have on the quality of care must always be based on a community-centered care model (3), where psychiatric hospitalization is a measure of last resort and to some extent can be considered a therapeutic "failure" in a large number of patients.

Readmission rates vary widely depending on the type of measure employed, with approximately 1 in 7 patients discharged from an acute psychiatric care unit estimated to be readmitted within 30 days and up to 40% readmitted within 1 year. In this regard, numerous studies have been conducted around the world to discern the variables that influence hospital readmission rates and to determine which specific interventions are effective in reducing readmission rates (4,5).

The factors influencing the risk of readmission have been studied for decades. There are variables that have frequently been associated with a higher recurrence of hospitalizations, some of them related to clinical and sociodemographic aspects of the patient, such as poor treatment adherence, substance abuse, psychiatric diagnosis of psychosis or affective disorder, suicidal ideation, gender, marital status, social isolation, etc., and others more associated with institutional factors, such as the involuntary nature of admission, length of stay, or the availability of an adequate care plan and community therapeutic resources after discharge (6).

Regarding interventions, there is an enormous heterogeneity in the available evidence, due both to the diversity of post-discharge interventions that have been developed in this regard, and to the variability of measures and results that are taken as a reference to assess their efficacy (1). In some studies, the number of readmissions within different time frames (30 days, 6 months, one year) has been used as the dependent variable, while in others, the effectiveness of post-hospitalization intervention is assessed using other parameters such as the duration of future hospitalizations or the reduction in suicidal ideation or attempts. Scientific knowledge on the

subject yields promising results. However, this heterogeneity makes it difficult to draw clear conclusions about this issue.

In a systematic review carried out in 2019, a classification of these interventions has been made based on a clustering method and according to their key components (1), and they can be divided into: Critical Time Interventions (CTI), Transitional Discharge Model (TDM), peer support, contact-based interventions, role-based interventions, psychoeducational interventions, multicomponent interventions and others. From this and other studies, it is evident that interventions based on the Transition to Discharge Model have yielded significant results in reducing readmissions, achieving earlier discharges from hospital units, and improving therapeutic adherence.

Interventions with a psychoeducational and skill-building profile have shown good results in reducing readmission rates, promoting self-management and behavioral regulation, and increasing levels of emotional well-being and symptom reduction. Post-discharge interventions focused on a single component in isolation (such as contact-based, peer support, role-based, pharmacological management, etc.) by themselves demonstrate inconsistent results regarding readmission reduction, varying across studies (1,7).

In summary, all studies reporting significant effects include elements of intensive case management, Cognitive Behavioral Therapy, and psychoeducation, either in combination or linked to another element such as peer support. The success of psychoeducational interventions and those focusing on the therapeutic relationship underscores the importance of addressing personal issues and emotional elements during care transition when aiming to reduce psychiatric readmissions (7).

On the other hand, clinical practice guidelines (CPG) for addressing severe mental illness emphasize the importance of psychosocial rehabilitation in the recovery process. This involves therapeutic actions aimed at training and developing personal and social skills, psychoeducational strategies with families and users, building social networks, and promoting personal autonomy, among others. The objective is to enhance the psychosocial functioning of individuals with severe mental illness and facilitate their adaptation and maintenance within the community (8,9). From all of this, it becomes clear the importance of conducting a multicomponent therapeutic approach that combines elements aimed at ensuring continuity of care and effective and intensive case management, with those aimed at providing a supportive bond and environment to address personal and emotional difficulties. This approach strengthens the patient's skills and support system, enhancing social support networks (7,9).

The aim of this study is, firstly, to create a tool for assessing the risk of early readmission that allows for stratification of admitted patients according to their risk level, based on the analysis of clinical and sociodemographic variables. The second objective is to implement an intervention program tailored to each risk level, involving coordination among all involved mental health units and a specific intensive program for patients at higher risk.

METHODS

- **Aims**

  General

  -To assess whether a Multicomponent Discharge Transition Intervention reduces the risk of early readmission compared to a control group following standard treatment.

  Secondary

  - To check whether the risk of early readmission is reduced with respect to the previous year in the experimental group and in the control group.

  -To check whether early readmission rates are reduced in the experimental group compared with the control group and with respect to readmission rates in the previous year.

  -Identify risk factors that are associated with early readmissions.

  -To test whether a scale for estimating the risk of early readmission has adequate psychometric characteristics for such estimation.

  -To test whether a Post-Discharge Recovery Support Psychotherapy Group improves outcome on measures of recovery, functioning, subjective well-being, social support, and satisfaction with mental health treatment in patients at high risk of early readmission.

  - To test whether the Transition to Discharge intervention also reduces the risk of frequent readmission (revolving door).

- **Design**

The present study is a quasi-experimental cluster clinical trial aimed at assessing the efficacy of a multicomponent discharge transition program for the reduction of early readmissions in a MHHU. The development of this study consists of two distinct parts or elements:

To carry out the main objective, a quasi-experimental design with a control group will be used, and within the intervention, an early readmission risk assessment scale will be created to categorize patients into different risk levels.

In addition, a study will be conducted to assess the predictive value and validity of the early readmission risk rating scale and to study the risk factors for early readmission.

- **Setting**

The present study will be carried out in the MHHU of the Regional University Hospital (RUH) of Malaga, a public hospital of the Andalusian Health Service. In addition to the Mental Health Clinical Management Unit of the HRU of Málaga, this MHHU is a reference for two other regional hospitals in the province of Málaga: The Málaga East Axarquía Hospital and North Málaga Health Management Area. The Mental Health Clinical Management Unit of the RUH of Malaga, according to figures from the 2022 database of users, serves a reference population of 336,968 people, while 150,823 people depend on the Mental Health Clinical Management La Axarquía and 109,958 depend on the Mental Health Clinical Management North of Málaga, resulting in a reference population of 597,749 people for hospitalization resources.

The MHHU has 40 beds in double rooms and is divided into two functional units. The access routes to hospitalization in this unit are admission from the Emergency Services, after evaluation by a psychiatrist, and programmed admission from another unit. The average occupancy rate is two thirds (28 beds) of the total capacity and the average stay in the year 2022 was 13.7 days, with a total number of admissions of 838. The data collected at the RUH of Malaga indicate an early readmission rate of 15.08% in the year 2022, using a time reference of 30 days until readmission.

The Spanish public health system is functionally organized into levels, with Primary Care comprising the first level and Ambulatory Specialized Care and hospital Emergency Services comprising the second level of care. The third level of care consists of hospital units with a high degree of specialization. The proposed intervention will primarily take place in the hospitalization unit (third level), as well as in the community-based outpatient care facilities

affiliated with said hospital, including the North Guadalmedina and Central Malaga Community Mental Health Units (second level).

• Intervention and control group

Intervention group

The intervention program is based on the Discharge Transition Model for the prevention of hospital readmission in Mental Health. For its development, a multidisciplinary readmission commission was established, comprised of professionals from various categories and from different Mental Health facilities. The aim was to address this issue in detail and actively participate in the review of available evidence and decision-making regarding the development and implementation of the current program.

This is a multicomponent program that initially involves the development of a scale to assess the risk of readmission for each patient, followed by its systematic application. This allows for stratification of patients according to their risk of early readmission and adaptation of the intervention to the needs of each risk level. The intervention includes elements aimed at promoting continuity of care after discharge, transitioning back to the community setting, as well as elements aimed at enhancing personal and emotional resources through psychotherapeutic approaches. The following describes the different components of this intervention program.

Construction of the Early Readmission Risk Scale

For the preliminary analysis of risk factors associated with readmission, a retrospective observation will be conducted. This will involve analyzing all episodes from the previous calendar year stored in the database of the MHHU of the RUH of Malaga, provided that the records are complete. "Cases" will be selected from episodes that resulted in readmission within 30 days post-discharge, while an equivalent number of "controls" will be randomly selected through simple random sampling. Following this analysis, a measurement instrument will be developed to determine the risk of early readmission for all patients admitted to the MHHU.

A literature search was conducted to identify variables that have been associated with readmission and early readmission in other populations. The following variables were selected

for analysis in the reference population: Sociodemographic factors (sex, age, marital status, legal incapacity, employment status, criminal history, and social functioning), psychiatric history (previous admissions, emergency service visits in the twelve months prior to admission, history of suicide attempts, attendance at community nursing follow-ups in the six months prior to admission, and somatic comorbidity), reasons for admission (presence of hetero- or auto-aggression or deficits in self-care), clinical characteristics (primary diagnosis, substance use, non-adherence to follow-up in the previous 12 months, and non-adherence to treatment up to one month before admission), admission characteristics (urgent or scheduled access route and length of stay), and discharge measures (coordination with referring physician in the CMHU and prescription of depot medication).

During admission to the hospitalization unit, all users must have the aforementioned Early Readmission Risk Scale of the MHHU of the RUH of Malaga administered. This will allow for the classification of patients according to their risk level, establishing defined cutoff points, resulting in three categories: Patients at low risk, medium risk, and high risk. This scale will be completed by the referring physician during the initial assessment interview upon admission to implement the proposed measures for each risk level. Additionally, the referring physician will establish contact with the case management figure responsible for the program for the referral of cases with a score indicative of a high risk of early readmission or patients with early readmission within 30 days post-discharge.

Intervention measures based on the risk of early readmission

For patients classified in the low-risk group, general measures would be applied. For patients in the medium-risk group, reinforced measures would be implemented. Lastly, for patients considered to be in the high-risk group, intensive case management measures would be applied, and if they meet the inclusion criteria, they would be included in the Post-Discharge Group Psychotherapeutic Intervention.

1. General measures

The following measures would be applied to patients with a low risk of readmission:

-Ensure coordination between physicians during admission and a follow-up appointment within 7 days.

-If the patient presents substance abuse, ensure an appointment at the Provincial Drug Dependency Center (PDC) upon discharge and record the date in the discharge report.

-If the patient presents social impairment, refer them to a Social Worker at the MHHU during admission and initiate a social history.

2. Reinforced measures

The following measures would be applied to patients with a medium risk of readmission. In addition to the previous measures, the following would be incorporated:

-Schedule at least three follow-up appointments: one (via telephone) with a psychiatrist from the MHHU within 24 hours post-discharge, and two at the Community Mental Health Unit: the first within 7 days and the second between days 21 and 30.

-If the patient presents social impairment, schedule an appointment with a social worker from the Community Mental Health Unit within 14 days post-discharge.

-If the patient has a Severe Mental Disorder, schedule a nursing visit during their stay at the MHHU.

3. Intensive measures

3.1 Intensive case management measures

The following measures would be applied to patients with a high risk of readmission or who have experienced early readmission. In addition to the measures from the previous levels, the following would be incorporated:

-Schedule at least three follow-up appointments: one, in this case, in-person, with a psychiatrist from the MHHU within 24 hours post-discharge, and two at the Community Mental Health Unit: the first within 7 days and the second between days 21 and 30.

-If the patient has a Severe Mental Disorder, schedule two nursing visits: one during the hospitalization and one in the first week post-discharge. The latter will preferably be conducted at the patient's home.

-If the patient has documented medication non-adherence, consider depot medication based on clinical characteristics.

-All readmissions and patients at high risk of readmission will be assigned a case management figure who will develop a follow-up program for each patient and manage all their appointments during the first month post-discharge. This includes reminding patients of appointments 24 hours in advance, reengaging patients in case of non-attendance, and coordinating with reference facilities.

3.2 Post-Discharge Psychotherapeutic Recovery Support Program

For application to patients at high risk of early readmission who meet the inclusion criteria. The proposed psychotherapeutic intervention is considered as an adjunct to the standard treatment received by patients, as well as to the intensive case management measures proposed. It consists of a multicomponent group psychotherapeutic intervention from a rehabilitative and recovery-oriented perspective (10) This intervention will be structured into 20 sessions, each lasting 90 minutes, held weekly in an open format. It will be directed by two cotherapy professionals. The group will consist of a maximum of 12 participants, who may join at different times.

The intervention program includes different areas of work that are developed in a transversal way throughout the 20 sessions, following an open and flexible semi-structured format. Each area of work was included based on the available evidence regarding the effectiveness of psychosocial and psychotherapeutic interventions collected in scientific literature, Clinical Practice Guidelines, and the Integrated Care Process in Severe Mental Disorder of the Andalusian Health Service (8–12). The contents addressed by the Post-discharge Recovery Support Psychotherapeutic Program can be grouped around the following areas:

- Initial Phase: Introduction. Explanation of the framework and group rules. Addressing group objectives. Exploring personal expectations and identifying needs. Initiating therapeutic rapport and fostering group cohesion. These aspects will be addressed throughout the intervention and will be more evident during the welcoming of new group participants.

- Interpersonal Management: With the aim of promoting interpersonal functioning and independence, as well as adaptation to the community, dysfunctional relationship patterns will be addressed, which will be manifested in the group's own functioning. Both social perception skills or reception, social cognition or processing skills, and behavioral response or expression skills will be addressed.

- Problem Solving: This area of work aims to establish a link between symptoms and practical difficulties in their immediate context. Identifying and breaking down the problem, setting achievable goals, generating solutions, implementing them, and evaluating the results will be some of the skills to work on.

• Symptom Management and Coping Resources: This involves promoting recognition of the clinical condition, facilitating awareness about the origin of distress, its course, and typical ways of expression, fostering self-awareness and self-management. The relationship with the symptom, its acceptance, and pharmacological management will be addressed, along with recognition of prodromes, self-care habits, and crisis management.

• Family intervention: Four multi-family sessions will be carried out on a monthly basis in an integrated manner. They will be mainly based on the optimization of communication strategies in the family environment and management of crisis situations.

• Values orientation and commitment to meaningful activities: The therapeutic approach is focused on achieving greater subjective well-being and attaining a more satisfying and meaningful life, always from a recovery-oriented and person-centered model.

• Relapse prevention: Anticipation of possible scenarios, detection of potential risks and implementation of effective coping strategies. Strategies aimed at enhancing self-control, self-efficacy and self-determination, through the joint development of safety plans and the enhancement of personal strengths.

Other aspects that will be addressed throughout the therapeutic process include emphasis on the therapeutic bond, group cohesion, strengthening social and family ties, peer support, and learning in the here and now of the group reality.

Control group

To assess the effectiveness of the Multicomponent Discharge Transition Program, users from Málaga East Axarquía Hospital and North Málaga Health Management Area will be employed as the control group. Participants in the control group will continue with their usual treatment.

Additionally, users from the Mental Health Management Unit of Regional Hospital of Málaga who were admitted the previous year and thus did not participate in the intervention program will also be used as a control group.

- **Participants and recruitment**

For the development of the present study, data from all hospital admission episodes at MHHU during the 12 months following the implementation of the Discharge Transition Intervention Program will be considered. Similarly, data from all users who have experienced any hospital admission episodes at UHSM in the year prior to the intervention will also be utilized.

The experimental group, to which the Discharge Transition Intervention Program will be applied, will consist of users whose Community Mental Health Units (CMHU) are affiliated with the Regional Hospital of Málaga. Users belonging to other hospitals in the province will be excluded from the intervention program and will form part of the control group.

Participants included in the Post-Discharge Group Psychotherapy Support Recovery Program will be those at high risk or with an early rehospitalization already occurred, who also meet the inclusion criteria. The relevance of their inclusion will be assessed through a clinical interview by the Specialist in Clinical Psychology in charge of the program, following these criteria.

Inclusion criteria:

- Be of legal age.
- Speak spanish fluently.
- Have had recent admission to the MHHU of the Regional Hospital of Málaga and a score considered as "High Risk" on the Early Rehospitalization Risk Scale or have experienced an early rehospitalization.
- Belong to the Clinical Management Unit of Mental Health of the RUH of Málaga.
- Have sufficient cognitive capacity to understand the rules and contents of the group intervention.

Exclusion criteria:

- Individuals whose primary diagnosis is a Mental and Behavioral Disorder due to psychoactive substance use.
- Moderate or severe intellectual disability.
- Clinical Management Unit belonging to a hospital other than the RUH of Málaga.
- Lack of commitment to attending sessions or complying with group rules.

- **Study variables**

Main outcome variables

The main outcome variable will be the risk of early reentry of the experimental group compared to the control group, which did not follow the intervention.

Secondary outcome variables

The risk of early rehospitalization of the admission episodes from the experimental group will be compared to the risk of early rehospitalization of admission episodes from the previous year.

Frequent rehospitalization will be assessed as having undergone at least two readmissions within a 6-month follow-up period. The risk of frequent rehospitalization will be considered as a secondary variable.

In order to assess the effectiveness of the Recovery Support Psychotherapeutic Program, pre- and post-intervention scales will be administered to all participants to take into account other psychological and clinical variables. This evaluation will be conducted by blinded evaluators before the program begins and upon its completion, after the last session. The instruments to be used are as follows:

-Core Om (13,14): It is a self-report questionnaire composed of 34 items that allows for a brief assessment of the patient's status, widely used for evaluating therapeutic change based on four dimensions: Subjective well-being, Problems/Symptoms, General functioning, and Risk scale. The questionnaire items are scored on a Likert scale from 0-4. It is a valid and reliable instrument in its Spanish version.

- The Duke Social Support Questionnaire (Duke-unk-11) (15,16), assesses the perceived degree of social support. It is a self-administered questionnaire consisting of 11 items and a Likert-type response scale (1-5).

- The Personal and Social Performance Scale (PSP) (17,18), It is a hetero-applied and very brief instrument that allows quantifying changes in the functional recovery of patients in the following areas: a) self-care; b) usual social activities, including work and study; c) personal and social relationships; and d) disturbing and aggressive behaviors. The result on the scale is established by assigning to each of the areas a severity level. The total score ranges from 0 to 100.

- Recovery Process Questionnaire (QPR-15-SP) (19) is a self-reported questionnaire used to assess progress in measures of recovery linked to overall psychological well-being, personal achievements, quality of life, and empowerment. It consists of 15 items on a Likert scale from 0 to 4, with a high score indicating recovery. It has adequate reliability and validity indices and has been psychometrically adapted and validated in the Spanish population (20).

- Client's Assessment of Treatment (CAT). This scale evaluates patient satisfaction with hospital treatment, and in this study, it will be adapted to extend this measure to the overall mental health treatment received. Users rate each item on a scale from 0 to 10 (21,22).

- **Data analysis**

In the analysis for the creation of the early rehospitalization risk scale, a univariate logistic regression analysis will be used. For the final selection of factors, a forward stepwise multivariate analysis will be performed, introducing variables with greater statistical significance. Finally, a scale will be developed to measure the risk of early rehospitalization in each admission episode, whose sensitivity and specificity will be tested beforehand using a receiver operating characteristic (ROC) curve. The construction of the scale will follow the procedure outlined in detail in Sullivan et al. (23).

To evaluate the differences between the intervention group and the control groups, a univariate and multivariate mixed logistic regression analysis will be conducted, introducing potential confounding variables (unit occupancy, age, sex, and the variables used in the scale for estimating the risk of early rehospitalization). To assess potential differences in Core Om, Duke-unk-11, PSP, and QPR among patients participating in the Post-Discharge Recovery Support Psychotherapy Program, the paired Student's t-test for repeated measures or the non-parametric Wilcoxon signed-rank test for a single sample will be used.

DISCUSSION

The present research study aims to analyze the risk factors for early rehospitalization of patients discharged from a short-term psychiatric hospitalization unit. Based on this information, the goal is to stratify the risk and direct more intensive therapeutic measures to those individuals with a higher likelihood of rehospitalization to reduce early rehospitalization rates.

Thus, determining the risk of psychiatric rehospitalization for individual patients is a critical step in efforts to address the potentially avoidable high rate of this negative outcome, as highlighted in the READMIT study (4). This study conducted in Canada succeeded in providing a framework to identify patients at high risk of rehospitalization through the development of a prognostic index with moderate discriminative capacity.

One of the main strengths of our study is that it will be conducted in a real-world context, and the instrument to be used for patient stratification will be developed in the same population where it will subsequently be applied, reducing the possibility of cultural factors or context-specific factors biasing the validity of the risk scale. Additionally, the individuals involved in the care of hospitalized patients will work directly on this instrument and subsequently on the intervention to be developed, which will consist of multiple components.

Among the challenges of the study are being able to fulfill all the measures outlined in the intervention program, as external factors may condition it: shortage of hospital beds, premature discharges or voluntary discharges, staffing deficits, lack of community resources, etc. Additionally, many factors associated with early rehospitalization may be difficult to address within the program itself: substance abuse, homelessness, difficulties associated with group work, cognitive deficits, heterogeneity of participating subjects, etc.

One of the major limitations of the study is that it will only be conducted in one inpatient unit, so generalization of the results to other settings will be problematic. As reflected in previous studies, such as the one cited above, its findings have not been able to effectively discriminate potentially readmitting patients in subsequent studies conducted with different populations (24). This tells us about the complexity of the phenomenon of early readmission, an event that is difficult to predict, multicausal and involves factors that require a complex approach (25).

Finally, an important aspect is that the treatment allocation is not randomized, which may introduce biases that will be addressed by using two control groups. However, there may potentially be confounding variables that will be considered in the analysis. Given these limitations, if this study yields satisfactory results, a likely future direction could be to develop a randomized, multicenter clinical trial at the regional or state level.

LIST OF ABBREVIATIONS

CAT: Client's Assessment of Treatment

CMHU: Community Mental Health Unit

CPG: Clinical Practice Guidelines

CTI: Critical Time Interventions

MHHU: Mental Health Hospitalization Unit

PDC: Provincial Drug Dependency Center

PSP: Personal and Social Performance Scale

QPR: Recovery Process Questionnaire

RUH: Regional University Hospital

TDM: Transitional Discharge Model

DECLARATIONS

Ethics approval and consent to participate

The protocol of the current study has been submitted and approved by the Provincial Research Ethics Committee of Málaga, with approval number:
For the study of risk factors and the development of the early rehospitalization risk assessment scale, as well as for comparing the rehospitalization risk between study groups, retrospective clinical data recorded in the unit's electronic records will be used, and obtaining informed consent has not been deemed necessary. Prior to participating in group psychotherapeutic intervention, participants will sign informed consent before commencement.

The study will be conducted according to national and international standards outlined in the Declaration of Helsinki and Kyoto. Confidentiality of the subjects included in the study will be ensured in accordance with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as European Regulation 2016/679 regarding the protection of individuals with regard to the processing of personal data and the free movement of such data.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

V. C.-A.: Participated in study design, acquisition of data and was major contributor in writing this manuscript; Y.G-I: participated in the conceptualization and revision of the manuscript; M.T-R: contributed in the conceptualization and revision of the manuscript; A. B-A: Participated in study design, provided access to the data and reviewed the manuscript. B. M.-K.: Participated in conceptualization and revision of the manuscript; J. G.-P.: Contributed to study and data analysis design and in the writing and revision of the manuscript. J. H.-I.: Participated in conceptualization, study design, writing and revision of the manuscript. All authors read and approved the final version.

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