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Medication adherence, self-efficacy and health literacy among patients with glaucoma: a mixed-methods study protocol

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ABSTRACT

Introduction As the world population ages, glaucoma is becoming an increasingly significant cause of blindness. A key component in the management of glaucoma is the use of prescribed medications and the adherence to treatment. However, there is evidence of low adherence to prescribed medication in chronic diseases, such as glaucoma. This study aims to explore the level of medication adherence, self-efficacy, social support and health literacy among the patients with glaucoma and to determine if there are any correlations between them. The ultimate aim is to use the information to develop an educational programme for patients with glaucoma at a later stage.

Methods and analysis This is a mixed-methods study which includes two stages: a descriptive study (stage 1) and focus group discussions (stage 2). Sample: Patients with glaucoma or ocular hypertension, using at least one kind of drops, from two ophthalmology clinics. Selected measures include: The Glaucoma Treatment Compliance Assessment Tool, The European Health Literacy Survey Questionnaire, The Glaucoma Medication Self-Efficacy Questionnaire and The Multidimensional Scale of Perceived Social Support. Two focus groups will be used for the collection of qualitative data, aiming to enrich the study with the patients' experiences. The data will be analysed with SPSS, using descriptive and inferential statistics for stage 1 whereas content analysis will be used for the data from the focus group discussions (stage 2).

Ethics and dissemination Permission to conduct the study was received from the National Bioethics Committee and the board of management of the two ophthalmology clinics. All participants will be informed fully on the purpose and methods of the study. Consent forms will be signed and at any time participants will have the right to withdraw. Confidentiality and the protection of data will be respected at all times.

strengths and limitations of this study

► The main strength of the study lies in the use of two different methodological approaches that will give a better understanding of the problem under study.
► The study is going to be conducted only in two ophthalmology clinics, however, the two clinics together accept the majority of glaucoma patients in the country.
► The sample size of the study is around 10% of the known population with glaucoma in the current country.
► We have chosen to use self-reporting instruments to assess adherence instead of monitoring devices, and that may overestimate adherence, however, there is no gold standard to assess adherence; both methods have their limitations.
► As far as we know, this is the first study aiming to determine if there are any correlations between medication adherence, self-efficacy, health literacy and social support.

since there is no mandatory case reporting system for glaucoma (such as the cancer registry). International statistics by WHO[3] show that glaucoma is the second leading cause of blindness (8%), worldwide, after cataracts (51%). Despite this, glaucoma presents a greater public health challenge since it will lead to irreversible blindness if left untreated or if the patient is not adherent to the treatment.[1 5 6]

The pathophysiology, presentation and treatment of glaucoma cannot be explained using a single definition due to the different types of glaucoma that exist. Generally, glaucoma is a chronic disease that 'exhibits a characteristic optic neuropathy which may result in progressive visual field loss'.[6] In essence, the most important risk factor for glaucoma is raised intraocular pressure (IOP). When the IOP is high for a long time, the optic nerve fibre is progressively damaged, with structural

INTRODUCTION

As the world population ages, glaucoma is becoming an increasingly significant cause of blindness.[1–3] The global prevalence of glaucoma for population aged 40–80 years is 3.54%,[4] while Quigley and Broman,[2] previously estimated that proportion to be 2.65%. However, the problem could be much greater

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changes and functional deficits.[5] Usually, defects in the visual field are asymptomatic at the beginning, but the peripheral vision is gradually affected and the patient observes a tunnel vision. This leads to delayed diagnosis and as a result to unchangeable visual field defects. The most acceptable intervention to prevent further loss of vision and control glaucoma is lowering IOP to a safe level for the eye.[5 6] The recommended steps to achieve IOP reduction are mainly topical medications followed by more invasive methods (such as laser or surgeries). In order to have a successful treatment, patients have to monitor for life and follow their doctor's medication plan with full consistency.

Although glaucoma is a sight-threatening condition, and it is important that it is treated early, there is evidence that around 26,5% of glaucoma patients seem to be non-adherent to treatment.[7–10] The European Glaucoma Society has given a wider range of non-adherence, between 30% and 70%.[5] It is worth mentioning that patients are considered adherent if they use 80% or more of the prescribed doses, and they classify as non-adherent or low adherent if they use less than 80% of the prescribed doses as suggested in prior research.[11–14] Based on the above, at least one patient out of four is less than 80% adherent to the treatment. According to WHO in 2020, 76 million people from 40 to 80 years of age have glaucoma.[15] This means that approximately 19 million people are non-adherent to their treatment and this is a very crucial finding since the lack of adherence to glaucoma therapy is closely related to the progression of glaucoma.[5 12 16 17]

Glaucoma, related to blindness, represents a substantial economic and psychological burden for the patient and the society as a whole.[14 16 17] To be more specific, the prevalence of glaucoma contributes to significant direct and indirect costs[18–21] ; whereas the annual cost per patient treatment increases as the severity of the disease worsens.[18] As the condition progresses, patients are less able to perform their daily activities and significant physical challenges start to appear. When glaucoma patients were compared with a healthy control group, it was found that they were over three times more likely to have had a fall in the previous 12 months and five times more likely to have been involved in a motor vehicle collision.[22] On the other hand, the psychological burden also increases as vision decreases. The impact of visual field loss on the patient's Quality of Life (QoL) is linear with greater visual field loss associated with a worse QoL.[23] Undoubtedly, individuals with glaucoma were at somewhat higher risk for depression, fractures, nursing home admissions and home healthcare service use,[24 25] while their families are exposed to an increased psychological burden.[26] Early diagnosis and appropriate therapy can prevent lifelong disability and preserve the patient's QoL.[5]

Consequently, all glaucoma patients require a careful monitoring by a specialist and a lifetime adherence to their treatment. Even so, almost one-fourth of the patients with glaucoma seem to be non-adherent to their

treatment. Every patient is different and there are several types of non-adherence. Failure to take the correct medication as prescribed due to underdosing or overdosing, wrong medication, wrong timing of dosages, incorrect self-administration, forgetfulness, side effects, issue of cost or missed refills are some of the reasons that may affect adherence.[5 7 27] The researchers made an effort to classify all these reasons into thematic maps. This led them to the conclusion that health literacy, self-efficacy and social support can explain the majority of these reasons. Taking into account that, a scoping review was conducted in order to synthesise research evidence and provide an overview of the possible relations between glaucoma medication adherence, self-efficacy, health literacy and social support. The results of this review were collected, summarised and reported in themes below.

Medication adherence and health literacy
Research has shown that patients with low literacy tend to self-manage chronic diseases poorly.[28–30] However, the mechanisms connecting health literacy and glaucoma management are not clear, so further research is needed to help researchers identify the relation between health literacy and medication adherence. Currently, there is evidence to show that low health literacy skills may be associated with low adherence to the prescribed glaucoma medication,[31–34] as well as that patients with decreased health literacy skills demonstrate more advanced visual field loss.[33] A cross-sectional survey, for example, found a positive correlation between health literacy and the number of refills obtained (p=0.003),[31] whereas an educational intervention study with the goal of improving glaucoma medication adherence by targeting health literacy levels, showed that medication adherence can be improved in less literate patients through literacy-level appropriate education.[32] Even though the results are encouraging, further research is needed concerning the way health literacy affects the adherence to glaucoma medications.

Medication adherence and self-efficacy
Another variable that can affect medication adherence, is self-efficacy. Glaucoma medications are administered via eye-drop bottles, and as a result, patients need to carry out specific tasks in order to achieve a desired outcome: they need (1) confidence to adhere and (2) confidence to administer their eye-drops correctly.[35] There is evidence to show that patients with higher glaucoma medication self-efficacy seem to be significantly more adherent.[7 36–39] But what can actually increase the self-efficacy of a glaucoma patient? According to the literature, patients who received education about glaucoma topics and expressed their personal views about glaucoma and its treatment, reported higher medication self-efficacy and significant increase in their confidence to overcome adherence-related barriers.[7 37–39] Consequently, it is extremely important to educate patients about glaucoma and assess their views about it. The health professionals must keep

in mind that patients who ask more questions about their glaucoma medications may be less confident in using them.[37] Interventions should be designed to increase patient medication self-efficacy, teach patients proper eye-drop techniques and address issues that affect adherence, such as forgetfulness or medication schedule.

Medication adherence and social support

Although to date, the relationship between glaucoma medication adherence and social support have yet to be fully assessed, Salman *et al*, found no significant associations between social support and adherence to glaucoma medications[40] while Cook *et al*, found that the social support was a significant predictor of self-reported medication adherence in univariate analysis (but non-significant in the multiple Poisson regression model).[36] On the other hand, a significant relationship between the two variables appears to exist as is evident from the large number of studies on other chronic diseases.[41–45] Among other findings, social support was significantly associated with higher levels of medication adherence,[42–45] was observed to reduce negative perceptions about medications,[41] found to be associated with greater asthma control and [41]QoL and had a positive correlation with treatment self-efficacy ($p<0.01$).[42 46] It is also supported by the literature that patients who receive information and emotional support benefit by displaying good adherence and collaboration in their care.[47] Nevertheless, evidence from the field of rationing research shows that patient education and support are the most often-missed types of nursing care worldwide.[48 49] Therefore, one of the ultimate aims of this study is the preparation of an educational programme, which can be a useful tool for nurses in educating and supporting patients with glaucoma on how to manage their disease.

In conclusion, glaucoma is becoming an increasingly significant cause of blindness. A key component in the management of glaucoma is the use of prescribed medications and the adherence to treatment. However, there is evidence of low medication adherence in patients with glaucoma and many factors seem be involved. This study aims to explore the level of medication adherence, self-efficacy, social support and health literacy among the patients with glaucoma and to determine if there are any correlations between them.

METHOD AND ANALYSIS

Review of evidence

In order to synthesise research evidence, we used a scoping review. The main purpose was to examine the extent and the range of research activity, to summarise and disseminate research findings and finally to identify research gaps in the existing literature.[50] The search was done on the 25th of March 2020, in three electronic databases: MEDLINE (and MEDLINE complete), CINAHL Plus and APA PsycINFO with the keywords: 'medication adherence' OR 'medication compliance' OR 'medication
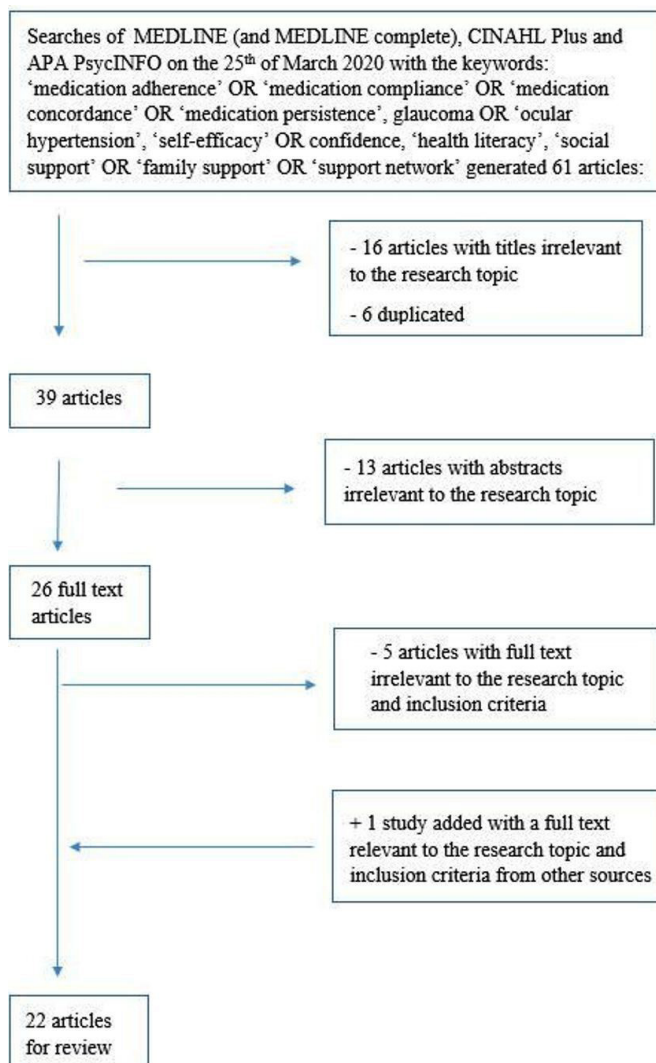

Figure 1 Flow diagram of search strategy. The flow diagram maps out the number of records identified, included and excluded, and the reasons for exclusions.

concordance' OR 'medication persistence', glaucoma OR 'ocular hypertension', 'self-efficacy' OR 'confidence', 'health literacy', 'social support' OR 'family support' OR 'support network'. Only studies in English were considered. No restrictions were set for research design or year of publication. The results were previously reported in themes whereas the search strategy is illustrated in figure 1.

Aim

The aim of the study is to investigate the level of medication adherence, self-efficacy, social support and health literacy among the patients with glaucoma and to determine if there are any correlations between them. Also, we will try to enrich our results with patients' views as far as the possible reasons of low medication adherence. We may use the results of this study for the development of an educational programme for patients with glaucoma in the future.

The main research questions are:

1. What is the level of medication adherence among patients with glaucoma?
2. What is the level of health literacy, self-efficacy and social support among patients with glaucoma?
3. Is there any correlation between medication adherence and health literacy, self-efficacy or social support?
4. Is there any correlation between self-efficacy and health literacy or social support?
5. How do patients with glaucoma explain low adherence and what are the possible reasons for that?

Design

This is a mixed-methods study with an explanatory sequential design, consisting of two stages. First, a descriptive study will take place to evaluate the level of medication adherence, self-efficacy, social support and health literacy in a large population of patients with glaucoma, through the use of structured questionnaires (stage 1). A qualitative research with focus group discussions will follow (stage 2), in order to help us explain the quantitative data by investigating the patients' perceptions of their glaucoma and the problems they are facing in following the treatment.

Stage 1: exploration of the level of medication adherence, self-efficacy, social support and health literacy in a large population

In this stage, four structured questionnaires were consistent with our research questions: (1) The Glaucoma Treatment Compliance Assessment Tool (GTCAT) to assess the level of medication adherence, (2) The European Health Literacy Survey Questionnaire (HLS-EU-Q6) to assess the health literacy among the patients, (3) The Glaucoma Medication Self-Efficacy Questionnaire (GMSEQ), to assess self-efficacy and (4) The Multidimensional Scale of Perceived Social Support (MSPSS) to assess the patient's social support. All the instruments were used in previous studies supporting their validity and reliability.[35 51–57]

The Glaucoma Treatment Compliance Assessment Tool

The GTCAT is an easy and quick questionnaire specially designed for patients with glaucoma. It contains 27 statements with 5-interval Likert-type scale response (eg, 1- disagree a lot, 5-agree a lot) and 1 open-ended question. The GTCAT assess the knowledge, the Health Belief Model (HBM) components (barriers, benefits, cues to action, self-efficacy, severity, susceptibility), the patient–physician relationship, and the patient's physical and mental health. The correct answers range from 0 to 27, with higher scores indicating greater adherence to the treatment. The GTCAT was developed by Mansberger et al[58] according to (1) the constructs of the HBM, (2) expert opinion and (3) previous studies regarding adherence in patients with glaucoma. It has been translated to other languages and it is a valid and reliable tool (Cronbach's alpha >0.7).[36 53 54 58 59]

European Health Literacy Survey Questionnaire

The HLS-EU-Q6 is the shortest version of the HLS-EU-Q47 which was developed and validated by the HLS-EU consortium among eight European countries: Austria, Bulgaria, Germany, Greece, Ireland, the Netherlands, Poland and Spain (n=1000 per country, n=8000 total sample). The HLS-EU-Q6 includes 6 statements with 5-interval Likert-type scale response (eg, 1- disagree a lot, 5-agree a lot) and was translated into Greek by the researchers after the Greek team attended the workgroup meetings for the development of the HLS-EU tool.[56 60 61] The HLS-EU-Q6 shows strong correlation with the full instrument, and researchers recommend the use of the shortest version of the instrument if the health literacy is not the primary variable (Cronbach's Alpha=0.8).[55]

Glaucoma Medication Self-Efficacy Questionnaire

To our knowledge, the Glaucoma Medication Self-Efficacy questionnaire is the only instrument specially designed to assess self-efficacy among patients with glaucoma. It consists of 10 questions assessing self-efficacy in glaucoma medication in general and six questions assessing self-efficacy in the eye-drop technique. The response categories are: 'not at all confident', 'somewhat confident', 'very confident' and 'does not apply'. It is important to mention that neither 'The eye-drop technique Self-Efficacy scale' was significantly associated with medication adherence, nor the 'Glaucoma Medication Adherence Self-Efficacy Scale' was significantly associated with any of the eye-drop technique measures. These findings are significant because they prove that the scales are measuring different aspects of glaucoma medication use (Cronbach's alpha=0.91).[35 57]

The Multidimensional Scale of Perceived Social Support

The MSPSS was developed by Zimet et al.[62] It has been widely used since then and has been translated and validated in various cultures.[63–70] The MSPSS consists of twelve items and three subscales: (1) significant other subscale, (2) family subscale and (3) friends subscale. Each item is scored on a likert scale ranging from 1 (very strongly disagree) to 7 (very strongly agree). Any mean scale score ranging from 1 to 2.9 would be considered low support, a score of 3–5 would be considered moderate support and a score from 5.1 to 7 would be considered high support. The MSPSS is a short and easy to understand scale, suitable for populations with limited literacy level (Cronbach's alpha=0.93).[52]

Cultural adaptation of the research instruments

The English versions of the GTCAT and the GMSEQ will be translated to Greek, using standard techniques, such as the forward-back translation.[71–74] A pilot phase of the study will follow, where the prefinal Greek versions of the GTCAT and the GMSEQ and the already translated HLS-EU and MSPSS will be pilot tested among a sample of 30 participants.[75 76] The target population will include all glaucoma patients, using at least one kind of drops

and visiting the private ophthalmology clinic during the recruitment process. Those 30 patients will be included only in the pilot study and not in the main study.

The validation of the instruments will include face validity, content validity (Content Validity Index) and factor analysis. More specifically, both methods of factor analysis: confirmatory and explanatory, are going to be used. First, confirmatory factor analysis will aim to validate the structure of the instruments, showing whether the structure of the new, translated versions is the same as the factor structure of the original instruments. Exploratory factor analysis will additionally examine the structure of the translated instruments, showing if any items should be removed/moved to other factors. The reliability will be checked with Cronbach's alpha method. This deemed necessary (especially for comparison purposes) since all the related articles that have used these instruments documented the values of Cronbach's alpha.

Analysis will be performed by SPSS V.24.0. Medication adherence will be the main variable while health literacy, self-efficacy and social support will be the secondary variables. Higher total scores on the questionnaires will indicate higher medication adherence, health literacy, self-efficacy and social support, respectively. Descriptive statistics, such as means, SD, medians or percentages, will be reported and correlations between the variables will be explored with parametric and non-parametric measures.

The main scale in the study is GTCAT and this will be used as the dependent variable in all the regression analyses that will be performed, in an effort to examine which factors affect the level of medication adherence. Therefore, linear regression models (multiple regression models) are suitable for our analysis, due to the fact that the dependent variable is numerical (continuous). The usual assumptions of linear regression will be examined (eg, normality, homoscedasticity, etc), as far as hierarchical regression, to examine the effects of the other factors (scales), adjusting for sociodemographic characteristics.

The sample
The sample will include glaucoma patients from two ophthalmology clinics in Cyprus (one private and one public). To achieve 95% CI with an acceptable error of 5%, the sample size calculator, Raosoft, revealed sample estimation at 263 participants. In order to accommodate for any missing or invalid questionnaires an additional 10% is necessary. As a result, our study will approach 289 participants. Similarly, other references on structural equation modelling (SEM), which includes Confirmatory Factor analysis, indicate a ratio of 10 responses per free parameters to obtain trustworthy estimates[77] or 10 participants per item in scale development.[78] Based on the questionnaires that we have in the current study and given the above guidelines, a sample size close to 300 will be sufficient enough for all the scales in our study (since the largest scale in our study includes 27 items).

The inclusion criteria are:

► Patients older than 18 years of age.
► Ability to read and understand Greek.
► Diagnosis of glaucoma or ocular hypertension, requiring treatment with hypotensive eye-drops (at least once per day).

The procedure
The PhD candidate will visit both clinics and ask the physicians to identify patients with glaucoma (during their prescreening process) who meet the inclusion criteria and inform them about the study. Patients who are willing to participate will be referred to the researcher for an informed consent and to complete the questionnaires, including a section for the demographic data. Due to the patients' problem of vision, the questionnaires will be completed with the researcher's help who will read out the questions, without encouraging the answers. This is the main reason that only one researcher, the PhD candidate, will be responsible for the collection of data.

Stage 2: focus group discussions
The collection of data through focus group discussions, after the completion of the stage 1, will allow us to examine in depth the patients' experiences of the daily use of glaucoma drops. The aim is to enrich the future educational programme with the specific needs of patients with glaucoma, since, the focus group discussions are invaluable for guiding the development of interventions and at the same time ensuring that these interventions meet patient needs[79] as expressed by them.

Purposive sampling will be employed to ensure a range of patient experiences with medication adherence is assessed. The patients will differ in terms of the number of years using eye-drops to stimulate interaction between them and explore different views of the investigated topic in order to provide enriched data.[80]

Patients will be recruited to participate in two focus groups, from patient lists provided by the ophthalmology clinic. Each group will consist of 7–10 participants[79 81] and the duration of the meeting will not exceed 1 hour. The inclusion criteria will be the same as the first stage of the study with an additional parameter whereby the participants will be informed that they will be audiorecorded (but will keep their anonymity) and will sign again an informed consent before the beginning of the study. In order to provide a comfortable setting and eliminate the impact of the clinic's environment, the participants will be invited to attend the focus groups in a meeting room on the University campus.

The focus groups will be conducted by one researcher who will act as a moderator. The moderator will not be known to the participants, in order to reduce social desirability bias and "contamination of the data".[82] The discussion will be audiorecorded and the non-verbal responses and interactions among the group members will be observed and written down by an independent observer. At the end of the session, the participants will be asked to fill in a questionnaire with demographic information.
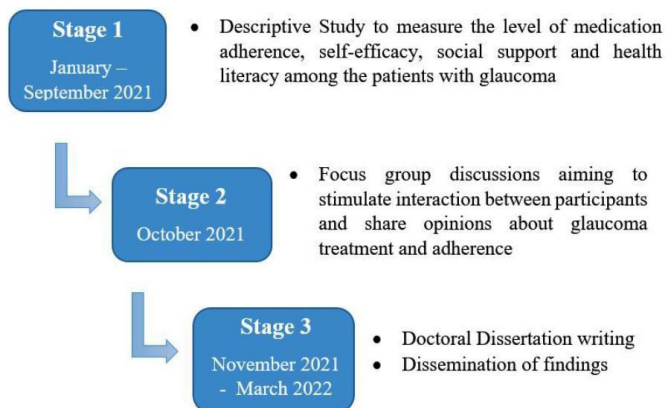
Figure 2 Timeline of the study. The descriptive study will begin in January 2021 and is expected to be completed in September 2021. A qualitative research with focus group discussions will follow in October 2021. Finally, the writing of the dissertation and the dissemination of findings will be completed by March 2022.

The focus group interviews will be tape-recorded and transcribed by the researcher and the analysis will be done by two investigators following a simple content analysis methodology.[83]

Integration of the data

This is a mixed-methods study with an explanatory sequential design, consisting of two stages; 'in sequential designs, the intent is to have one phase of the mixed-methods study build on the other'.[84] At first, the researcher will collect and analyse the quantitative data, and then will inform the findings with qualitative data.[85] The qualitative data from the focus group discussions can be used to assess the validity of the quantitative findings. According to Fetters *et al*, 'several advantages can accrue from integrating the two forms of data', hence, we assume that both stages will provide important insights into medication adherence and will help us clarify the possible reasons for low adherence, in relation to the patients' feelings and experiences about their glaucoma management and treatment. The timeline of the study is illustrated in figure 2.

Patient and public involvement

During the both stages of the study, patients and public involvement will be of high importance. If the patients are not willing to participate, the study design will not be achievable.

ETHICAL CONSIDERATION AND DISSEMINATION

Permissions to conduct the study were obtained from the National Bioethics Committee and the board of management of the private and public clinics from where we will recruit the sample. Additionally, the Commissioner Bureau of Privacy Protection will be notified. All participants will be informed fully on the purpose and methods of the study. Consent forms will be signed and at any time participants will have the right to withdraw. Confidentiality of the participants will be respected. Researchers will

safeguard the well-being of the participants during the data collection. Data from the two stages of the study will be stored in the researcher's office, where no one else is allowed to entry. The PhD candidate will be responsible for collecting, analysing, coding and recording the data; however, the supervising committee will monitor the whole procedure. The research team will be the only ones who will have access to the data (through the PhD candidate). If any important modification of the protocol takes place, all the relevant parties will be informed (ethics committee, health ministry). Dissemination strategy includes presentations in international and national scientific conferences. All the results of the study will be submitted to scientific journals for publication.

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