PHYSICAL AND CHEMICAL RESTRAINTS QUESTIONNAIRE: DEVELOPMENT AND VALIDATION STUDY

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LIST OF SYMBOLS, ABBREVIATIONS OR NOMENCLATURES

ED Emergency Department

EDHUSM Emergency Department Hospital UniversitiSains Malaysia

ICC Item characteristic curves

IRT Item Response Theory

USM UniversitiSains Malaysia

HERC Human Research Ethics Committee

IQR Inter Quartile Range

Abstrak

Pengenalan: Kekanganfizikaldanubatdigunakan di JabatanKecemasanuntukmengawalpesakit yang agresifdisebabkanolehpelbagaietiologi.Walaupunpenggunaankekanganfizikaldanubatmewujudkanpersekitaranselamatuntukpesakitdankakitanganperubatan, iabolehmemudaratkanpesakit.Tiadagarispanduanberkaitanpenggunaankekanganfizikaldanubatwujudsetakatini.Kajianinibertujuanuntukmelaksanakanpengesahanisi, muka, dan idea terhadapKQPPCR-BM, satu set soalankajiselidikberkenaankekanganfizikaldanubat yang direkauntukjururawat,pembantupegawaiperubatandanpegawaiperubatan.Penilaiantahap pengetahuandi kalangankumpulansasaransupayalangkah-langkah boleh diambil untuk menambah baik pengetahuan mereka dan digunakan sebagai pra dan pasca ujian.

Kaedah: Kajianinimengandungiduafasa,pembangunanset soalankajiselidikdanpengesahanidea.Kajiselidikdibangunkandenganpengesahanisidengan panel pakardanpengesahanmukadengan 30 orang responden. Fasakeduaadalahfasapengesahan idea yang menggunakananalisisstatistik "*Item Response Theory*" (IRT) dengan151 orang responden.

Keputusan: 41 item dihasilkan daripada semakan kajian lepas dan 30 item telah dipilih selepas kesahihan kandungan dan muka. Penilaian psikometrik menggunakan pakej *lte* untuk IRT menyempitkan item terakhir kepada 11 item. Model keseluruhan sesuai adalah mencukupi dengan *Root Mean Squared Error*(RMSE) 0.087.Semua item mempunyai pemuatan standard yang standard antara 0.3 dan 0.9 dan kebolehpercayaan marginal pada 0.608.

Kesimpulan: Kaji selidik KQPPCR-BM memenuhi semua langkah psikometrik dan menyediakan alat yang sah dan boleh dipercayai untuk menilai pengetahuan tentang kekangan fizikal dan kimia di kalangan kakitangan perubatan.

Abstract

Introduction: Physical and chemical restraints have been used frequently in Emergency Departments to deal with aggressive patients irrespective of the aetiology. As much as application of physical and chemical restraints can render the vicinity to be safe for patient and healthcare personnel, it still possess inherent danger to patient. There appears no uniform guideline on applying restraints to patients. This study attempts to develop and validate a questionnaire to assess knowledge of nurses, medical assistants and doctors on chemical and physical restraints. This Knowledge Questionnaire on Patient's Physical and Chemical Restraint (KQPPCR-BM) is expected to assess knowledge of target group, so that steps can be taken to improve their knowledge and can be used for pre-test and post-test assessment.

Methods: This study consist of two phases, questionnaire development and psychometric assessment. Questionnaire development consist of content validity with five expert panel and face validity using 30 respondents. The second phase was the psychometric assessment phase using Item Response Theory (IRT) using 151 respondents.

Results: 41 items were generated from literature review and 30 items were selected after content and face validity. Psychometric evaluation using *lte* package for Item Response Theory (IRT) narrowed down final items to 11. The overall model fit was adequate with a root mean squared error of approximation value of 0.087.All the items have good standardized loading between 0.3 and 0.9 and marginal reliability of 0.608.

Conclusion: The KQPPCR-BM questionnaire satisfied all psychometric measures and provides a new valid and reliable tool to assess knowledge of physical and chemical restraint among healthcare personnel.

Keyword: Physical restraint, chemical restraint, KQPPCR-BM

CHAPTER 1: INTRODUCTION

1.1 Physical and Chemical Restraint

The World Health organization (WHO) defines aggressiveness as every use of physical force or power, threat or real against own self, another person or against a group or community that may result in or has a high probability of death, psychological harm, developmental changes or deprivation.[1]By applying the same definition to healthcare setting, aggression is considered as threat or real against own self, to other patients and healthcare personnel which may result in physical and psychological harm or death. Health sector is recognized, nationally and internationally, as an area of particular vulnerability, by being in direct contact with people in higher anxiety and stress situations apart from diseases. Recent data from Centers for Disease Control and Prevention (CDC) and National Institute for Occupational Safety and Health (NIOSH), rate of nonfatal assaults occurs four times more in healthcare sectors than other sectors.[2]It is further stated that 50% of healthcare workers will be victims of physical violence during their career.[3]

Aggressiveness can be broadly categorized as patient factors and environmental factors. Aggressiveness could be caused by derangement of electrolytes, renal or hepatic insufficiency, circulatory or vascular issues, hormones, head trauma, acute psychosis, substance abuse, mood or personality disorders, dementia or infection. Environmental factors that predispose patients for violent behavior are poor staffing, low levels of patient–staff interaction, lack of privacy, overcrowding, poor physical facilities and availability of equipment that can be used as weapons, especially in rooms used for dual purposes (psychiatric and general medical assessment).[4]

Most of the time, etiology of patient's aggressiveness will be not found prior to their aggressive behavior. As such, handling of violent patient is initial step prior to finding the culprit of violent behavior. However, there are cues from the patient that can predict the possibility of violent behavior. If these cues can be noticed, we can diffuse the situation before it escalates and gets out of the control. Phases of violence are divided to three, phase one being anxiety, followed by defensiveness and ends with physical aggression.[5] This three phases of violence should be understood to initiate de-escalation before harm occurs or restraint procedures are used. Restraint should be considered when previous efforts of rapport and trust, to set limits and to inform patient of the consequences of not cooperating failed. Dealing with aggressive patient will inadvertently require healthcare staff to exert certain level of autonomy and brute force, which is hardly acceptable by society and by medical or nursing fraternity itself.[6] Liberal use of both chemical and physical restraint carries as much risk as not using restraints when indicated.

Restraining should be applied to prevent harm to oneself, other patients, caregivers, other staffs and also to prevent serious disruption or damage to environment.[7] It should never be used for staff convenience. Restraints should actually allow physician to perform a medically indicated examination in a patient with altered mental status or administer treatment safely.[8] Chemical restraints should be considered in conjunction with or without physical restraints. Physical restraint can be counterproductive because a thorough clinical examination or proper history cannot be completed while patient is struggling.[9] Every institution should have a detailed protocol for the application of restraint which includes who should apply, how many should be involved and how to apply.[10] All members of the team should be appropriately trained and familiar with restraint procedure.

As any other medical procedure, physicians should be familiar with the risks associated with the use of physical restraints. Patient injury or death under restraint is considered as one of the top ten sentinel events in the ED.[10] There are many issues that can be the source or cause of patient's injury or death. These issues include miscommunication among staff or between staff and patient, procedural noncompliance, inadequate patient assessment, and restraint of a patient in a room not under continuous observation by staff. Abrasions and bruising are the most common complications and death is not uncommon even though the factors related to excited delirium, including acute intoxication, withdrawal, and untreated psychosis apart from the restraint itself are more likely to contribute to sudden death. Protracted struggling against restraints can lead to hyperthermia, increased sympathetic tone with vasoconstriction, and lactic acid release from prolonged isotonic muscle contractions leading to metabolic acidosis.[11,12,13]Cardiovascular collapse from this metabolic acidosis has been found in many restraint-associated deaths. Complications associated with struggling against physical restraints such as dehydration, lactic acidosis, hyperthermia or rhabdomyolysis can be minimized by employing chemical restraint early. Any complications from the restraining procedure need to be documented fully.

As stated above, healthcare staffs must be knowledgeable in handling aggressive patients in Emergency Department. However due to differing syllabus during undergraduate medical training, nursing school for both nurses and assistant medical officers, their current knowledge level must be assessed prior to tailoring the training to suit the target population. So far, there has been no single questionnaire to assess the knowledge on chemical and physical restraint.This Knowledge Questionnaire on Patient's Physical and Chemical Restraint (KQPPCR-BM) is developed in national

language (Bahasa Malaysia,BM) which is widely understandable to assess their knowledge level.

1.2 Questionnaire

Researchers have been assessing knowledge using questionnaires.Literature review indicates there is no validated questionnaire to assess knowledge on chemical and physical restraint in other main languages let alone in Bahasa Malaysia.

Questionnaire that are developed by own needs validation and psychometric evaluation. Validation processes decides whether the content of the questionnaire is being perceived by the respondent as what the researcher intended.[14] A valid questionnaire fulfils all these 5 criteria: (1) the content of each item represent the original idea, (2) the item matches both the respondent's and observer's understanding, (3) the internal structure is reliable, (4) there is connection of scores from a different item that is intended for the same idea, and(5) each score has its own significance.[15]

Once a questionnaire is developed, the initial step in validation process is content validation with experts in the area of research, to determine whether the items in the questionnaire can adequately represent the construct or the idea that it intends to measure. The next step will be face validation in which a pre-testing is carried out to ensure the target subject understands each item the way the researcher intended. Following these steps, a final version of the questionnaire is produced, which undergoes psychometric evaluation.[16]Knowledge based questionnaire employs either true or false response. This uni-dimensional data can be validated using Item Response Theory (IRT) which can provide a better insight into the difficulty and discriminative ability of questions or test items in a test.[17]

1.3 Justification of Study

As stated in introduction above, healthcare staffs must be knowledgeable in handling aggressive patients in Emergency Department. However due to differing syllabus during undergraduate medical training, nursing school for both nurses and assistant medical officers, their current knowledge level must be assessed prior to tailoring the training to suit the target population. This questionnaire is tailored to assess their knowledge level in Bahasa Malaysia which is widely understandable here and also to suit our working culture. Conclusion of this questionnaire can be used to retrain current staff or to be added to medical undergraduate training or nursing training in the future.

CHAPTER 2: STUDY PROTOCOL

2.1 Introduction

Healthcare personnel in Emergency Department are frequently exposed to aggressive patients during their working shifts.Eventhough preventive measures are taken to provide safer working environment, it will only prevent assault or abuse by relatives.Direct contact is still needed to deal with patients who are combative and aggressive due to medical,surgical or psychiatric illness.Proper restraint is needed to avoid patient from injuring himself and healthcare personnel.Application of improper restraint is detrimental to both patient and staffs, even causing mortality.This questionnaire will be made in native language and will be used to assess knowledge level among doctors, nurses and assistant medical officers.This study will deal with knowledge component only instead of usual knowledge,attitude and perception as author intend to come up with adequate number of items without overburdening respondents with large number of items.Physical restraints and chemical restraints are usually used to calm combative patients depending on circumstances.The aims of this study are to perform content, face, and construct validations to a recently developed questionnaire to assess the knowledge on physical and chemical restraint among healthcare personnel in Malaysia. It will be a non-interventionalstudy. In this study, psychometric assessment of the questionnaire will be done using IRT for dichotomous data to ensure the validity and reliability of the developed questionnaire.

2.2 Research Objectives

2.2.1 General Objective

The aim of this study is to produce a validated Knowledge Questionnaire on Patient's Physical and Chemical Restraint (KQPPCR-BM) in Bahasa Malaysiaamong healthcare personnel in ED Hospital UniversitiSains Malaysia (EDHUSM).

2.2.2 Specific Objective

2.2.2.1 To develop Knowledge Questionnaire on Patient's Physical and Chemical Restraint (KQPPCR) in Bahasa Malaysia

2.2.2.2 To complete an initial qualitative evaluation of KQPPCR-BM with a small sample of healthcare personal to identify semantic, conceptual, and psychometric problems

2.2.2.3 To calculate the construct validity of the newly developed questionnaire.

2.3 Research Methodology

2.3.1 Study design:

This study is a cross-sectional study.

2.3.2 Study duration:

This study is conducted from February 2018 to February 2019.

2.3.3 Study location:

This study is conducted at Emergency DepartmentHUSM.

2.3.4 Study population:

Healthcare personnel working in ED Hospital USM.

2.3.5 Sample size:

a) Phase 1 is the Questionnaire Development phase. The sample size needed for pre-testing of the drafted questionnaire is 30 respondents.[18]

b) Phase 2 is the Psychometric Evaluation phase of the finalized questionnaire using IRT. The sample size needed for the internal structure validation is at least 100 subjects or 5-10 samples per item for IRT.[19]

2.3a Phase 1: Questionnaire Development

During Phase 1, a new questionnaire will be produced de novo based on literature review on physical and chemical restraint in emergency department. During this phase, the questionnaire will undergo preliminary validation by means of content and face validation. The result of this phase is the first version of the questionnaire.The newly produced questionnaire consists of two sections; the socio demographic data and knowledge section. The sociodemographic data includes age, sex, first and second language, years of working in the ED and the respondent's designation. The knowledge section will assess the respondent's knowledge on physical and chemical restraint in ED using dichotomous type ofquestionnaire. It is divided into four domains;Patient's Safety, Legal and Ethical Practice, Scientific Knowledge and Quality of Care.[20]Upon the development of questionnaire, there were few meetings with the expert panel to ascertain the content validity of the questionnaire. The members in the expert panel includesthree Emergency Physicians a matron and senior assistant medical officer. In the meeting with the expert panel, further improvement of the questionnaire was discussed to judge whether each item is relevant to the construct, whether there is adequate number of items to cover the construct, and whether there is enough number

of items proportionate to the importance of the construct.Content Validity Index were calculated for the items and cvi of 1.0 will be accepted.[21]

After the meeting, the questionnaire will be edited to be used for the next part, the face validation.Once the questionnaire is edited, pre-testing will be done to ascertain the response process of the questionnaire, the face validity. For this part of the study, the inclusion criteria are the assistant medical officers, staff nurses and doctors in ED Hospital USM. They will be selected via convenient sampling. The sample size will be 30 respondents to allow good probability of detecting common problems.[18] For the purpose of face validation, the questionnaire will be administered by the researcher to the respondents during their free time in an unused room in ED HospitalUSM. The respondents were allowed to read and understand the entire questionnaire. After the respondents have finished, there was a short interview by the researcher to determine whether the respondents can understand the questions as the researcher expected. The respondents were asked about the first thing that comes to their mind when they read each item and how they chose their answers. Any difficult or inappropriate word pointed out by the respondents was changed for an alternative word. All suggestions and comments from the respondents were noted and recorded.The results of pre-testing were discussed with the expert panel to be further evaluated if each comment and suggestions given by the respondents is appropriate. Then, subsequent modifications of the questionnaire, were carried out. Once the last editing is done and confirmed with the expert panel, the final edited version of the questionnaire was ready to be used in the next phase.

2.3b Phase 2: Psychometric Evaluation

Once Phase 1 is completed, Phase 2 or the psychometric evaluation of the questionnaire, commenced to assess the construct validity and the internal reliability of the final version of the questionnaire. The sample size for this phase is five subjects per item.[22]Inclusion criteria are the healthcare personnel currently working in ED Hospital USM including medical officers, house officers, assistant medical officers and staff nurses. The respondents from Phase 1 of this study were excluded in this phase.In this phase, the preliminary questionnaire from Phase 1 was used as the research tool. The questionnaire, together with the consent form, were given by the researcher to the respondents during their free time in one unused room in ED Hospital USM. They were given enough time for about 30 minutes before returning the completed questionnaire to the researcher. The data collection took few months to complete.The result of this phase will be recorded into Statistical Package for the Social Science (SPSS) version 22 for analysis. After that, the internal consistency of the questionnaire was assessed using IRT. From IRT, each item will be given its difficulty and discrimination values and the whole test needs to be unidimensional to ensure reliability of the test.

2.4 Research Tool and Data Collection

2.4.1 Research Tool

The research will use the newly developed Knowledge Questionnaire on Physical and Chemical Restraint

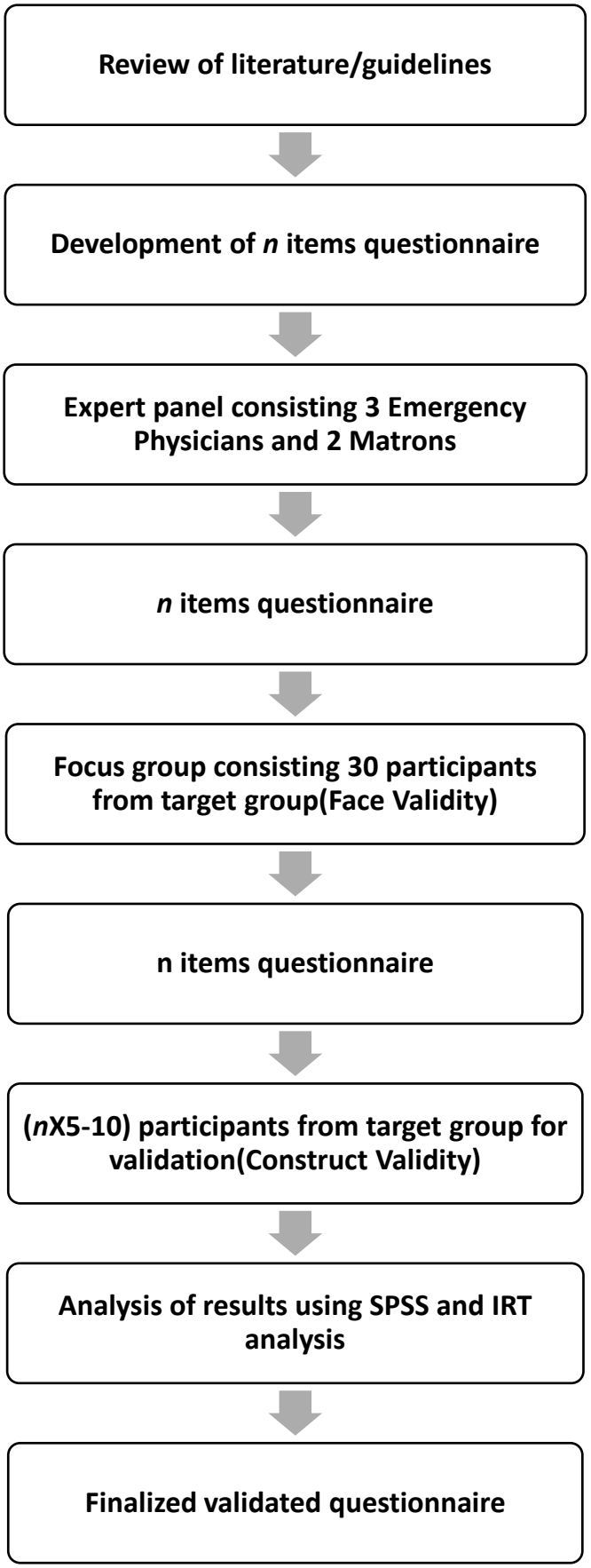
2.4.2 Data Collection

The data were collected personally by the researcher after approval by the Human Research Ethics Committee (HREC) UniversitiSains Malaysia (USM). Written consent was given to the respondents to be read and understood before a verbal explanation of the study by the researcher. Enrolment into this study was entirely voluntary and if the respondent wishes to withdraw from the study at any point of time, the respondent was allowed to do so. The questionnaire was given to consenting respondents individually, or in a group, in an unused room in EDHUSM. The respondents were given enough time to understand each item in the questionnaire and allowed to answer without pressure. If any difficulty arises while answering the questionnaire, the respondentswere able clarify with the researcher personally.

2.5 Ethical Consideration

There is no subject vulnerability in this study. The respondents involved in this research are healthcare personnel from EDHUSM. They must be consented before entering the study. The respondents were given enough time to understand the consent and purpose of the survey before deciding to join the study. The respondents were enrolled voluntarily and were not pressurized when answering the questionnaire. During the study, if the respondent feels unhappy or pressurized, the respondent was given a choice whether to perform at other time or to withdraw. The respondents were assured that their responses will not be traceable to them individually as to affect their work performance assessments.The research team members who are also the members of ED Hospital USM will not have any personal benefits from this study. There is no conflict of interest when proposing this study. All questionnaire forms were anonymous and recorded into the SPSS software. Only the researcher can access the data. The data were presented as a grouped data and will not address the respondents individually. In the event of any respondent that answered badly, the respondent was be identified to maintain confidentiality.As this is a validation study, participants will not be provided with feedback post study. There is no token of appreciation or incentives for the respondents.

2.6 Study Flow Chart



2.7 Gantt Chart

	2018					2019							
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mac	Apr	May	Jun	July	Aug
Designing the assessment tools	→	→	→										
Data collection/ entry				→	→	→	→						
Data analysis								→	→	→			
Final report and presentation											→	→	→