The Validity and Reliability of the Chula COVID-19 Psychosocial Home Isolation Evaluation Tool (CCPHIET)

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Abstract

Background: The cumulative number of patients during the COVID-19 pandemic led to a significant shortage of hospital beds. Many patients may not require hospitalization and can be clinically observed in home settings. However, some psychosocial factors are correlated with unsuccessful home isolation (HI), which might negatively affect the transmission control in the community. Therefore, we developed a new psychosocial screening tool (CCPHIET) for assessing HI suitability and examined its validity and reliability.

Methods: This cross-sectional descriptive study included COVID-19 patients who were deemed to be medically safe for 14 days of HI. The CCPHIET is comprised of 8 clinical domains pertinent to HI behavioral compliance and risk. We explored its statistical validity and reliability and discussed the potential utility of this tool.

Results: A total of 65 COVID-19 patients participated in this study. Most patients (58.5%) were evaluated as good candidates for HI. The CCPHIET has an acceptable content validity (IOC index > 0.5), moderate internal consistency (Cronbach's alpha = 0.611) and substantial to excellent inter-rater reliability (Intraclass correlation coefficient = 0.944, Cohen's kappa= 0.627).

Conclusions: To compromise between strict and costly absolute institutional quarantine and the potentially unsuccessful absolute HI, the CCPHIET may help to identify good candidates for HI in mild and asymptomatic COVID-19 patients. This psychosocial information would support the physicians in matching each patient to the most suitable setting. Therefore, safe medical care is provided, unnecessary use of medical resources is spared, and local transmission is contained.

1. Background

The third wave of the COVID-19 pandemic in Thailand started in April 2021. The cumulative number of cases had increased 10 times from 29,000 cases in early April to 290,000 cases in early July 2021[1]. This sharply raised concern about the shortage of medical resources in public health sections of the country. There had been continuous reports of hospital bed shortage in the intensive care and general medicine units, which in turn caused hospitals to limit COVID-19 testing due to initial regulations mandating hospitals to take responsibility for patients tested positive at their respective institutions. Limitations on COVID-19 testing further hampered the effectiveness of pandemic control [1, 2]. Rising COVID-19 cases and the lack of COVID-19 beds also lead to burnout, as well as other physical and psychological impacts on the wellbeing of health care personnel [3].

It is estimated that the proportion of pre-symptomatic/asymptomatic COVID-19 patients ranges between 15.6 – 45% [4, 5]. When mild symptomatic cases are included, approximately up to 90% of all COVID-19 cases are uncomplicated [6]. Severe disease, on the other hand, is reported in approximately 10-20% of all cases [7]. Therefore, it may imply that a significant majority of COVID-19 cases do not require inpatient hospitalization and could be clinically observed by the individual and a caregiver in home settings.

There has been a debate about what is the best infectious control strategy for asymptomatic/mildly symptomatic COVID-19 patients. Reports from China demonstrate that containing most of the infected cases in hospitals or dedicated health isolation places such as field hospitals, newly built isolation shelters, or hotels with health monitoring system would greatly reduce household and community transmission in later weeks [8]. However, this strict institutional isolation policy consumes an enormous amount of hospital beds, healthcare workers, healthcare

equipment, and requires strong law enforcement. Consequently, institutional isolation may stir up problematic psychological issues when individuals were held in an unfamiliar hospital environment for 14 days [9]. On the other hand, the United States of America and European countries applied the home isolation (HI) measure with home monitoring protocol for asymptomatic/mildly symptomatic COVID-19 cases to spare hospital beds and medical resources for severely sick patients [10, 11]. India also implemented this HI policy as this option could reduce up to 4/5th of overall COVID-19 hospitalized bed requirements [12]. Nonetheless, many COVID-19 patients may not be able to follow self-isolation regulations and are at risk of spreading the virus to others. Reports in the United Kingdom and Israel show that home quarantine failure rate was up to 43% and 75% respectively [13, 14]. Dickens et al in 2020 used the infectious simulation model and concluded that institutional based isolation is more efficacious than home based isolation in terms of transmission control [15]. Despite this finding, the practice of absolute institutional isolation seems to be impossible in Thailand due to the steeply rising number of new cases since June 2021, which overloaded hospital capacity in many areas of the country during July to September. Therefore, we needed a model or tool that could be a middle ground between home and institutional isolation practices while being able to balance between community transmission control and medical resource shortage.

In transplant psychiatry, all solid organ transplant candidates must be psychosocially evaluated by the transplant psychiatrists or psychologists to assess the overall psychological, behavioral, and social risks [16]. The standard psychosocial assessment tools commonly used in a field of transplant psychiatry are Psychosocial Assessment of Candidates for Transplantation (PACT) in 1989 [17], the Transplant Evaluation Rating Scale (TERS) in 1993 [18], and the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) in 2012 [19, 20]. The main

concept of all the above tools is to thoroughly assess the knowledge, compliance, health behavior, support system, home environment, psychopathology, coping to illness, and substance use problems of the patients so the transplant team can identify and categorize the psychosocial risk and readiness of each pre-transplant patient. In a similar fashion, we can apply the described pre-transplant psychosocial evaluation concepts into the asymptomatic/mildly symptomatic COVID-19 patients. It would be beneficial to develop a new psychosocial assessment tool that can assess and identify good candidates who can fully comply with the 14-day HI protocol, as well as pinpoint patients who would likely fail home isolation. This new tool could also identify potential psychosocial and environmental risks that should be addressed before the patient can be safely sent back home.

To address this issue, our research team developed a new psychosocial screening tool, based on the knowledge about the correlated positive and negative factors of the HI protocol adherence and the concepts of the pre-transplant psychosocial evaluation tools. This new tool is called the “Chula COVID-19 Psychosocial Home Isolation Evaluation Tool” (CCPHIET). Hopefully, CCPHIET can be part of a compromising solution in the dilemma between strict and costly absolute institutional quarantine versus the potentially unsuccessful absolute HI. During the current COVID-19 crisis in Thailand, we planned to study the validity and reliability of the CCPHIET among the Thai asymptomatic or mildly symptomatic COVID-19 patients who were recommended for HI by internists.

2. Material and methods

2.1 Study design, setting, population and sample

This cross-sectional descriptive study aimed to develop an original tool for psychosocial assessment of HI suitability in COVID-19 patients and examined its validity and reliability. The sample population were the patients who had a positive Nucleic Acid Amplification Test (NAAT) for SARS-CoV-2 infection by using Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) according to the WHO case definition [21]. All the subject information was collected between August to September 2021 at the King Chulalongkorn Memorial Hospital, Bangkok, Thailand. Asymptomatic or mild symptomatic COVID-19 patients were assessed by internal medicine physicians to be physically safe for 14 days of COVID-19 HI protocol. Two major subgroups enrolled into this study were patients who had recently tested positive for COVID-19 (post-swab HI), and patients who had been admitted, but were medically stable enough to be discharged before completing 14 days of institutional quarantine (post-discharge HI). Both groups of patients were required to isolate themselves within their residence for an additional 14 days. The patients with the above conditions aged between 18-60 years were included into the study. The exclusion criteria were patients who developed moderate to severe symptoms of COVID-19 infection during HI, unable to cooperate with the psychiatric interview (e.g. dementia, delirium, intellectual disability, having active severe psychiatric conditions posing risk to self or others on discharge, unable to communicate in Thai language, unable to use smartphones and online chat program), and unwilling to participate in study. A total of 65 asymptomatic/mild symptomatic COVID-19 patients met the above criteria and consented to participate in the study.

2.2 Data collection method and measurement

Participant recruitment

Patients who were assessed as physically appropriate for HI were contacted by the investigators via video call and informed about the study protocol, along with potential benefits and risks. If the patient was willing to participate, the investigator would interview the patient according to the CCPHIET questionnaire.

CCPHIET development

To develop the CCPHIET questionnaire, the researchers reviewed the literature regarding COVID-19 symptom characteristics, transmission method, natural course, prevention protocol, and HI policy[22-26]. Based on several clinical domains of the Center for Disease Control and Prevention's HI protocol[27, 28] and pre-solid organ transplant psychosocial evaluation tools, the researchers chose 8 clinical domains that were likely to be relevant to HI compliance. These 8 domains were 1) appropriateness of the housing and surrounding environment 2) COVID-19 symptom knowledge 3) ability to provide basic medical care for self at home 4) commitment and cooperation in community transmission prevention 5) previous health care behavior 6) support system during the home quarantine 7) psychopathology and 8) substance use problems. We then listed the potential questions, features, characters, symptoms, histories, behaviors, and demographical backgrounds from the COVID-19/transplant literatures associated with these 8 domains. Subsequently, we reviewed all questions and items of each domain and shaped it to be objective, specific, and relevant to HI compliance and risk. The tool instruction, contraindication items, and scoring system were also developed through this process. In summary, each of the 8 major clinical domains contained 5 specific questions where each question represents 1 scoring point. The point will be obtained if the patient could describe a

correct, suitable, or appropriate answer for that specific question. The total CCPHIET score is 40. A tentative score grading was estimated by the researchers, with a score of 33-40 indicating a good candidate for home quarantine and expected to be highly compliant with the home isolation without creating further disease transmission in the community. Patients who scored between 25-32 are deemed to be minimally acceptable, meaning that some psychosocial risks are identified, and these risks should be addressed to improve suitability for HI. Scoring less than 25 may indicate a high-risk candidate for whom the medical team should consider institutional care due to psychosocial factors. CCPHIET assessment was designed for an online video or telephone interview conducted by medical professionals with some background in mental health or social work. However, general health workers may also use this tool if there is an urgent need in each community.

Questionnaire validation

Two experienced staff psychiatrists, an infectious disease staff physician, a transplant nurse coordinator, and senior social worker (total=5 examiners) examined and reviewed the CCPHIET for content validity. Item-object congruence (IOC) was rated by each content expert, and questions with IOC less than 0.5 were adjusted accordingly.

Investigators interviewed the patients via a video chat program by using the CCPHIET questionnaire protocol, with 2 raters scoring each patient. This step took approximately 8-15 minutes per patient. The questionnaire items were asked as open questions, with further clarification if necessary. The raters then interpreted the patients' answers and scored each item in yes/no format. Demographic data, including age, gender, marital status, years of education, and monthly income was also collected during the interview. The result of the initial psychosocial evaluation

and recommendations were later communicated with the infectious disease specialists and medical HI coordinators so they could make a final decision regarding the HI treatment. The identified psychosocial risks were cooperatively managed by the medical HI clinicians, social workers, and psychiatrists of our research group. Both post-swab/post-discharge HI patients were still in contact with their HI clinicians/coordinators throughout the isolation period for urgent medical consultations.

2.3 Statistical analysis

Demographic data was summarized as frequency, mean, or median as appropriate. Inter-rater reliability was calculated with intraclass correlation using two-way random effects model and Cohen's kappa. Cronbach's alpha was used to measure internal consistency Spearman's rank correlation coefficient was used to explore correlation between demographic data and CCPHIET scores. All data was analyzed with SPSS version 22.

2.4 Statement of Ethics

Approval was obtained from the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand on 18th August 2021 (Registration number 620/64, Certificate of approval number 1168/2021), in compliance with the International Guideline for Human Research protection, as required by the Declaration of Helsinki, was conducted according to the Thai and International ethics and privacy laws.

3. Results

Patient Characteristics

A total of 65 patients were recruited for our study. Most patients were female, with ages ranging from 18 to 60. More than half of our study population had no more than 12 years of formal education. The median income was 13,000 Thai Baht, which is considered low-to-middle. There were 9 participants without current income, 2 of which were students.

Characteristic	
Gender, number (%)	
Male	25 (38.5)
Female	40 (61.5)
Age, mean ± SD	35.1 ± 10.8
Marital status, number (%)	
Single	30 (46.2)
Married	35 (53.8)
Education, number (%)	
0-6 years	14 (21.5)
7-12 years	23 (35.4)
Vocational education	7 (10.8)
Bachelor's degree or above	21 (32.3)
Monthly income*, median (IQR)	13000 (10000, 20000)
Employment (%)	
Employed, with income	56 (86.2)
No current income	9 (13.8)

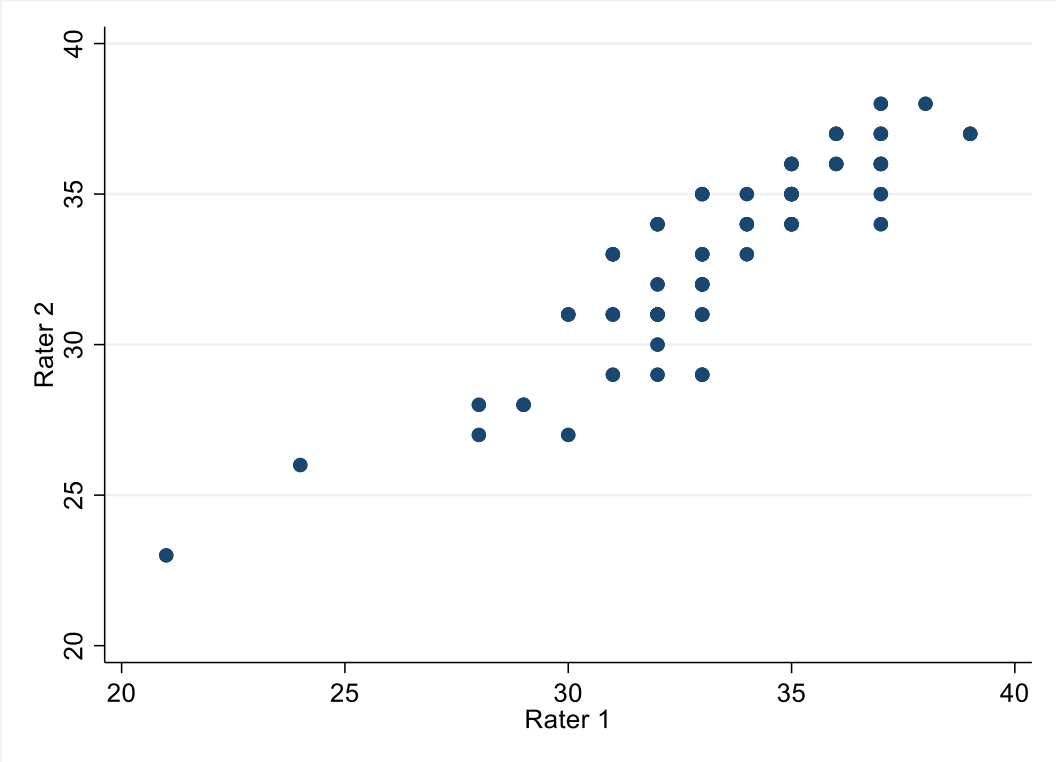
SD = standard deviation, IQR = interquartile range

*Income in Thai Baht

Questionnaire characteristics

The item-object congruence of all items in the final questionnaire was more than 0.5. Cronbach's alpha demonstrated an internal consistency of 0.611 (95%CI 0.462, 0.735), which is in the acceptable range [29]. For interrater reliability, the total score of 65 patients rated by two independent raters (psychiatrists) were analyzed with intraclass correlation coefficient (ICC). The two-way random-effect model on absolute agreement ICC of the two raters was 0.944 (95%CI 0.907, 0.966) which represented an excellent reliability level[30]. High consistency was observed in scatter plot (Figure 1). Interrater agreement on categorical measurement (good candidate, minimally acceptable candidate, and at-risk candidate) was substantial using Cohen's Kappa statistic (0.627, 95%CI 0.435, 0.820).[30, 31].

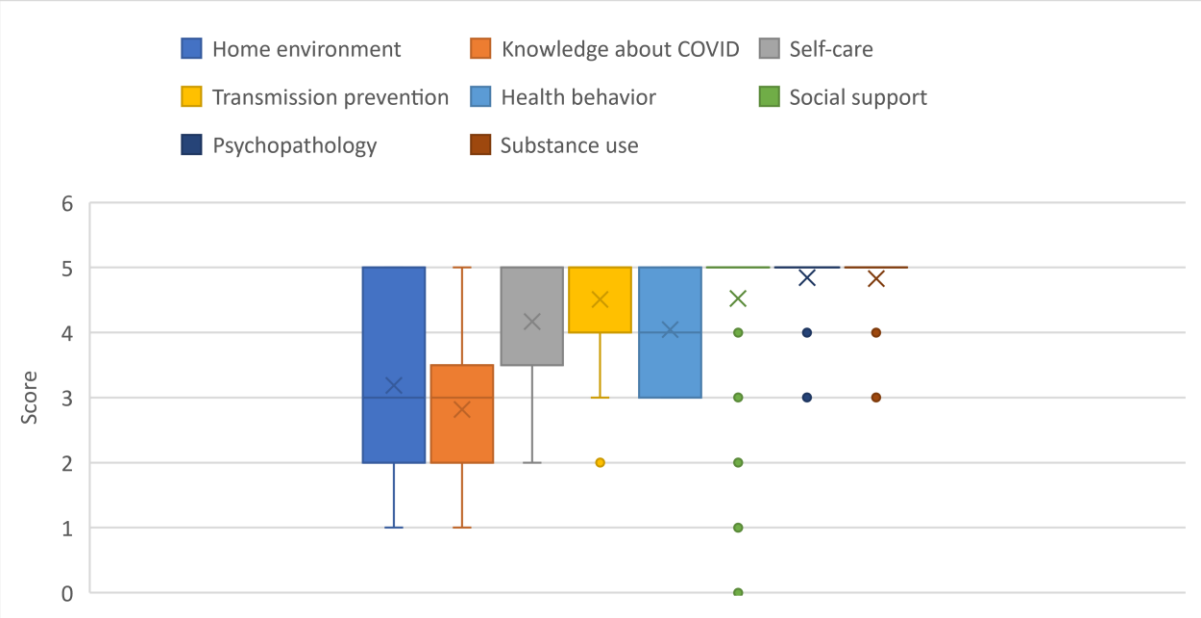
Figure 1: Scatter plot of agreement between two independent raters



Suitability for home isolation

Most of the patients (58.5%) were evaluated as good candidates for HI. Only one patient was evaluated as 'at risk' for non-adherence to HI, with a total score of 23. The median total score was 34 (IQR 31, 35) out of a full score of 40. The majority of the patients had no psychopathology, good social support, and no evidence of substance abuse, which resulted in 80-88% of patients receiving a full score of 5 in each of these domains. Potential commitment to transmission prevention was also mostly good (mean score 4.5). Our study population had moderate knowledge about COVID-19 symptoms (mean score 2.8), while demonstrating better knowledge about self-care (mean score 4.2). Health behavior, including use of masks, social distancing, and general health maintenance, was generally good (mean score 4.0). Suitability of home environment was more diversified, with 40% of patients scoring 1-2, and 47.7% of patients receiving a score of 4-5.

Figure 2: Box-and-whisker plot of scores in each question



Higher education correlated with better health behavior (Spearman's rho 0.294, p = 0.017), while higher income correlated with better home environment (Spearman's rho 0.262, p = 0.035) and better knowledge about COVID-19 (Spearman's rho 0.298, p = 0.016). It is likely that these factors led to the positive correlation seen between education and income with higher total scores on the CCPHIET. Being married was correlated with worse health behavior (Spearman's rho -0.314, p = 0.011), which may be due to more difficulty in social distancing and less opportunities for general health maintenance.

4. Discussion

We developed a new screening tool with the aim to systematically assess the psychosocial suitability for HI and correctly identify asymptomatic/mild symptomatic COVID-19 patients with high potential of HI success. CCPHIET has an acceptable content validity (IOC index > 0.5), moderate internal consistency (Cronbach's alpha = 0.611) and substantial to excellent reliability (ICC of the two raters was 0.944, and Cohen's kappa= 0.627).

Most of the subjects in this study were married, employed, middle adulthood females with low to moderate education and income level. This demographic background likely represented the overcrowded communities of Bangkok which was most affected by the delta variant during the study month. Almost 60% and 40% of the COVID-19 patients in this study were categorized as good, and minimally acceptable candidates for HI by the CCPHIET scoring system. This number is concordant with the 57% compliance rate of self-quarantine survey in Israel during the pandemic in 2020 [13]. By teaching important health care information and arranging for adequate home support, we might be able to improve some risk factors of the minimally acceptable candidates to be more suitable for the HI protocol. Therefore, the percentage of the COVID-19 patients that can be referred to HI settings may exceed 60% of all asymptomatic/mild symptomatic cases. The median total CCPHIET score of 34/40 from the study cohort was not unexpectedly high, as the purpose of this tool is to detect patients who can provide good self-care and have high level of compliance with COVID-19 prevention at home.

Less than 10% of the patients in our cohort reported psychopathology and substance use issues. This number was lower than the 20-30% proportion of depression and anxiety in the COVID-19 Thai patients in field hospitals[32] and 25%

proportion of mental health and substance use comorbidity found in the hotel-based isolation cohort for the homeless in San Francisco, USA[33]. Up to 88% of the sample had a good support system which assured that they would have adequate food and water supply, as well as other physical and psychological support from their family, friends, or community. The availability of a support system was identified as an important factor for HI success in previous literatures [14, 26, 34]. The study patients were also demonstrated to have moderate to good level knowledge in terms of COVID-19 symptoms, self-care, and prevention methods. These were the factors attributing to good quarantine adherence described in the previous studies as well[35-37]. Nearly half (40%) of the patients scored equal or less than 2 points in the home environment domain. Therefore, we encouraged the CCPHEIT rater to explore the information regarding the home environment in detail. Many COVID-19 home care resources recommend that the setting for HI should have a separate bedroom, bathroom, or at least have enough space to accommodate social distancing with the ability to disinfect the sharing area[27, 38].

Along with the development and validation of this tool, we learned that CCPHIET helped categorize the post-swab COVID-19 patients into psychosocially good, minimally acceptable, poor, or contraindicated candidates for HI. This psychosocial information would support the physicians in matching each patient to the most suitable medical setting, whether it is institutional treatment or home-based treatment. This would ensure that our COVID-19 patients would receive appropriate medical care in the right medical settings during this overwhelming pandemic, while balancing patient autonomy with the transmission risk in the community. Moreover, this tool would also help physicians to consider early home discharge for symptomatic COVID-19 patients who have improved without the need to contain

them within the medical unit for a full duration of 14 days (Figure 3). The risks identified by CCPHIET screening would guide physicians to educate, address, or adjust those risks to reduce the community transmission after discharge.

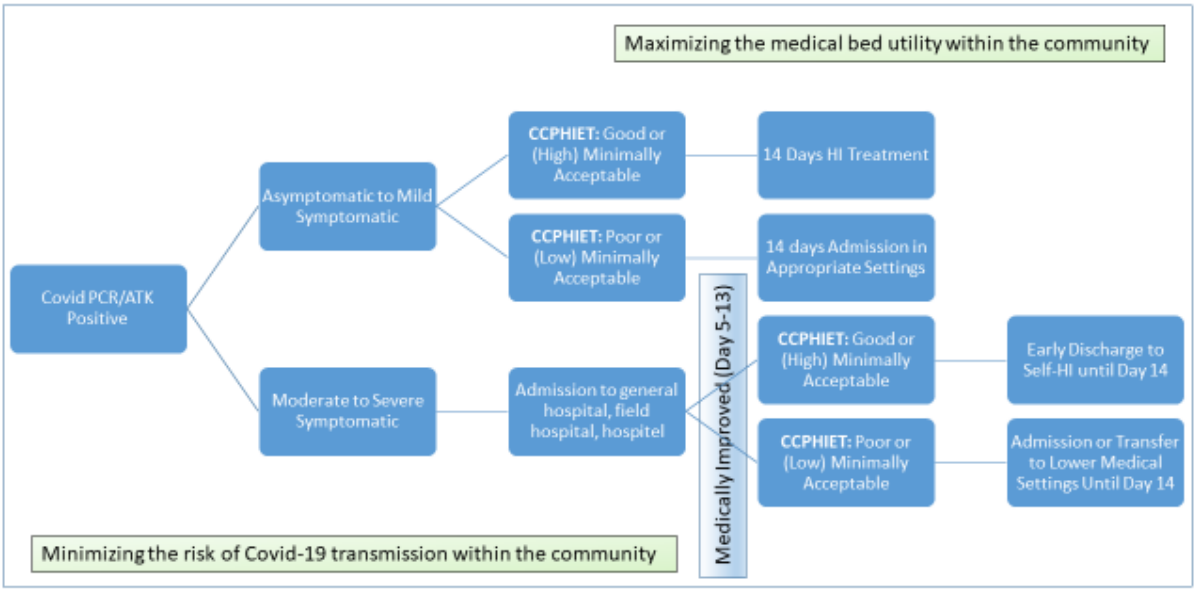


Figure 3: Proposed diagram of CCPHEIT use in the Covid-19 steps of care and settings.

There are some limitations in this study. Unfortunately, we did not recruit the group of patients who were likely to have adverse psychosocial and environmental backgrounds due to our hospital regulations and the time constraints during the pandemic. The CCPHEIT scoring results of this study might have been lower if we were able to include this problematic group into the calculation. We only demonstrated a content validity of the CCPHEIT but did not report other validity values such as the sensitivity and specificity, due to lack of other accepted external standards of suitability for home isolation. Cronbach's alpha was in the low range of an acceptable value, but this may be due to the multidimensional nature of our questionnaire. The original CCPHEIT is in Thai version and was examined in Thai

patients. The questionnaire was translated into English, although the English version has not yet been validated. Future directions for the CCPHEIT development would be to fully implement it into the real world COVID-19 medical system and explore its predictability and utility, impact on transmission control, and as well as economic benefits on a larger scale.

5. Conclusion

Chula COVID-19 Psychosocial Home Isolation Evaluation Tool (CCPHIET) is a newly developed psychosocial assessment tool which was designed to identify good candidates for HI in asymptomatic/mild symptomatic COVID-19 patients. It demonstrated moderate to good validity and reliability profile. Implementing this tool into the COVID-19 care system might increase the possibility of safer and more successful HI outcomes for both post-swab and post-discharge COVID-19 patients, and consequently help decrease unnecessary hospitalization to spare medical resources for more severe COVID-19 patients.

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Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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