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Validation of the Malay version of the Hypertension-Self Care Profile Self Efficacy Assessment tool

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3 **TITLE PAGE**

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5 **Title: Validation of the Malay version of the Hypertension-Self Care Profile Self Efficacy**
6 **Assessment tool**

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ABSTRACT

Objectives

Self-efficacy and self-care measures are key attributes to optimal control of essential hypertension. Self-efficacy can be measured by the Hypertension-Self-Care Profile (HTN-SCP) tool but its utility is dependent on the literacy and understanding by the subjects. A Malay version of the HTN-SCP Tool was developed to assess self-efficacy of Malay-literate patients with hypertension in the multi-ethnic Asian population in Singapore. The study aimed to determine the test-retest reliability of this tool which has been translated in Malay language.

Methods and Material

145 Malay-literate patients, aged 41-70 years, with essential hypertension were recruited in a polyclinic (primary care clinic) in Singapore. They administered the web-based HTN-SCP tool in the test and 63 (43%) of them completed the retest two weeks later. The Cronbach's alpha and Intra-class correlation coefficient (ICC) were computed to assess its test-retest reliability and internal consistency.

Results

The Cronbach's alpha/ICC for "Behavior" (0.851/0.664), "Motivation" (0.928/0.655) and "Self-efficacy" (0.945/0.682) domains showed high internal consistency, fair to good reliability and stability. No floor or ceiling effect was found for the "behavior" and "motivation" domains. However, the borderline ceiling effect (15.2) for "self-efficacy" suggested that limited discriminating power of the tool for patients with high self-efficacy. Positive association was shown between HTN-SCP score and reported self-care measures but it was not statistically significant.

Conclusion

Overall, the modified HTN-SCP tool showed satisfactory test-retest reliability and internal consistency amongst the Malay-literate study population. Further research is needed for its application in general practice to identify patients with low self-efficacy for possible intervention.

Article summary

The Malay version of hypertension self-care profile tool (HTN-SCP) has been validated in Malay-literate patients with essential hypertension.

The results showed satisfactory test-retest reliability and internal consistency of the tool

Its application to identify patients with low self-efficacy will be tested with further research.

INTRODUCTION

Hypertension is often the most prevalent risk factor for vascular diseases in developed and developing countries.[1] Maintaining optimal blood pressure amongst patients with hypertension is key to avert vascular complications such as stroke and cardiac diseases.[2] However, achieving stable blood pressure (BP) control requires these patients to undertake multiple measures consistently, such as salt and fat restriction in diet, regular physical exercises, self-monitoring of BP and weight and adherence to prescribed BP lowering medications.[3][4]

The capacity to conduct these self-care activities is related to an individual's self-efficacy.[5][6] Thus assessing self-efficacy of patients with hypertension provides the healthcare provider an insight into their vascular risk status, and decision support in designing individualized care plan. Questionnaire-based instruments have been developed to facilitate the multi-faceted assessment of self-efficacy. One example is the English-based Hypertension-Self-Care Profile (HTN-SCP) questionnaire developed by Han et al, which covers three key domains of behavior, motivation and self-efficacy.[7] Aside from Americans of Korean ethnicity, the instrument has been validated in Singapore where English is the main language of communication amongst its multi-ethnic Asian population.[8]

Among the 5.61 million local population, 13.4% are of Malay ethnicity.[9] According to the 2010 census, elderly Malay residents are more likely to have lower English literacy, with Malay residents aged over 45 years are far more likely to be literate in Malay only.[10] Yet, hypertension increases in prevalence with age. Singapore is also facing a rapidly aging population and prevalence of hypertension is expected to rise significantly by the next decade.[11] A Malay version of the HTN-SCP instrument is postulated to ease the assessment of self-efficacy amongst the older Malay patients with hypertension. To ensure that they understand the content and contextualized to the local setting, the translated instrument needs to be validated amongst the local Malay-literate patients with hypertension. The validated instrument will allow its application not only in local Malay patients with hypertension, but will also cater to the larger Malay-literate population in Malaysia and other parts of South-East Asia.

METHODS

Aim

The study aimed to determine the test-retest reliability of the Malay version of the HTN-SCP amongst Malay hypertensive patients who are managed in a public primary care clinic in Singapore.

Development of the Malay version of the HTN SCP instrument

The original English-based HTN-SCP instrument has been enhanced in selected items to contextualize to the dietary habits of the local Asian patients with hypertension.[7] The enhanced version was subsequently validated in an earlier study, which showed satisfactory test-retest reliability, as reflected in the internal consistency coefficient (ICC) and Cronbach-alpha indicators. Next, the investigators engaged a commercial agency, whose two independent professional and certified bi-linguists in English and Malay carried out the forward and backward translation of the instrument content respectively. The draft Malay version of the HTN-SCP was then pilot-tested amongst independent bilingual staff within the institution department of research and nurses at the study site. Minor amendments were carried out to the instrument after this preliminary assessment.

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3 The Malay version (HTN-SCP-M) was finalized after approval by the investigator team members, who
4 are also bilingual in English and Malay.
5

6 7 **Subjects**

8 The target subjects were patients of Malay ethnicity with essential hypertension based on their
9 diagnosis code in the electronic medical records at the study site. They were either Singaporean
10 citizens or Permanent Residents.
11

12 13 **Inclusion criteria**

14 Subjects must be between the age of 41 and 70 years on enrolment. They were treated with blood
15 pressure lowering medication for their essential hypertension for at least 1 year.
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18 Subjects were screened by the investigators and research assistants to be able to read and
19 understand the written language as a minimal standard of Malay proficiency. They had to be
20 internet-savvy in order to access the web-based administration of the instrument.
21

22 23 **Exclusion criteria**

24 Subjects who lacked proficiency in the written Malay language and access to internet, were unwilling
25 to execute the test, or were screened to have cognitive, visual or auditory impairment were
26 excluded from the study.
27
28

29 30 **Recruitment of subjects at study site**

31 The study was conducted in a typical public primary care clinic located in an estate in north-eastern
32 Singapore serving a population of about 140 000 multi-ethnic Asian population (2015). The
33 investigators and research assistants identified potential subjects by their Malay names or attire and
34 approached them before or after their medical consultation at the study site. The subjects were next
35 screened to confirm their ethnicity and fulfillment of their eligibility criteria. They were provided
36 with information on the study procedure in Malay and their doubts were clarified before obtaining
37 their written informed consent according to stipulations by the institution review board.
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39

40 41 **Ethics Approval**

42 Ethics approval was granted from the Centralised Institutional Review Board (CIRB) for this study.
43 Ref no: 2016/2332.
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45

46 47 **Administration of the instrument**

48 To ensure anonymity, each subject was given unique study identification number after enrolment,
49 which was used to log in to a free web-based online instrument (Qualtrics) for both the test and
50 retest. They were instructed on the step-by-step procedure to administer the web-based HTN-SCP-M
51 during the test.
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54 After the completion of the test, the subjects were provided with information sheet, instructing
55 them to access the online platform for the retest using their personal electronic devices (smart
56 mobile phone, tablet, laptop or computers) on specified date two weeks later in order to complete
57 the study. The investigators would send reminders via calls, phone messages and electronic mails to
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3 defaulters after the stipulated retest dates. Those that failed to complete the retest beyond a one-
4 week grace period were excluded from the reliability analysis. Participation by the subjects were
5 voluntary, with no incentive provided for their study participation.
6

7 8 **Sample size calculation**

9
10 The COSMIN checklist recommended a good sample of between 50 to 99 study subjects for
11 assessing their test-retest reliability.[12] In view of a significant drop-out rate for the retest using a
12 web-based approach from an earlier study by the principal investigator, the target recruitment size
13 was increased to 150 to account for attrition.
14

15 16 **Data management and Statistical analysis**

17
18 The demographics of study participants were reported. Differences between the overall HTN-SCP-M
19 scores and recommended self-management activities were assessed using independent t-test.
20

21
22 Ceiling and floor effects were considered present when it is higher than 15%.[13] Internal
23 consistency indicates the extent to which the items in a subscale are correlated, in order to evaluate
24 homogeneity using Cronbach's Alpha statistic.[14] A value of 0.7 was considered acceptable while
25 above 0.8 to 0.9 was considered good to excellent internal consistency.[15]
26

27
28 The agreement between repeated measurements (Test- retest) was evaluated through the use of
29 the intra-class correlation coefficient (ICC). An ICC coefficient of ≥ 0.75 was considered as evidence
30 of measurement stability. ICC between 0.4 and 0.75 indicates fair to good reliability, and $ICC < 0.4$
31 indicates poor reliability.[16]
32

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34 A p-value of less than 0.05 was considered as statistically significant. All analyses were performed
35 using the IBM SPSS Statistics for Windows, Version 23.0, IBM Corp, released 2013.
36

37 38 **RESULTS**

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40 A total of 768 subjects were approached by the investigators and research assistants, of which 204
41 patients satisfied the eligibility criteria. With 59 refusal of consent, 145 of them were recruited for
42 the test segment of the study, resulting in a response rate of 71%. Subsequently, 63 (43%) of the
43 recruited subjects completed the retest of the HTN-SCP-M on-line.
44

45
46 The demographics of the respondents were presented in Table 1. There were more females (66.9%)
47 than males (33.1), and the majority of them (66.2%) had up to secondary education. Among the
48 subjects, 19.3% of them had hypertension only, while the majority had other co-morbidities, such as
49 hyperlipidemia (59.5%) and type 2 diabetes mellitus (34.6%).
50

51
52 Table 2 reveals self-care measures reported by the subjects, which are relevant to hypertension
53 management. Majority of them (71.7%) measured their BP at home but only 57.9% documented
54 these measurements regularly. The HTN-SCP-M scores of the subjects who recorded their BP
55 readings were significantly higher than those without BP documentation. The same finding was
56 observed in those who measured their weight regularly.
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58
59 Overall, the HTN-SCP-M scores of those who performed the self-care measures, such as
60 documentation of their weight at home, keeping a food diary, using health-related mobile phone

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3 application and had reduction of BP lowering medication were higher than those who without such
4 activities, although these differences did not attain statistical significance.
5

6 7 **Floor and Ceiling Effect**

8 Table 3: The mean score for the “Self-Efficacy” domain within the HTN-SCP-M was highest,
9 compared to those in the “Behavior” and “Motivation” domains. The “self-efficacy” domain
10 presented a borderline ceiling effect of 15.2% (Table 3). The other two domains show minimal ceiling
11 effect (<15%).
12

13 14 **Internal Consistency**

15
16 All 3 domains showed excellent internal consistencies: the Cronbach’s alpha for “Behavior” was
17 0.851, 0.928 for “Motivation” and 0.945 for “Self-efficacy” domains respectively.
18

19 20 **Test-Retest Reliability**

21 The Intra-class Correlation Coefficient (ICC) for all domains ranged from 0.655 to 0.682, which
22 suggested fair to good reliability and stability.
23

24 25 **DISCUSSION**

26
27 Overall, the Malay version of the HTN-SCP instrument (HTN-SCP-M) has attained satisfactory test-
28 retest reliability and internal consistency amongst the study population based on the Cronbach’s
29 alpha and ICC indices. Whilst the flooring effect was minimal, the results showed borderline ceiling
30 effect for the self-efficacy domain. It suggests potential limitation to the discriminating power of the
31 instrument amongst those with high scores in the self-efficacy domain. However, this subset of the
32 study population with higher capacity for self-efficacy to control their blood pressure are not the
33 target patients of concern to clinicians. Attention should focus on the group of patients with lower
34 self-efficacy capacity, reflected by the lower HTN-SCP-M scores, who are at risks of poor blood
35 pressure control.
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38
39 The next step will be to test the application of the HTN-SCP-M on the local Malay-literate patients
40 with hypertension to determine the correlation between its scores and self-care activities. The total
41 aggregated score in this study was significantly associated with patients’ self-reporting of their
42 documentation of their home blood pressure monitoring and weight measurement. For other self
43 care measures such as keeping a food diary, the positive correlation between the total scores and
44 reported self-care measures was not statistically significant.
45

46
47 Nonetheless, the sample size of the study population was not computed to determine the
48 differences in self-care measures based on the instrument score. Further adequately powered study
49 with larger number of subjects and incorporating reliable and objective assessment of self-care
50 measures is needed to assess if the instrument can be used to stratify Malay-literate patients into
51 varying capacities for health behavior, motivation and self-efficacy.
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54 The study has its strength and limitations. The use of a web-based approach in implementing the
55 test-retest reliability evaluation enabled the patients to self-administer the instrument remotely
56 using their smart-phone, tablets, computer and laptop at their preferred timing and venue. Despite
57 the convenience of this method, the uptake of the retest segment was suboptimal amidst reminders
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3 by the investigators. In retrospect, the uptake could be ameliorated with incentives and nominal
4 reimbursement for the effort and time by the participants, even though the cost in carrying out the
5 on-line retest was minimal.
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8 Assessing the self-efficacy capacity of illiterate Malay patients using the printed form of the
9 instrument remains a challenge. However, most of these patients can understand conversational
10 Malay. Developing an auditory presentation of the questions in the instrument is one potential
11 solution which requires evaluation in further study.
12

13 **Conclusion**

14
15 The Malay version of the HTN-SCP has satisfactory test-retest reliability and internal consistency. The
16 total scores of the Malay-based instrument have shown potential association with patients' self-
17 reporting of their self-care behavior, which require further research for its validation.
18

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25 survey.
26
27

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31 profit sectors.
32

33 **Competing interest**

34
35 The authors have read and understood BMJ policy on declaration of interests and declare that they
36 have no competing interests.
37
38

39 **Authors' contributions**

40
41 NCT designed the study protocol. DBMY and KCS were involved in the recruitment and
42 administration of the questionnaire. YLEK was involved in data analysis. NCT drafted the manuscript
43 while all authors reviewed and improved the final manuscript before submission.
44
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46 **Data sharing statement**

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48 Anonymous data will be shared upon request if researchers/reviewers are interested.
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50 **References**

51
52 1. Global Health Observatory Data, Raised Blood Pressure - Situation and trends. WHO website.
53 http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/. Updated 2008.
54 Accessed January 1, 2017.
55
56
57
58
59
60

- 1
2
3 2.Q&As on hypertension. World Health Organization (WHO) website.
4 <http://www.who.int/features/qa/82/en/>. Updated September 2015. Accessed January 1, 2017.
5
- 6 3. Hypertension in adults: Diagnosis and Management, Clinical guideline (CG127). National Institute
7 for Health and Care Excellence (NICE) website. <https://www.nice.org.uk/guidance/cg127>. Updated
8 2016. Accessed January 26, 2017.
9
- 10 4. Eckel RH, Jakicic JM, Ard JD, et al. AHA/ACC guideline on lifestyle management to reduce
11 cardiovascular risk: a report of the American College of Cardiology/American Heart Association task
12 force on practice guidelines. *Circulation*. 2014;129:S76-99doi:10.1161/01.cir.0000437740.48606.d1.
13
- 14 5. Warren-Findlow J, Seymour RB, Brunner Huber LR. The Association Between Self-Efficacy and
15 Hypertension Self-Care Activities Among African American Adults. *Journal of Community Health*.
16 2012;37(1):15-24. doi:10.1007/s10900-011-9410-6.
17
- 18 6. Lee JE, Han HR, Song H et al. Correlates of self-care behaviors for managing hypertension among
19 Korean Americans: a questionnaire survey. *Int J Nurs Stud*. 2010;47(4):411-7doi:
20 10.1016/j.ijnurstu.2009.09.011.
21
- 22 7. Han HR, Lee H, Commodore-Mensah Y et al. Development and validation of the Hypertension Self-
23 care Profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs*. 2014;29:E11-20doi:
24 10.1097/JCN.0b013e3182a3fd46.
25
- 26 8. Koh YL et al. Using a Web-Based Approach to Assess Test-Retest Reliability of the "Hypertension
27 Self-Care Profile" Tool in an Asian Population: A Validation Study. *Medicine(Baltimore)*.
28 2016;95(9):e2955doi: 10.1097/MD.00000000002955.
29
- 30 9. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. Population Trends
31 2016. 2016. ISSN 1793-2424: 3-5
32
- 33 10. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. Census of
34 Population 2010 Statistical Release 1, Demographic Characteristics, Education, Language and
35 Religion. 2011. ISBN 978-981-08-7808-5. Table 39.
36
- 37 11. Malhotra R, Chan A, Malhotra C et al. Prevalence, awareness, treatment and control of
38 hypertension in the elderly population of Singapore. *Hypertension Research*. 2010;33:1223-
39 1231doi: :10.1038/hr.2010.177
40
- 41 12. Terwee CB, Mokink LB, Knol DL et al. Rating the methodological quality in systematic reviews of
42 studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res*.
43 2012;21:651-7doi: 10.1007/s11136-011-9960-1
44
- 45 13. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement
46 properties of health status questionnaires. *J Clin Epidemiol*. 2007;60:34-
47 42doi:10.1016/j.jclinepi.2006.03.012
48
- 49 14. Andresen EM. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med*
50 *Rehabil*. 2000;81:S15-S20doi:10.1053/apmr.2000.20619
51
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42
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51
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55
56
57
58
59
60

15. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika*. 1951;16:297-334doi:10.1007/BF02310555.

16. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment*. 1994;6:284-290doi:10.1037/1040-3590.6.4.284

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Table 1: Baseline characteristics of study population

Demographic characteristics	n (%)
Gender	
Male	48 (33.1)
Female	97 (66.9)
Age, Mean (SD)	58 (6.8)
Highest Level of education	
Primary	17 (11.7)
Secondary	96 (66.2)
JC/ Polytechnic/ ITE	23 (15.9)
University	9 (6.2)
Other Comorbidities	
Hypertension only	28 (19.3)
Diabetes	78 (53.8)
Dyslipidemia	95 (65.5)
Heart disease	10 (6.9)
Stroke	4 (2.8)
Others	17 (11.7)
Number of medication, Median (IQR)	1 (1-2)

Table 2. Association between Self-Reported Self-Care Activities and the Overall Mean Scores of the Hypertension Self-Care Profile

	N (%)	Overall Mean HTN-SCP Score (SD)		p-value
		Yes	No	
Do you measure your blood pressure at home	104 (71.7)	189.3 (27.3)	180 (24.9)	0.06
Do you record your blood pressure readings regularly	84 (57.9)	190.9 (27.7)	180.8 (24.8)	0.03*
Do you keep a food diary	18 (12.4)	187.8 (37.1)	186.5 (25.3)	0.85
Do you measure your weight regularly	86 (59.3)	190.5 (26.9)	181.1 (26.2)	0.04*
Do you record your weight regularly	39 (26.9)	190.1 (29.6)	185.4 (25.9)	0.35
Do you use any mobile apps to monitor your health or medical condition?	35 (24.1)	192.1 (28.9)	184.9 (26.1)	0.17
Has your doctor ever reduced your HBP medications	43 (29.7)	186.3 (27.5)	186.8 (26.8)	0.93

Table 3. Reliability indices of the HTN-SCP-M instrument

Domains	Mean (SD)	Ceiling effect proportion (%)	First assessment score, Median (IQR)	Second assessment score, Median (IQR)	Cronbach's alpha	ICC (95% CI)
Behaviour	50.3 (10.1)	0	55 (48-58)	58 (53-64)	0.851	0.664 (0.500-0.783)
Motivation	65.8 (10.4)	14 (9.7)	67 (60-74)	66 (60-74)	0.928	0.655 (0.487-0.776)
Self-efficacy	66.4 (11.2)	22 (15.2)	67 (61-76)	67 (60-74)	0.945	0.682 (0.524-0.795)

Note: Each domain has 20 items

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	-
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	5
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	-

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5-6
		(b) Give reasons for non-participation at each stage	-
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	5
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	5
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7
Generalisability	21	Discuss the generalisability (external validity) of the study results	7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	7

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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TITLE PAGE

Title: Validation of the Malay version of the Hypertension-Self Care Profile Self Efficacy Assessment tool

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Keywords: hypertension, self-Care, instrument, Malay

Word Count: 2307

ABSTRACT

Objectives

Self-efficacy and self-care measures are key attributes to optimal control of essential hypertension. Self-efficacy can be measured by the Hypertension-Self-Care Profile (HTN-SCP) tool but its utility is dependent on the literacy and understanding of the subjects. A Malay version of the HTN-SCP Tool was developed to assess self-efficacy of Malay-literate patients with hypertension in the multi-ethnic Asian population in Singapore. The study aimed to determine the test-retest reliability of this tool which has been translated in Malay language.

Methods and Material

145 Malay-literate patients, aged 41-70 years, with essential hypertension were recruited in a polyclinic (primary care clinic) in Singapore. Forty-three percent of them completed both the first and second HTN SCP tool online, with a period of two weeks in between. The Cronbach's alpha and Intra-class correlation coefficient (ICC) were computed to assess its test-retest reliability and internal consistency.

Results

The Cronbach's alpha/ICC for "Behavior" (0.851/0.664), "Motivation" (0.928/0.655) and "Self-efficacy" (0.945/0.682) domains showed high internal consistency, fair to good reliability and stability. No floor or ceiling effect was found for the "behavior" and "motivation" domains. However, the borderline ceiling effect (15.2) for "self-efficacy" suggested that limited discriminating power of the tool for patients with high self-efficacy. Positive association was shown between HTN-SCP score and reported self-care measures but it was not statistically significant.

Conclusion

Overall, the translated HTN-SCP tool showed satisfactory test-retest reliability and internal consistency amongst the Malay-literate study population. Further research is needed for its application in general practice to identify patients with low self-efficacy for possible intervention.

Article summary

The Malay version of hypertension self-care profile tool (HTN-SCP) has been validated in Malay-literate patients with essential hypertension.

The results showed satisfactory test-retest reliability and internal consistency of the tool

Its application to identify patients with low self-efficacy will be tested with further research.

INTRODUCTION

1
2
3 Hypertension is often the most prevalent risk factor for vascular diseases in developed and
4 developing countries.[1] Maintaining optimal blood pressure amongst patients with hypertension is
5 key to avert vascular complications such as stroke and cardiac diseases.[2] However, achieving stable
6 blood pressure (BP) control requires these patients to undertake multiple measures consistently,
7 such as salt and fat restriction in diet, regular physical exercises, consumption of alcohol, self-
8 monitoring of BP and weight and adherence to prescribed BP lowering medications.[3][4]
9

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11 The capacity to conduct these self-care activities is related to an individual's self-efficacy.[5][6] Thus
12 assessing self-efficacy of patients with hypertension provides the healthcare provider an insight into
13 their vascular risk status, and decision support in designing individualized care plan. Questionnaire-
14 based instruments have been developed to facilitate the multi-faceted assessment of self-efficacy.
15 One example is the English-based Hypertension-Self-Care Profile (HTN-SCP) questionnaire developed
16 by Han HR et al, which covers three key domains of behavior, motivation and self-efficacy.[7] Her
17 team had used two validated theoretical approaches, Orem's self-care model [8] and Motivational
18 Interviewing (MI) [9] to develop the questionnaire. The Orem's model depicts the enablement of
19 individuals to embark on deliberate actions such as taking medication and physical activity as
20 indicators of self-care.[8] Using similar constructs such as those from the Social Cognitive Theory and
21 Health Belief Model, MI indicates a commitment to change (i.e. motivation) and reflects the
22 development of confidence for behavior change.[9] Self-efficacy predicts medication adherence,
23 physical activity, diet and weight control.[7] Han HR et al reported high reliability estimates and
24 strong evidence of validity of the HBP SCP when the study was carried out in an inner city American
25 population. Their results suggest that the questionnaire can be used to assess and identify gaps in
26 self-care behaviour, motivation, and self-efficacy in patients with hypertension.
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30 The test-retest reliability assessment of this English-based questionnaire had also been performed in
31 Singapore, where English is the main language of communication of its population on the developed
32 island state.[10] Among the 5.61 million multi-ethnic Asian population in Singapore, 13.4% are of
33 Malay ethnicity.[11] According to the Singapore 2010 Population Census, 37% of the local Malay
34 population had up to "below secondary" education or equivalent of grade 6 educational level. [12]
35 The questions of the original version of HTN SCP were developed to pitch at grade 6 level. [7]
36 Uncertainty arises if over a third of the overall Malay population could understand the English-based
37 questionnaire. Moreover, hypertension is more prevalent among the more senior residents. Based
38 on the same census, only 5.5% of Malays of age 55 years and older, and 4.4% of Malays with "below
39 secondary education" are proficient and use English at home. [12] Hence, approximately one in
40 twenty Malay patients with hypertension would have potential difficulties in using the locally
41 validated HTN SCP instrument.
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45
46 Singapore is also facing a rapidly aging population and the prevalence of hypertension is expected to
47 rise significantly by the next decade.[13] A Malay version of the HTN-SCP instrument is postulated to
48 ease the assessment of self-efficacy amongst the older Malay patients with hypertension. To ensure
49 that they understand the content and contextualized to the local setting, the translated instrument
50 needs to be tested on stability and reliability amongst the local Malay-literate patients with
51 hypertension. The instrument will allow its application not only in local Malay patients with
52 hypertension, but will also cater to the larger Malay-literate population in Malaysia and other parts
53 of South-East Asia.
54

55 56 **METHODS** 57 58 59 60

Aim

The study aimed to determine the test-retest reliability of the Malay version of the HTN-SCP amongst Malay hypertensive patients who are managed in a public primary care clinic in Singapore.

Development of the Malay version of the HTN SCP instrument

The original English-based HTN-SCP instrument has been enhanced in selected items to contextualize to the dietary habits of the local Asian patients with hypertension.[7] The enhanced version was subsequently validated in an earlier study, which showed satisfactory test-retest reliability, as reflected in the internal consistency coefficient (ICC) (0.671, 0.762, and 0.720 for the 3 domains) and Cronbach-alpha indicators (0.857, 0.948, and 0.931 respectively). Next, the investigators engaged a commercial agency, whose two independent professional and certified bi-linguists in English and Malay carried out the forward and backward translation of the instrument content respectively. The draft Malay version of the HTN-SCP was then pilot-tested amongst independent bilingual staff within the institution department of research and nurses at the study site. Minor amendments were carried out to the instrument after this preliminary assessment. The Malay version (HTN-SCP-M) was finalized after approval by the investigator team members, who are also bilingual in English and Malay.

Subjects

The target subjects were patients of Malay ethnicity with essential hypertension based on their diagnosis code in the electronic medical records at the study site. They were either Singaporean citizens or Permanent Residents.

Inclusion criteria

Subjects must be between the age of 41 and 70 years on enrolment. They were treated with blood pressure lowering medication for their essential hypertension for at least 1 year.

Subjects were screened by the investigators and research assistants to be able to read and understand the written language as a minimal standard of Malay proficiency. They had to be internet-savvy in order to access the web-based administration of the instrument.

Exclusion criteria

Subjects who lacked proficiency in the written Malay language and access to internet, were unwilling to execute the test, or were screened to have cognitive, visual or auditory impairment were excluded from the study.

Recruitment of subjects at study site

The study was conducted in a typical public primary care clinic located in an estate in north-eastern Singapore serving a population of about 140 000 multi-ethnic Asian population (2015). The investigators and research assistants identified potential subjects by their Malay names or attire and approached them before or after their medical consultation at the study site. The subjects were next screened to confirm their ethnicity and fulfillment of their eligibility criteria. They were provided

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2
3 with information on the study procedure in Malay and their doubts were clarified before obtaining
4 their written informed consent according to stipulations by the institution review board.
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6 7 Ethics Approval

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9 Ethics approval was granted from the Centralised Institutional Review Board (CIRB) for this study.
10 Ref no: 2016/2332.

11 12 Administration of the instrument

13
14 To ensure anonymity, each subject was given unique study identification number after enrolment,
15 which was used to log in to a free web-based online instrument (Qualtrics) for both the test and
16 retest. They were instructed on the step-by-step procedure to administer the web-based HTN-SCP-M
17 during the test. The web design ensured mandatory filling of the response to each question before
18 the subject was allowed to progress to the next question. This format eliminated any missing data.
19

20
21 After the completion of the test, the subjects were provided with information sheet, instructing
22 them to access the online platform for the retest using their personal electronic devices (smart
23 mobile phone, tablet, laptop or computers) on specified date two weeks later in order to complete
24 the study. The investigators would send reminders via calls, phone messages and electronic mails to
25 defaulters after the stipulated retest dates. Those that failed to complete the retest beyond a one-
26 week grace period were excluded from the reliability analysis. Participation by the subjects were
27 voluntary, with no incentive provided for their study participation.
28
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30 31 Sample size calculation

32
33 The COSMIN checklist recommended a good sample of between 50 to 99 study subjects for
34 assessing their test-retest reliability.[14] In view of a significant drop-out rate for the retest using a
35 web-based approach from an earlier study by the principal investigator, the target recruitment size
36 was increased to 150 to account for attrition.
37

38 39 Data management and Statistical analysis

40
41 The demographics of study participants were reported. Differences between the overall HTN-SCP-M
42 scores and recommended self-management activities were assessed using independent t-test.
43

44
45 Ceiling and floor effects were derived from the percentage of respondents with the highest and
46 lowest scale scores. Ceiling and floor effects were considered present when it is higher than 15%.[15]
47 Internal consistency indicates the extent to which the items in a subscale are correlated, in order to
48 evaluate homogeneity using Cronbach's Alpha statistic.[16] A value of 0.7 was considered acceptable
49 while above 0.8 to 0.9 was considered good to excellent internal consistency.[17]

50
51 The agreement between repeated measurements (Test- retest) was evaluated through the use of
52 the intra-class correlation coefficient (ICC). An ICC coefficient of ≥ 0.75 was considered as evidence
53 of measurement stability. ICC between 0.4 and 0.75 indicates fair to good reliability, and $ICC < 0.4$
54 indicates poor reliability.[18]
55

56
57 A p-value of less than 0.05 was considered as statistically significant. All analyses were performed
58 using the IBM SPSS Statistics for Windows, Version 23.0, IBM Corp, released 2013.
59
60

RESULTS

A total of 768 subjects were approached by the investigators and research assistants, of which 204 patients satisfied the eligibility criteria. With 59 refusal of consent, 145 of them were recruited for the test segment of the study, resulting in a response rate of 71%. Subsequently, 63 (43%) of the recruited subjects completed the retest of the HTN-SCP-M on-line.

The demographics of the respondents were presented in Table 1. There were more females (66.9%) than males (33.1), and the majority of them (66.2%) had up to 10 years of education. Among the subjects, 19.3% of them had hypertension only, while the majority had other co-morbidities, such as dyslipidemia (59.5%) and type 2 diabetes mellitus (34.6%).

Table 1: Baseline characteristics of study population

Demographic characteristics	n (%)
Gender	
Male	48 (33.1)
Female	97 (66.9)
Age, Mean (SD)	58 (6.8)
Highest Level of education	
Primary	17 (11.7)
Secondary	96 (66.2)
JC/ Polytechnic/ ITE	23 (15.9)
University	9 (6.2)
Other Comorbidities	
Hypertension only	28 (19.3)
Diabetes	78 (53.8)
Dyslipidemia	95 (65.5)
Heart disease	10 (6.9)
Stroke	4 (2.8)
Others	17 (11.7)
Number of medication, Median (IQR)	1 (1-2)

Table 2 reveals self-care measures reported by the subjects, which are relevant to hypertension management. Majority of them (71.7%) measured their BP at home but only 57.9% documented these measurements regularly. The HTN-SCP-M scores of the subjects who recorded their BP readings were significantly higher than those without BP documentation. The same finding was observed in those who measured their weight regularly.

Table 2. Association between Self-Reported Self-Care Activities and the Overall Mean Scores of the Hypertension Self-Care Profile

	N (%)	Overall Mean HTN-SCP Score (SD)		
		Yes	No	p-value
Do you measure your blood pressure at home	104 (71.7)	189.3 (27.3)	180 (24.9)	0.06
Do you record your blood pressure readings regularly	84 (57.9)	190.9 (27.7)	180.8 (24.8)	0.03*
Do you keep a food diary	18 (12.4)	187.8 (37.1)	186.5 (25.3)	0.85
Do you measure your weight regularly	86 (59.3)	190.5 (26.9)	181.1 (26.2)	0.04*
Do you record your weight regularly	39 (26.9)	190.1 (29.6)	185.4 (25.9)	0.35
Do you use any mobile apps to monitor your health or medical condition?	35 (24.1)	192.1 (28.9)	184.9 (26.1)	0.17
Has your doctor ever reduced your HBP medications	43 (29.7)	186.3 (27.5)	186.8 (26.8)	0.93

The HTN-SCP-M scores of those who performed self-care measures, such as home BP measurements, keeping a food diary, documentation of weight and using health-related mobile phone application, were higher than those who without such activities, although these differences did not attain statistical significance (Table 2).

Floor and Ceiling Effect

Table 3: The mean score for the “Self-Efficacy” domain within the HTN-SCP-M was highest, compared to those in the “Behavior” and “Motivation” domains. The “self-efficacy” domain presented a borderline ceiling effect of 15.2% (Table 3). The other two domains show minimal ceiling effect (<15%).

Table 3. Reliability indices of the HTN-SCP-M instrument

Domains	Mean (SD)	Ceiling effect proportion (%)	First assessment score, Median (IQR)	Second assessment score, Median (IQR)	Cronbach's alpha	ICC (95% CI)
Behaviour	50.3 (10.1)	0	55 (48-58)	58 (53-64)	0.851	0.664 (0.500-0.783)
Motivation	65.8 (10.4)	14 (9.7)	67 (60-74)	66 (60-74)	0.928	0.655 (0.487-0.776)
Self-efficacy	66.4 (11.2)	22 (15.2)	67 (61-76)	67 (60-74)	0.945	0.682 (0.524-0.795)

Note: Each domain has 20 items

Internal Consistency

All 3 domains showed excellent internal consistencies: the Cronbach's alpha for "Behavior" was 0.851, 0.928 for "Motivation" and 0.945 for "Self-efficacy" domains respectively.

Test-Retest Reliability

The Intra-class Correlation Coefficient (ICC) for all domains ranged from 0.655 to 0.682, which suggested fair to good reliability and stability.

DISCUSSION

Overall, the Malay version of the HTN-SCP instrument (HTN-SCP-M) has attained satisfactory test-retest reliability and internal consistency amongst the study population based on the Cronbach's alpha and ICC indices. Whilst the flooring effect was minimal, the results showed borderline ceiling effect for the self-efficacy domain. It suggests potential limitation to the discriminating power of the instrument amongst those with high scores in the self-efficacy domain. However, this subset of the study population with higher capacity for self-efficacy to control their blood pressure is not the target patients of concern to clinicians. Attention should focus on the group of patients with lower self-efficacy capacity, reflected by the lower HTN-SCP-M scores, who are at risks of poor blood pressure control.

The next step will be to test the application of the HTN-SCP-M on the local Malay-literate patients with hypertension to determine the correlation between its scores and self-care activities. The total aggregated score in this study was significantly associated with patients' self-reporting of their documentation of their home blood pressure monitoring and weight measurement. For other self care measures such as keeping a food diary, the positive correlation between the total scores and reported self-care measures was not statistically significant.

Nonetheless, the sample size of the study population was not computed to determine the differences in self-care measures based on the instrument score. Further adequately powered study with larger number of subjects and incorporating reliable and objective assessment of self-care measures is needed to assess if the instrument can be used to stratify Malay-literate patients into varying capacities for health behavior, motivation and self-efficacy.

The study has its strength and limitations. The use of a web-based approach in implementing the test-retest reliability evaluation enabled the patients to self-administer the instrument remotely using their smart-phone, tablets, computer and laptop at their preferred timing and venue. Despite the convenience of this method, the uptake of the retest segment was suboptimal amidst reminders by the investigators. In retrospect, the uptake could be ameliorated with incentives and nominal reimbursement for the effort and time by the participants, even though the cost in carrying out the on-line retest was minimal.

Conclusion

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3 The Malay version of the HTN-SCP has satisfactory test-retest reliability and internal consistency. The
4 total scores of the Malay-based instrument have shown potential association with patients' self-
5 reporting of their self-care behavior, which require further research for its validation.
6

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8
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13 survey.
14
15

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17
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19 profit sectors.
20

21 **Competing interest**

22
23 The authors have read and understood BMJ policy on declaration of interests and declare that they
24 have no competing interests.
25
26

27 **Authors' contributions**

28
29 NCT designed the study protocol. DBMY and KCS were involved in the recruitment and
30 administration of the questionnaire. YLEK was involved in data analysis. NCT drafted the manuscript
31 while all authors reviewed and improved the final manuscript before submission.
32
33

34 **Data sharing statement**

35
36 Anonymous data will be shared upon request if researchers/reviewers are interested.
37

38 **References**

- 39
40 1. Global Health Observatory Data, Raised Blood Pressure - Situation and trends. WHO website.
41 http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/. Updated 2008.
42 Accessed January 1, 2017.
43
44 2. Q&As on hypertension. World Health Organization (WHO) website.
45 <http://www.who.int/features/qa/82/en/>. Updated September 2015. Accessed January 1, 2017.
46
47 3. Hypertension in adults: Diagnosis and Management, Clinical guideline (CG127). National Institute
48 for Health and Care Excellence (NICE) website. <https://www.nice.org.uk/guidance/cg127>. Updated
49 2016. Accessed January 26, 2017.
50
51 4. Eckel RH, Jakicic JM, Ard JD, et al. AHA/ACC guideline on lifestyle management to reduce
52 cardiovascular risk: a report of the American College of Cardiology/American Heart Association task
53 force on practice guidelines. *Circulation*. 2014;129:S76-99doi:10.1161/01.cir.0000437740.48606.d1.
54
55
56
57
58
59
60

- 1
2
3 5. Warren-Findlow J, Seymour RB, Brunner Huber LR. The Association Between Self-Efficacy and
4 Hypertension Self-Care Activities Among African American Adults. *Journal of Community Health*.
5 2012;37(1):15-24. doi:10.1007/s10900-011-9410-6.
6
- 7
8 6. Lee JE, Han HR, Song H et al. Correlates of self-care behaviors for managing hypertension among
9 Korean Americans: a questionnaire survey. *Int J Nurs Stud*. 2010;47(4):411-7doi:
10 10.1016/j.ijnurstu.2009.09.011.
11
- 12
13 7. Han HR, Lee H, Commodore-Mensah Y et al. Development and validation of the Hypertension Self-
14 care Profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs*. 2014;29:E11-20doi:
15 10.1097/JCN.0b013e3182a3fd46.
16
- 17
18 8. Orem DE. *Concepts of Practice*. 3rd ed. New York, NY: McGraw-Hill; 1985.
19
- 20
21 9. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People to Change Addictive Behaviour*.
22 New York, NY: Guilford Press; 1991.
23
- 24
25 10. Koh YL et al. Using a Web-Based Approach to Assess Test-Retest Reliability of the "Hypertension
26 Self-Care Profile" Tool in an Asian Population: A Validation Study. *Medicine(Baltimore)*.
27 2016;95(9):e2955doi: 10.1097/MD.00000000002955.
28
- 29
30 11. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. *Population Trends*
31 2016. 2016. ISSN 1793-2424: 3-5
32
- 33
34 12. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. *Census of*
35 *Population 2010 Statistical Release 1, Demographic Characteristics, Education, Language and*
36 *Religion*. 2011. ISBN 978-981-08-7808-5. Table 39.
37
- 38
39 13. Malhotra R, Chan A, Malhotra C et al. Prevalence, awareness, treatment and control of
40 hypertension in the elderly population of Singapore. *Hypertension Research*. 2010;33:1223-
41 1231doi: :10.1038/hr.2010.177
42
- 43
44 14. Terwee CB, Mokkink LB, Knol DL et al. Rating the methodological quality in systematic reviews of
45 studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res*.
46 2012;21:651-7doi: 10.1007/s11136-011-9960-1
47
- 48
49 15. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement
50 properties of health status questionnaires. *J Clin Epidemiol*. 2007;60:34-
51 42doi:10.1016/j.jclinepi.2006.03.012
52
- 53
54 16. Andresen EM. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med*
55 *Rehabil*. 2000;81:S15-S20doi:10.1053/apmr.2000.20619
56
- 57
58 17. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika*. 1951;16:297-
59 334doi:10.1007/BF02310555.
60

1
2
3
4
5
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41
42
43
44
45
46
47
48
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50
51
52
53
54
55
56
57
58
59
60

18. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment*. 1994;6:284-290doi: 10.1037/1040-3590.6.4.284

For peer review only

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	-
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	5
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	-

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5-6
		(b) Give reasons for non-participation at each stage	-
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	5
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	5
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7
Generalisability	21	Discuss the generalisability (external validity) of the study results	7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	7

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

What is the test-retest reliability of the Malay version of the Hypertension Self Care Profile Self Efficacy Assessment tool? A validation study in primary care

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TITLE PAGE

Title: What is the test-retest reliability of the Malay version of the Hypertension Self Care Profile Self Efficacy Assessment tool? A validation study in primary care

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ABSTRACT

Objectives

Self-efficacy and self-care measures are key attributes to optimal control of essential hypertension. Self-efficacy can be measured by the Hypertension-Self-Care Profile (HTN-SCP) tool but its utility is dependent on the literacy and understanding of the subjects. A Malay version of the HTN-SCP Tool was developed to assess self-efficacy of Malay-literate patients with hypertension in the multi-ethnic Asian population in Singapore. The study aimed to determine the test-retest reliability of this tool which has been translated in Malay language.

Methods and Material

145 Malay-literate patients, aged 41-70 years, with essential hypertension were recruited in a polyclinic (primary care clinic) in Singapore. Forty-three percent of them completed both the first and second HTN SCP tool online, with a period of two weeks in between. The Cronbach's alpha and Intra-class correlation coefficient (ICC) were computed to assess its test-retest reliability and internal consistency.

Results

The Cronbach's alpha/ICC for "Behavior" (0.851/0.664), "Motivation" (0.928/0.655) and "Self-efficacy" (0.945/0.682) domains showed high internal consistency, fair to good reliability and stability. No floor or ceiling effect was found for the "behavior" and "motivation" domains. However, the borderline ceiling effect (15.2) for "self-efficacy" suggested that limited discriminating power of the tool for patients with high self-efficacy. Positive association was shown between HTN-SCP score and reported self-care measures but it was not statistically significant.

Conclusion

Overall, the translated HTN-SCP tool showed satisfactory test-retest reliability and internal consistency amongst the Malay-literate study population. Further research is needed for its application in general practice to identify patients with low self-efficacy for possible intervention.

Strengths and limitations of the study

The study validated a novel tool in Malay language to assess the self-efficacy of local Malay literate patients with hypertension, as well as those in Malaysia and other parts of South-East Asia.

This study used a web-based method to conduct the test-retest reliability assessment for the convenience of participants but this approach also resulted in significant dropouts from the study.

The "self-efficacy" domain of the tool is limited by a borderline ceiling effect.

INTRODUCTION

Hypertension is often the most prevalent risk factor for vascular diseases in developed and developing countries.[1] Maintaining optimal blood pressure amongst patients with hypertension is key to avert vascular complications such as stroke and cardiac diseases.[2] However, achieving stable blood pressure (BP) control requires these patients to undertake multiple measures consistently, such as salt and fat restriction in diet, regular physical exercises, consumption of alcohol, self-monitoring of BP and weight and adherence to prescribed BP lowering medications.[3][4]

The capacity to conduct these self-care activities is related to an individual's self-efficacy.[5][6] Thus assessing self-efficacy of patients with hypertension provides the healthcare provider an insight into their vascular risk status, and decision support in designing individualized care plan. Questionnaire-based instruments have been developed to facilitate the multi-faceted assessment of self-efficacy. One example is the English-based Hypertension-Self-Care Profile (HTN-SCP) questionnaire developed by Han HR et al, which covers three key domains of behavior, motivation and self-efficacy.[7] Her team had used two validated theoretical approaches, Orem's self-care model [8] and Motivational Interviewing (MI) [9] to develop the questionnaire. The Orem's model depicts the enablement of individuals to embark on deliberate actions such as taking medication and physical activity as indicators of self-care.[8] Using similar constructs such as those from the Social Cognitive Theory and Health Belief Model, MI indicates a commitment to change (i.e. motivation) and reflects the development of confidence for behavior change.[9] Self-efficacy predicts medication adherence, physical activity, diet and weight control.[7] Han HR et al reported high reliability estimates and strong evidence of validity of the HBP SCP when the study was carried out in an inner city American population. Their results suggest that the questionnaire can be used to assess and identify gaps in self-care behaviour, motivation, and self-efficacy in patients with hypertension.

The test-retest reliability assessment of this English-based questionnaire had also been performed in Singapore, where English is the main language of communication of its population on the developed island state.[10] Among the 5.61 million multi-ethnic Asian population in Singapore, 13.4% are of Malay ethnicity.[11] According to the Singapore 2010 Population Census, 37% of the local Malay population had up to "below secondary" education or equivalent of grade 6 educational level. [12] The questions of the original version of HTN SCP were developed to pitch at grade 6 level. [7] Uncertainty arises if over a third of the overall Malay population could understand the English-based questionnaire. Moreover, hypertension is more prevalent among the more senior residents. Based on the same census, only 5.5% of Malays of age 55 years and older, and 4.4% of Malays with "below secondary education" are proficient and use English at home. [12] Hence, approximately one in twenty Malay patients with hypertension would have potential difficulties in using the locally validated HTN SCP instrument.

Singapore is also facing a rapidly aging population and the prevalence of hypertension is expected to rise significantly by the next decade.[13] A Malay version of the HTN-SCP instrument is postulated to ease the assessment of self-efficacy amongst the older Malay patients with hypertension. To ensure that they understand the content and contextualized to the local setting, the translated instrument needs to be tested on stability and reliability amongst the local Malay-literate patients with hypertension. The instrument will allow its application not only in local Malay patients with hypertension, but will also cater to the larger Malay-literate population in Malaysia and other parts of South-East Asia.

METHODS

Aim

The study aimed to determine the test-retest reliability of the Malay version of the HTN-SCP amongst Malay hypertensive patients who are managed in a public primary care clinic in Singapore.

Development of the Malay version of the HTN SCP instrument

The original English-based HTN-SCP instrument has been enhanced in selected items to contextualize to the dietary habits of the local Asian patients with hypertension.[7] The enhanced version was subsequently validated in an earlier study, which showed satisfactory test-retest reliability, as reflected in the internal consistency coefficient (ICC) (0.671, 0.762, and 0.720 for the 3 domains) and Cronbach-alpha indicators (0.857, 0.948, and 0.931 respectively). Next, the investigators engaged a commercial agency, whose two independent professional and certified bi-linguists in English and Malay carried out the forward and backward translation of the instrument content respectively. The draft Malay version of the HTN-SCP was then pilot-tested amongst independent bilingual staff within the institution department of research and nurses at the study site. Minor amendments were carried out to the instrument after this preliminary assessment. The Malay version (HTN-SCP-M) was finalized after approval by the investigator team members, who are also bilingual in English and Malay.

Subjects

The target subjects were patients of Malay ethnicity with essential hypertension based on their diagnosis code in the electronic medical records at the study site. They were either Singaporean citizens or Permanent Residents.

Inclusion criteria

Subjects must be between the age of 41 and 70 years on enrolment. They were treated with blood pressure lowering medication for their essential hypertension for at least 1 year.

Subjects were screened by the investigators and research assistants to be able to read and understand the written language as a minimal standard of Malay proficiency. They had to be internet-savvy in order to access the web-based administration of the instrument.

Exclusion criteria

Subjects who lacked proficiency in the written Malay language and access to internet, were unwilling to execute the test, or were screened to have cognitive, visual or auditory impairment were excluded from the study.

Recruitment of subjects at study site

The study was conducted from May 2016 to Dec 2016 in a typical public primary care clinic located in an estate in north-eastern Singapore serving a population of about 140 000 multi-ethnic Asian population (2015). The investigators and research assistants identified potential subjects by their Malay names or attire and approached them before or after their medical consultation at the study

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2
3 site. The subjects were next screened to confirm their ethnicity and fulfillment of their eligibility
4 criteria. They were provided with information on the study procedure in Malay and their doubts
5 were clarified before obtaining their written informed consent according to stipulations by the
6 institution review board.
7

8 9 Ethics Approval

10
11 Ethics approval was granted from the Centralised Institutional Review Board (CIRB) for this study.
12 Ref no: 2016/2332.
13

14 Administration of the instrument

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16 To ensure anonymity, each subject was given unique study identification number after enrolment,
17 which was used to log in to a free web-based online instrument (Qualtrics) for both the test and
18 retest. They were instructed on the step-by-step procedure to administer the web-based HTN-SCP-M
19 during the test. The web design ensured mandatory filling of the response to each question before
20 the subject was allowed to progress to the next question. This format eliminated any missing data.
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23 After the completion of the test, the subjects were provided with information sheet, instructing
24 them to access the online platform for the retest using their personal electronic devices (smart
25 mobile phone, tablet, laptop or computers) on specified date two weeks later in order to complete
26 the study. The investigators would send reminders via calls, phone messages and electronic mails to
27 defaulters after the stipulated retest dates. Those that failed to complete the retest beyond a one-
28 week grace period were excluded from the reliability analysis. Participation by the subjects were
29 voluntary, with no incentive provided for their study participation.
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32 Sample size calculation

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34 The COSMIN checklist recommended a good sample of between 50 to 99 study subjects for
35 assessing their test-retest reliability.[14] In view of a significant drop-out rate for the retest using a
36 web-based approach from an earlier study by the principal investigator, the target recruitment size
37 was increased to 150 to account for attrition.
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40 Data management and Statistical analysis

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42 The demographics of study participants were reported. Differences between the overall HTN-SCP-M
43 scores and recommended self-management activities were assessed using independent t-test.
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46 Ceiling and floor effects were derived from the percentage of respondents with the highest and
47 lowest scale scores. Ceiling and floor effects were considered present when it is higher than 15%.[15]
48 Internal consistency indicates the extent to which the items in a subscale are correlated, in order to
49 evaluate homogeneity using Cronbach's Alpha statistic.[16] A value of 0.7 was considered acceptable
50 while above 0.8 to 0.9 was considered good to excellent internal consistency.[17]
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53 The agreement between repeated measurements (Test- retest) was evaluated through the use of
54 the intra-class correlation coefficient (ICC). An ICC coefficient of ≥ 0.75 was considered as evidence
55 of measurement stability. ICC between 0.4 and 0.75 indicates fair to good reliability, and $ICC < 0.4$
56 indicates poor reliability.[18] This analysis excluded those who dropped out from the study for the
57 retest 2 weeks after their recruitment.
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A p-value of less than 0.05 was considered as statistically significant. All analyses were performed using the IBM SPSS Statistics for Windows, Version 23.0, IBM Corp, released 2013.

RESULTS

A total of 768 subjects were approached by the investigators and research assistants, of which 204 patients satisfied the eligibility criteria. With 59 refusal of consent, 145 of them were recruited for the test segment of the study, resulting in a response rate of 71%. Subsequently, 63 (43%) of the recruited subjects completed the retest of the HTN-SCP-M on-line. Reasons for drop-out include patients unable to be contacted for reminder, patients refusal to complete even after reminder, and patients' completion of the retest after an extended period beyond two to three weeks.

The demographics of the respondents were presented in Table 1. There were more females (66.9%) than males (33.1), and the majority of them (66.2%) had up to 10 years of education. Among the subjects, 19.3% of them had hypertension only, while the majority had other co-morbidities, such as dyslipidemia (59.5%) and type 2 diabetes mellitus (34.6%).

Table 1: Baseline characteristics of study population

Demographic characteristics	n (%)
Gender	
Male	48 (33.1)
Female	97 (66.9)
Age, Mean (SD)	58 (6.8)
Highest Level of education	
Primary	17 (11.7)
Secondary	96 (66.2)
JC/ Polytechnic/ ITE	23 (15.9)
University	9 (6.2)
Other Comorbidities	
Hypertension only	28 (19.3)
Diabetes	78 (53.8)
Dyslipidemia	95 (65.5)
Heart disease	10 (6.9)
Stroke	4 (2.8)
Others	17 (11.7)
Number of medication, Median (IQR)	1 (1-2)

Table 2 reveals self-care measures reported by the subjects, which are relevant to hypertension management. Majority of them (71.7%) measured their BP at home but only 57.9% documented these measurements regularly. The HTN-SCP-M scores of the subjects who recorded their BP readings were significantly higher than those without BP documentation. The same finding was observed in those who measured their weight regularly.

Table 2. Association between Self-Reported Self-Care Activities and the Overall Mean Scores of the Hypertension Self-Care Profile

	N (%)	Overall Mean HTN-SCP Score (SD)		
		Yes	No	p-value
Do you measure your blood pressure at home	104 (71.7)	189.3 (27.3)	180.0 (24.9)	0.06
Do you record your blood pressure readings regularly	84 (57.9)	190.9 (27.7)	180.8 (24.8)	0.03*
Do you keep a food diary	18 (12.4)	187.8 (37.1)	186.5 (25.3)	0.85
Do you measure your weight regularly	86 (59.3)	190.5 (26.9)	181.1 (26.2)	0.04*
Do you record your weight regularly	39 (26.9)	190.1 (29.6)	185.4 (25.9)	0.35
Do you use any mobile apps to monitor your health or medical condition?	35 (24.1)	192.1 (28.9)	184.9 (26.1)	0.17
Has your doctor ever reduced your HBP medications	43 (29.7)	186.3 (27.5)	186.8 (26.8)	0.93

The HTN-SCP-M scores of those who performed self-care measures, such as home BP measurements, keeping a food diary, documentation of weight and using health-related mobile phone application, were higher than those who without such activities, although these differences did not attain statistical significance (Table 2).

Floor and Ceiling Effect

Table 3: The mean score for the “Self-Efficacy” domain within the HTN-SCP-M was highest, compared to those in the “Behavior” and “Motivation” domains. The “self-efficacy” domain presented a borderline ceiling effect of 15.2% (Table 3). The other two domains show minimal ceiling effect (<15%).

Table 3. Reliability indices of the HTN-SCP-M instrument

Domains	Mean (SD)	Ceiling effect proportion (%)	First assessment score, Median (IQR)	Second assessment score, Median (IQR)	Cronbach's alpha	ICC (95% CI)
Behaviour	50.3 (10.1)	0	55 (48-58)	58 (53-64)	0.851	0.664 (0.500-0.783)
Motivation	65.8 (10.4)	14 (9.7)	67 (60-74)	66 (60-74)	0.928	0.655 (0.487-0.776)
Self-efficacy	66.4 (11.2)	22 (15.2)	67 (61-76)	67 (60-74)	0.945	0.682 (0.524-0.795)

Note: Each domain has 20 items

Internal Consistency

All 3 domains showed excellent internal consistencies: the Cronbach’s alpha for “Behavior” was 0.851, 0.928 for “Motivation” and 0.945 for “Self-efficacy” domains respectively.

Test-Retest Reliability

The Intra-class Correlation Coefficient (ICC) for all domains ranged from 0.655 to 0.682, which suggested fair to good reliability and stability.

DISCUSSION

Overall, the Malay version of the HTN-SCP instrument (HTN-SCP-M) has attained satisfactory test-retest reliability and internal consistency amongst the study population based on the Cronbach’s alpha and ICC indices. Whilst the flooring effect was minimal, the results showed borderline ceiling effect for the self-efficacy domain. It suggests potential limitation to the discriminating power of the instrument amongst those with high scores in the self-efficacy domain. However, this subset of the study population with higher capacity for self-efficacy to control their blood pressure is not the target patients of concern to clinicians. Attention should focus on the group of patients with lower self-efficacy capacity, reflected by the lower HTN-SCP-M scores, who are at risks of poor blood pressure control.

The next step will be to test the application of the HTN-SCP-M on the local Malay-literate patients with hypertension to determine the correlation between its scores and self-care activities. The total aggregated score in this study was significantly associated with patients’ self-reporting of their documentation of their home blood pressure monitoring and weight measurement. For other self

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3 care measures such as keeping a food diary, the positive correlation between the total scores and
4 reported self-care measures was not statistically significant.
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7 Nonetheless, the sample size of the study population was not computed to determine the
8 differences in self-care measures based on the instrument score. Further adequately powered study
9 with larger number of subjects and incorporating reliable and objective assessment of self-care
10 measures is needed to assess if the instrument can be used to stratify Malay-literate patients into
11 varying capacities for health behavior, motivation and self-efficacy.
12

13 The study has its strength and limitations. The use of a web-based approach in implementing the
14 test-retest reliability evaluation enabled the patients to self-administer the instrument remotely
15 using their smart-phone, tablets, computer and laptop at their preferred timing and venue. Despite
16 the convenience of this method, the uptake of the retest segment was suboptimal amidst reminders
17 by the investigators. In retrospect, the uptake could be ameliorated with incentives and nominal
18 reimbursement for the effort and time by the participants, even though the cost in carrying out the
19 on-line retest was minimal.
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21

22 **Conclusion**

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24 The Malay version of the HTN-SCP has satisfactory test-retest reliability and internal consistency. The
25 total scores of the Malay-based instrument have shown potential association with patients' self-
26 reporting of their self-care behavior, which require further research for its validation.
27
28

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36
37

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41 profit sectors.
42
43

44 **Competing interest**

45
46 The authors have read and understood BMJ policy on declaration of interests and declare that they
47 have no competing interests.
48

49 **Authors' contributions**

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51 NCT designed the study protocol. DBMY and KCS were involved in the recruitment and
52 administration of the questionnaire. YLEK was involved in data analysis. NCT drafted the manuscript
53 while all authors reviewed and improved the final manuscript before submission.
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56 **Data sharing statement**

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58 Anonymous data will be shared upon request if researchers/reviewers are interested.
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References

1. Global Health Observatory Data, Raised Blood Pressure - Situation and trends. WHO website. http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/. Updated 2008. Accessed January 1, 2017.
2. Q&As on hypertension. World Health Organization (WHO) website. <http://www.who.int/features/qa/82/en/>. Updated September 2015. Accessed January 1, 2017.
3. Hypertension in adults: Diagnosis and Management, Clinical guideline (CG127). National Institute for Health and Care Excellence (NICE) website. <https://www.nice.org.uk/guidance/cg127>. Updated 2016. Accessed January 26, 2017.
4. Eckel RH, Jakicic JM, Ard JD, et al. AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association task force on practice guidelines. *Circulation*. 2014;129:S76-99doi:10.1161/01.cir.0000437740.48606.d1.
5. Warren-Findlow J, Seymour RB, Brunner Huber LR. The Association Between Self-Efficacy and Hypertension Self-Care Activities Among African American Adults. *Journal of Community Health*. 2012;37(1):15-24. doi:10.1007/s10900-011-9410-6.
6. Lee JE, Han HR, Song H et al. Correlates of self-care behaviors for managing hypertension among Korean Americans: a questionnaire survey. *Int J Nurs Stud*. 2010;47(4):411-7doi: 10.1016/j.ijnurstu.2009.09.011.
7. Han HR, Lee H, Commodore-Mensah Y et al. Development and validation of the Hypertension Self-care Profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs*. 2014;29:E11-20doi: 10.1097/JCN.0b013e3182a3fd46.
8. Orem DE. *Concepts of Practice*. 3rd ed. New York, NY: McGraw-Hill; 1985.
9. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People to Change Addictive Behaviour*. New York, NY: Guilford Press; 1991.
10. Koh YL et al. Using a Web-Based Approach to Assess Test-Retest Reliability of the "Hypertension Self-Care Profile" Tool in an Asian Population: A Validation Study. *Medicine(Baltimore)*. 2016;95(9):e2955doi: 10.1097/MD.00000000002955.
11. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. *Population Trends 2016*. 2016. ISSN 1793-2424: 3-5
12. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. *Census of Population 2010 Statistical Release 1, Demographic Characteristics, Education, Language and Religion*. 2011. ISBN 978-981-08-7808-5. Table 39.
13. Malhotra R, Chan A, Malhotra C et al. Prevalence, awareness, treatment and control of hypertension in the elderly population of Singapore. *Hypertension Research*. 2010;33:1223-1231doi: :10.1038/hr.2010.177

- 1
2
3 14. Terwee CB, Mokkink LB, Knol DL et al. Rating the methodological quality in systematic reviews of
4 studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res.*
5 2012;21:651-7doi: 10.1007/s11136-011-9960-1
6
7
8 15. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement
9 properties of health status questionnaires. *J Clin Epidemiol.* 2007;60:34-
10 42doi:10.1016/j.jclinepi.2006.03.012
11
12 16. Andresen EM. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med*
13 *Rehabil.* 2000;81:S15–S20doi:10.1053/apmr.2000.20619
14
15 17. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika.* 1951;16:297-
16 334doi:10.1007/BF02310555.
17
18 18. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized
19 assessment instruments in psychology. *Psychological Assessment.* 1994;6:284-290doi:
20 10.1037/1040-3590.6.4.284
21
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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	-
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	5
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	6

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	6
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6-7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

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TITLE PAGE

Title: What is the test-retest reliability of the Malay version of the Hypertension Self Care Profile Self Efficacy Assessment tool? A validation study in primary care

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ABSTRACT

Objectives

Self-efficacy and self-care measures are key attributes to optimal control of essential hypertension. Self-efficacy can be measured by the Hypertension-Self-Care Profile (HTN-SCP) tool but its utility is dependent on the literacy and understanding of the subjects. A Malay version of the HTN-SCP Tool was developed to assess self-efficacy of Malay-literate patients with hypertension in the multi-ethnic Asian population in Singapore. The study aimed to determine the test-retest reliability of this tool which has been translated in Malay language.

Methods and Material

145 Malay-literate patients, aged 41-70 years, with essential hypertension were recruited in a polyclinic (primary care clinic) in Singapore. Forty-three percent of them completed both the first and second HTN SCP tool online, with a period of two weeks in between. The Cronbach's alpha and Intra-class correlation coefficient (ICC) were computed to assess its test-retest reliability and internal consistency.

Results

The Cronbach's alpha/ICC for "Behavior" (0.851/0.664), "Motivation" (0.928/0.655) and "Self-efficacy" (0.945/0.682) domains showed high internal consistency, fair to good reliability and stability. No floor or ceiling effect was found for the "behavior" and "motivation" domains. However, the borderline ceiling effect (15.2) for "self-efficacy" suggested that limited discriminating power of the tool for patients with high self-efficacy. Positive association was shown between HTN-SCP score and reported self-care measures but it was not statistically significant.

Conclusion

Overall, the translated HTN-SCP tool showed satisfactory test-retest reliability and internal consistency amongst the Malay-literate study population. Further research is needed for its application in general practice to identify patients with low self-efficacy for possible intervention.

Strengths and limitations of the study

This study used a web-based method in administrating the test, showing its potential application in clinical practice.

Without incentive, the web-based method resulted in significant dropouts in the re-test segment of the study.

Reliability assessment of the "self-efficacy", "behavior" and "motivation" domains may be limited by ceiling and floor effects.

The study excluded subjects who were not internet-savvy and those who were not proficient in written Malay language.

INTRODUCTION

Hypertension is often the most prevalent risk factor for vascular diseases in developed and developing countries.[1] Maintaining optimal blood pressure amongst patients with hypertension is key to avert vascular complications such as stroke and cardiac diseases.[2] However, achieving stable blood pressure (BP) control requires these patients to undertake multiple measures consistently, such as salt and fat restriction in diet, regular physical exercises, consumption of alcohol, self-monitoring of BP and weight and adherence to prescribed BP lowering medications.[3][4]

The capacity to conduct these self-care activities is related to an individual's self-efficacy.[5][6] Thus assessing self-efficacy of patients with hypertension provides the healthcare provider an insight into their vascular risk status, and decision support in designing individualized care plan. Questionnaire-based tools have been developed to facilitate the multi-faceted assessment of self-efficacy. One example is the English-based Hypertension-Self-Care Profile (HTN-SCP) questionnaire developed by Han HR et al, which covers three key domains of behavior, motivation and self-efficacy.[7] Her team had used two validated theoretical approaches, Orem's self-care model [8] and Motivational Interviewing (MI) [9] to develop the questionnaire. The Orem's model depicts the enablement of individuals to embark on deliberate actions such as taking medication and physical activity as indicators of self-care.[8] Using similar constructs such as those from the Social Cognitive Theory and Health Belief Model, MI indicates a commitment to change (i.e. motivation) and reflects the development of confidence for behavior change.[9] Self-efficacy predicts medication adherence, physical activity, diet and weight control.[7] Han HR et al reported high reliability estimates and strong evidence of validity of the HBP SCP when the study was carried out in an inner city American population. Their results suggest that the questionnaire can be used to assess and identify gaps in self-care behaviour, motivation, and self-efficacy in patients with hypertension.

The test-retest reliability assessment of this English-based questionnaire had also been performed in Singapore, where English is the main language of communication of its population on the developed island state.[10] Among the 5.61 million multi-ethnic Asian population in Singapore, 13.4% are of Malay ethnicity.[11] According to the Singapore 2010 Population Census, 37% of the local Malay population had up to "below secondary" education or equivalent of grade 6 educational level. [12] The questions of the original version of HTN SCP were developed to pitch at grade 6 level. [7] Uncertainty arises if over a third of the overall Malay population could understand the English-based questionnaire. Moreover, hypertension is more prevalent among the more senior residents. Based on the same census, only 5.5% of Malays of age 55 years and older, and 4.4% of Malays with "below secondary education" are proficient and use English at home. [12] Hence, approximately one in twenty Malay patients with hypertension would have potential difficulties in using the locally validated HTN SCP tool.

Singapore is also facing a rapidly aging population and the prevalence of hypertension is expected to rise significantly by the next decade.[13] A Malay version of the HTN-SCP tool is postulated to ease the assessment of self-efficacy amongst the older Malay patients with hypertension. To ensure that they understand the content and contextualized to the local setting, the translated tool needs to be tested on stability and reliability amongst the local Malay-literate patients with hypertension. The tool will allow its application not only in local Malay patients with hypertension, but will also cater to the larger Malay-literate population in Malaysia and other parts of South-East Asia.

METHODS

Aim

The study aimed to determine the test-retest reliability of the Malay version of the HTN-SCP amongst Malay hypertensive patients who are managed in a public primary care clinic in Singapore.

Development of the Malay version of the HTN SCP tool

The original English-based HTN-SCP tool has been enhanced in selected items to contextualize to the dietary habits of the local Asian patients with hypertension.[7] The enhanced version was subsequently validated in an earlier study, which showed satisfactory test-retest reliability, as reflected in the internal consistency coefficient (ICC) (0.671, 0.762, and 0.720 for the 3 domains) and Cronbach-alpha indicators (0.857, 0.948, and 0.931 respectively). Next, the investigators engaged a commercial agency, whose two independent professional and certified bi-linguists in English and Malay carried out the forward and backward translation of the content respectively. The draft Malay version of the HTN-SCP was then pilot-tested amongst independent bilingual staff within the institution department of research and nurses at the study site. Minor amendments were carried out to the tool after this preliminary assessment. The Malay version (HTN-SCP-M) was finalized after approval by the investigator team members, who are also bilingual in English and Malay.

Subjects

The target subjects were patients of Malay ethnicity with essential hypertension based on their diagnosis code in the electronic medical records at the study site. They were either Singaporean citizens or Permanent Residents.

Inclusion criteria

Subjects must be between the age of 41 and 70 years on enrolment. They were treated with blood pressure lowering medication for their essential hypertension for at least 1 year.

Subjects were screened by the investigators and research assistants to be able to read and understand the written language as a minimal standard of Malay proficiency. They had to be internet-savvy in order to access the web-based administration of the tool.

Exclusion criteria

Subjects who lacked proficiency in the written Malay language and access to internet, were unwilling to execute the test, or were screened to have cognitive, visual or auditory impairment were excluded from the study.

Recruitment of subjects at study site

The study was conducted from May 2016 to Dec 2016 in a typical public primary care clinic located in an estate in north-eastern Singapore serving a population of about 140 000 multi-ethnic Asian population (2015). The investigators and research assistants identified potential subjects by their Malay names or attire and approached them before or after their medical consultation at the study

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2
3 site. The subjects were next screened to confirm their ethnicity and fulfillment of their eligibility
4 criteria. They were provided with information on the study procedure in Malay and their doubts
5 were clarified before obtaining their written informed consent according to stipulations by the
6 institution review board.
7

8 9 **Ethics Approval**

10
11 Ethics approval was granted from the Centralised Institutional Review Board (CIRB) for this study.
12 Ref no: 2016/2332.
13

14 15 **Administration of the tool**

16 To ensure anonymity, each subject was given unique study identification number after enrolment,
17 which was used to log in to a free web-based online tool (Qualtrics) for both the test and retest.
18 They were instructed on the step-by-step procedure to administer the web-based HTN-SCP-M during
19 the test. The web design ensured mandatory filling of the response to each question before the
20 subject was allowed to progress to the next question. This format eliminated any missing data.
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23 After the completion of the test, the subjects were provided with information sheet, instructing
24 them to access the online platform for the retest using their personal electronic devices (smart
25 mobile phone, tablet, laptop or computers) on specified date two weeks later in order to complete
26 the study. The investigators would send reminders via calls, phone messages and electronic mails to
27 defaulters after the stipulated retest dates. Those that failed to complete the retest beyond a one-
28 week grace period were excluded from the reliability analysis. Participation by the subjects were
29 voluntary, with no incentive provided for their study participation.
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32 33 **Sample size calculation**

34 The COSMIN checklist recommended a good sample of between 50 to 99 study subjects for
35 assessing their test-retest reliability.[14] In view of a significant drop-out rate for the retest using a
36 web-based approach from an earlier study by the principal investigator, the target recruitment size
37 was increased to 150 to account for attrition.
38
39

40 41 **Data management and Statistical analysis**

42 The demographics of study participants were reported. Differences between the overall HTN-SCP-M
43 scores and recommended self-management activities were assessed using independent t-test.
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46 Ceiling and floor effects were derived from the percentage of respondents with the highest and
47 lowest scale scores. Ceiling and floor effects were considered present when it is higher than 15%.[15]
48 Internal consistency indicates the extent to which the items in a subscale are correlated, in order to
49 evaluate homogeneity using Cronbach's Alpha statistic.[16] A value of 0.7 was considered acceptable
50 while above 0.8 to 0.9 was considered good to excellent internal consistency.[17]
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53 The agreement between repeated measurements (Test- retest) was evaluated through the use of
54 the intra-class correlation coefficient (ICC). An ICC coefficient of ≥ 0.75 was considered as evidence
55 of measurement stability. ICC between 0.4 and 0.75 indicates fair to good reliability, and $ICC < 0.4$
56 indicates poor reliability.[18] This analysis excluded those who dropped out from the study for the
57 retest 2 weeks after their recruitment.
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A p-value of less than 0.05 was considered as statistically significant. All analyses were performed using the IBM SPSS Statistics for Windows, Version 23.0, IBM Corp, released 2013.

RESULTS

A total of 768 subjects were approached by the investigators and research assistants, of which 204 patients satisfied the eligibility criteria. With 59 refusal of consent, 145 of them were recruited for the test segment of the study, resulting in a response rate of 71%. Subsequently, 63 (43%) of the recruited subjects completed the retest of the HTN-SCP-M on-line. Reasons for drop-out include patients unable to be contacted for reminder, patients refusal to complete even after reminder, and patients' completion of the retest after an extended period beyond two to three weeks.

The demographics of the respondents were presented in Table 1. There were more females (66.9%) than males (33.1), and the majority of them (66.2%) had up to 10 years of education. Among the subjects, 19.3% of them had hypertension only, while the majority had other co-morbidities, such as dyslipidemia (59.5%) and type 2 diabetes mellitus (34.6%).

Table 1: Baseline characteristics of study population

Demographic characteristics	n (%)
Gender	
Male	48 (33.1)
Female	97 (66.9)
Age, Mean (SD)	58 (6.8)
Highest Level of education	
Primary	17 (11.7)
Secondary	96 (66.2)
JC/ Polytechnic/ ITE	23 (15.9)
University	9 (6.2)
Other Comorbidities	
Hypertension only	28 (19.3)
Diabetes	78 (53.8)
Dyslipidemia	95 (65.5)
Heart disease	10 (6.9)
Stroke	4 (2.8)
Others	17 (11.7)
Number of medication, Median (IQR)	1 (1-2)

Table 2 reveals self-care measures reported by the subjects, which are relevant to hypertension management. Majority of them (71.7%) measured their BP at home but only 57.9% documented these measurements regularly. The HTN-SCP-M scores of the subjects who recorded their BP readings were significantly higher than those without BP documentation. The same finding was observed in those who measured their weight regularly.

Table 2: Association between Self-Reported Self-Care Activities and the Overall Mean Scores of the Hypertension Self-Care Profile

	N (%)	Overall Mean HTN-SCP Score (SD)		p-value
		Yes	No	
Do you measure your blood pressure at home	104 (71.7)	189.3 (27.3)	180.0 (24.9)	0.06
Do you record your blood pressure readings regularly	84 (57.9)	190.9 (27.7)	180.8 (24.8)	0.03*
Do you keep a food diary	18 (12.4)	187.8 (37.1)	186.5 (25.3)	0.85
Do you measure your weight regularly	86 (59.3)	190.5 (26.9)	181.1 (26.2)	0.04*
Do you record your weight regularly	39 (26.9)	190.1 (29.6)	185.4 (25.9)	0.35
Do you use any mobile apps to monitor your health or medical condition?	35 (24.1)	192.1 (28.9)	184.9 (26.1)	0.17
Has your doctor ever reduced your HBP medications	43 (29.7)	186.3 (27.5)	186.8 (26.8)	0.93

The HTN-SCP-M scores of those who performed self-care measures, such as home BP measurements, keeping a food diary, documentation of weight and using health-related mobile phone application, were higher than those who without such activities, although these differences did not attain statistical significance (Table 2).

Floor and Ceiling Effect

Table 3: The mean score for the “Self-Efficacy” domain within the HTN-SCP-M was highest, compared to those in the “Behavior” and “Motivation” domains. The “self-efficacy” domain presented a borderline ceiling effect of 15.2% (Table 3). The other two domains show minimal ceiling effect (<15%).

Table 3. Reliability indices of the HTN-SCP-M tool

Domains	Mean (SD)	Ceiling effect proportion (%)	First assessment score, Median (IQR)	Second assessment score, Median (IQR)	Cronbach's alpha	ICC (95% CI)
Behaviour	50.3 (10.1)	0	55 (48-58)	58 (53-64)	0.851	0.664 (0.500-0.783)
Motivation	65.8 (10.4)	14 (9.7)	67 (60-74)	66 (60-74)	0.928	0.655 (0.487-0.776)
Self-efficacy	66.4 (11.2)	22 (15.2)	67 (61-76)	67 (60-74)	0.945	0.682 (0.524-0.795)

Note: Each domain has 20 items

Internal Consistency

All 3 domains showed excellent internal consistencies: the Cronbach's alpha for “Behavior” was 0.851, 0.928 for “Motivation” and 0.945 for “Self-efficacy” domains respectively.

Test-Retest Reliability

The Intra-class Correlation Coefficient (ICC) for all domains ranged from 0.655 to 0.682, which suggested fair to good reliability and stability.

DISCUSSION

The study demonstrated efforts to validate a tool in a specific Asian language, which has been originally developed in English in North America.[7] It followed a successful test-retest reliability assessment of the HTN-SCP tool in English, which is contextualized to the multi-ethnic Asian community in primary care setting in Singapore.[10] The over-arching aim is to expand the scope of the tool to appraise the self-efficacy of patients with hypertension in diverse populations. In spite of incorporating innovative approach in this study riding on the rapidly and extensively internet-connected community, the validation framework is aligned to the STROBE guidelines.[19]

Overall, the Malay version of the HTN-SCP tool (HTN-SCP-M) has attained satisfactory test-retest reliability and internal consistency amongst the study population based on the Cronbach's alpha and ICC indices. Whilst the flooring effect was minimal, the results showed borderline ceiling effect for the self-efficacy domain. It suggests potential limitation to the discriminating power of the tool amongst those with high scores in the self-efficacy domain. However, this subset of the study population with higher capacity for self-efficacy to control their blood pressure is not the target patients of concern to clinicians. Attention should focus on the group of patients with lower self-efficacy capacity, reflected by the lower HTN-SCP-M scores, who are at risks of poor blood pressure control.

The next step will be to test the application of the HTN-SCP-M on the local Malay-literate patients with hypertension to determine the correlation between its scores and self-care activities. The total aggregated score in this study was significantly associated with patients' self-reporting of their documentation of their home blood pressure monitoring and weight measurement. For other self-care measures such as keeping a food diary, the positive correlation between the total scores and reported self-care measures was not statistically significant.

Nonetheless, the sample size of the study population was not computed to determine the differences in self-care measures based on the score. Further adequately powered study with larger number of subjects and incorporating reliable and objective assessment of self-care measures is needed to assess if the tool can be used to stratify Malay-literate patients into varying capacities for health behavior, motivation and self-efficacy.

The study has its strength and limitations. It excluded patients who lacked access or were not competent internet users. The use of a web-based approach in implementing the test-retest reliability evaluation enabled the patients to self-administer the tool remotely using their smart-phone, tablets, computer and laptop at their preferred timing and venue. Despite the convenience of this method, the uptake of the retest segment was suboptimal, even with the use of reminders by the investigators. In retrospect, the uptake could potentially be improved with incentives and nominal reimbursement for the effort and time by the participants, even though the cost in carrying out the on-line retest was minimal. Nevertheless, the demographic profiles, in terms of gender,

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3 ethnic group, age and number of medications, of those who dropped out of the study were similar
4 to those who completed the study.
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6 The study also excluded patients with poor literacy of written Malay language, and those with
7 cognitive, auditory and visual impairment. Future research will target expanded application of the
8 tool to bridge these gaps, leveraging on voice-annotated administration based on info-
9 communication technology and related tool to capture observations of self-efficacy by caregivers
10 and proxies.
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13 The study shows viable web-based administration of self-efficacy assessment, and indicates its
14 potential application in routine clinical practice using this approach. However, the significant
15 dropouts in the subsequent re-test highlight the challenge in serial measurements if the intention is
16 to chart improvement in self-efficacy after interventions. Either spacing out the intervals between
17 repeat administrations of the HTN SCP or the use of a shorter, user-friendly version of the tool can
18 be possible solutions.
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21 The findings in this study can potentially be extrapolated to the larger ethnically similar Malay
22 population in the neighboring countries. This Malay version of the tool can be utilized to evaluate
23 the self-efficacy of Malay patients with hypertension in the community, including those who are
24 managed by the public polyclinics in Malaysia (Kesehatan Klinik).
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29 **Conclusion**

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31 The Malay version of the HTN-SCP has satisfactory test-retest reliability and internal consistency. The
32 total scores of the Malay-based tool have shown potential association with patients' self-reporting
33 of their self-care behavior, which require further research for its validation.
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35

36 **Acknowledgement**

37
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42 role in recruiting participants and administrating the survey.
43
44

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48 profit sectors.
49

50 **Competing interest**

51
52 The authors have read and understood BMJ policy on declaration of interests and declare that they
53 have no competing interests.
54

55 **Authors' contributions**

1
2
3 NCT designed the study protocol. DBMY and KCS were involved in the recruitment and
4 administration of the questionnaire. YLEK was involved in data analysis. NCT drafted the manuscript
5 while all authors reviewed and improved the final manuscript before submission.
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7 **Data sharing statement**

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9 Anonymous data will be shared upon request if researchers/reviewers are interested.
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11 **References**

- 12
13
14 1. Global Health Observatory Data, Raised Blood Pressure - Situation and trends. WHO website.
15 http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/. Updated 2008.
16 Accessed January 1, 2017.
17
18 2. Q&As on hypertension. World Health Organization (WHO) website.
19 <http://www.who.int/features/qa/82/en/>. Updated September 2015. Accessed January 1, 2017.
20
21 3. Hypertension in adults: Diagnosis and Management, Clinical guideline (CG127). National Institute
22 for Health and Care Excellence (NICE) website. <https://www.nice.org.uk/guidance/cg127>. Updated
23 2016. Accessed January 26, 2017.
24
25 4. Eckel RH, Jakicic JM, Ard JD, et al. AHA/ACC guideline on lifestyle management to reduce
26 cardiovascular risk: a report of the American College of Cardiology/American Heart Association task
27 force on practice guidelines. *Circulation*. 2014;129:S76-99doi:10.1161/01.cir.0000437740.48606.d1.
28
29 5. Warren-Findlow J, Seymour RB, Brunner Huber LR. The Association Between Self-Efficacy and
30 Hypertension Self-Care Activities Among African American Adults. *Journal of Community Health*.
31 2012;37(1):15-24. doi:10.1007/s10900-011-9410-6.
32
33 6. Lee JE, Han HR, Song H et al. Correlates of self-care behaviors for managing hypertension among
34 Korean Americans: a questionnaire survey. *Int J Nurs Stud*. 2010;47(4):411-7doi:
35 10.1016/j.ijnurstu.2009.09.011.
36
37 7. Han HR, Lee H, Commodore-Mensah Y et al. Development and validation of the Hypertension Self-
38 care Profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs*. 2014;29:E11-20doi:
39 10.1097/JCN.0b013e3182a3fd46.
40
41 8. Orem DE. Concepts of Practice. 3rd ed. New York, NY: McGraw-Hill; 1985.
42
43 9. Miller WR, Rollnick S. Motivational Interviewing: Preparing People to Change Addictive Behaviour.
44 New York, NY: Guilford Press; 1991.
45
46 10. Koh YL et al. Using a Web-Based Approach to Assess Test-Retest Reliability of the "Hypertension
47 Self-Care Profile" Tool in an Asian Population: A Validation Study. *Medicine(Baltimore)*.
48 2016;95(9):e2955doi: 10.1097/MD.00000000002955.
49
50 11. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. Population Trends
51 2016. 2016. ISSN 1793-2424: 3-5
52
53
54
55
56
57
58
59
60

- 1
2
3 12. Department of Statistics, Ministry of Trade & Industry, Republic of Singapore. Census of
4 Population 2010 Statistical Release 1, Demographic Characteristics, Education, Language and
5 Religion. 2011. ISBN 978-981-08-7808-5. Table 39.
6
7
8 13. Malhotra R, Chan A, Malhotra C et al. Prevalence, awareness, treatment and control of
9 hypertension in the elderly population of Singapore. *Hypertension Research*. 2010;33:1223-
10 1231doi: :10.1038/hr.2010.177
11
12 14. Terwee CB, Mokkink LB, Knol DL et al. Rating the methodological quality in systematic reviews of
13 studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res*.
14 2012;21:651-7doi: 10.1007/s11136-011-9960-1
15
16 15. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement
17 properties of health status questionnaires. *J Clin Epidemiol*. 2007;60:34-
18 42doi:10.1016/j.jclinepi.2006.03.012
19
20 16. Andresen EM. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med*
21 *Rehabil*. 2000;81:S15-S20doi:10.1053/apmr.2000.20619
22
23 17. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika*. 1951;16:297-
24 334doi:10.1007/BF02310555.
25
26 18. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized
27 assessment instruments in psychology. *Psychological Assessment*. 1994;6:284-290doi:
28 10.1037/1040-3590.6.4.284
29
30 19. STROBE Statement: Available checklists. [https://strobe-statement.org/index.php?id=available-](https://strobe-statement.org/index.php?id=available-checklists)
31 [checklists](https://strobe-statement.org/index.php?id=available-checklists) (accessed 29 May 2017).
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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	-
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	5
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	6

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	6
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6-7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	9

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.