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APPENDIX A

Information Sheet and Consent for Research Participants (English Version)

Study Participant Information Sheet

Study Introduction and Objectives

I, Suzilawati Mohamed Ariffin, Student ID 561235811, Research ID (Malaysian): NMRR-14-1615-23580, is a master student at the Faculty of Nursing, Chiang Mai University, Thailand and conducting a study entitled “Intensive Care Experience among Intensive Care Unit Survivors”. This study will fulfill my thesis study requirement for my degree. This study has the following objectives:

1. To explore the intensive care experience among ICU survivors.

You are being invited to take part in this study because you have qualities and characteristics needed for this study. Please read this information sheet carefully to make sure that you understand this study and what you will be asked to do. If you have any questions regarding this study or if you wish to consult with someone regarding this study, you are most welcome to do so. Once you understand this study and agree to take part, you will be asked to sign this form or make your mark in front of study staff and if necessary an impartial witness. We will offer you a copy of this form to keep.

Study Purpose

This study is being conducted to gather the information about intensive care experience among intensive care unit (ICU) survivors who have received treatment in ICU. The information from this study may be used to help health care providers in term of creating care plan and applying good care to the patient during their stay in ICU.

Study Participants

This study is for women and men aged 18 to 64. There will be a total of 142 participants in this study. We plan to enroll participants from three government hospitals in Malaysia, which are 32 participants from Hospital Tengku Ampuan Afzan,

47 participants from Hospital Raja Permaisuri Bainun, and 63 participants from Hospital Taiping.

Study Procedures

If you are agree to take part in this study and if you are found to be eligible for the study, then you may begin today. Some people may not be able to join the study because they do not meet all of the requirements. However, you might be terminated from joining this project when you met some circumstances: your health condition deteriorating, too many questions are left behind, no name or signature or I/C number on the consent form.

Subject's responsibilities

All participants will be asked to complete 2 set of questionnaires. Participants will be given up until one whole day to complete the questionnaires if they want too. Although we hope that you will be comfortable answering all of the questions openly and honestly, please remember that you may refuse to answer any of the questions, or stop taking part in the study completely, at any time. You may also request a break during any of the activities. After completing the sets of questionnaire, you may return it back personally to the person whom taking the consent.

How long must I take part in the study?

You will be asked to take part in one interview only. Two set of questionnaires (ICEQ and additional questions) will be given to you and you are given up to one day to complete it and return it back to corresponded person. All the questionnaires are self administered by the participants. However, you may ask the researcher or research assistant if you have any inquiry about the questions.

Risks and/or Discomforts

During the interview, we will collect information about your health. The risk to you in taking part in this interview is that some of the questions may be uncomfortable to answer. If any of the questions make you upset, you may go to another question or totally stop answering the questions. You do not have to answer any question that makes you uncomfortable. However, to reduce the discomfort feeling during answering

the questions, participants will be given one whole day to complete and think of the answer. We will make every effort to protect your privacy and confidentiality while you are in the study.

Study Benefits

This study is part of a thesis study requirement for my degree. There may be no direct benefit to you from this study. However, the knowledge gained from this study may be helpful in providing basic information about other people who are experiencing same situation as you.

Protecting Data Confidentiality

Your medical record and study data will be access by the researcher or research assistant. Your data will be sealed in the envelope and will be stored in the office of Kulliyah of Nursing, International Islamic University Malaysia by the researcher after analyze the data from all the participants. It will be kept up to five years and will be destroyed by the researcher after reach the limit time. Any publication of this study will not use your name or identify you personally. However, your records may be reviewed by the Chiang Mai University Faculty of Nursing Research Ethics Committee, and study staff. Your personal information may also be disclosed if required by law.

Costs of Taking Part in the Study

There is no cost to you for taking part in this study.

Payment

You will not receive payment for taking part in this study. However, you will receive a small token from the researcher as a thankful gift for participating with this study.

Participant Rights

Taking part in this study is complete up to you. You have the right to take part in the study if you choose to, or to refuse to take part at all. If you agree to take part in the study, you have the right to withdraw from the study at any time. If you decide to leave the study, your rights to medical or other services will not be affected.

You have the legal right to access your personal information collected by the study. If you wish to access this information, please let me know and you will be provided the information according to the rules and regulations set by Chiang Mai University.

Who Do You Call if You Have Questions or Problems?

For questions about this study or research related injury, you can contact:

Suzilawati Mohamed Ariffin, Principal Investigator

Chiang Mai University Faculty of Nursing

110 Intavaroros Road, Chiang Mai 50200

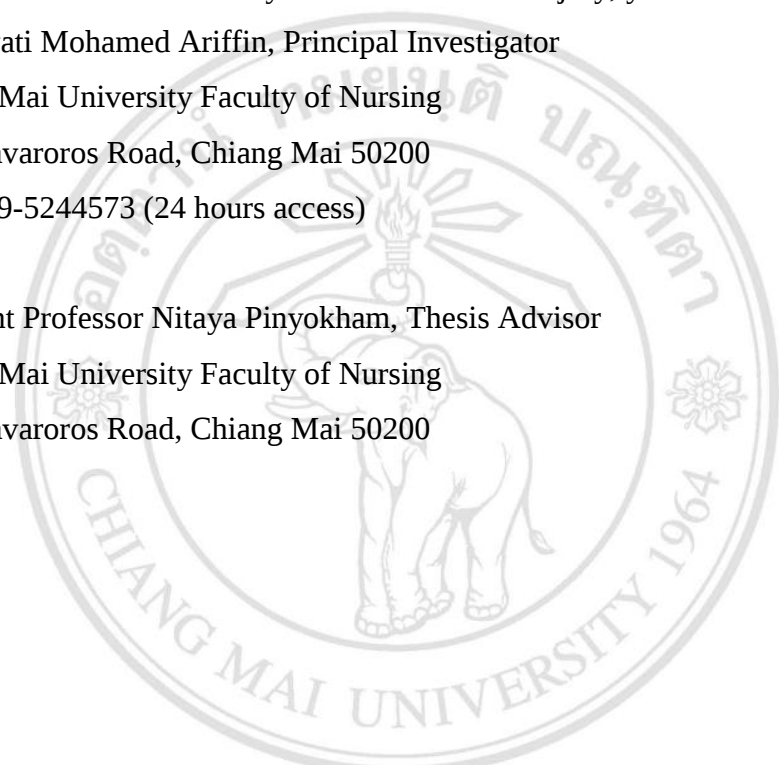
Tel: 019-5244573 (24 hours access)

Or

Assistant Professor Nitaya Pinyokham, Thesis Advisor

Chiang Mai University Faculty of Nursing

110 Intavaroros Road, Chiang Mai 50200

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Patient Consent Form

Title of project: Intensive Care Experience among ICU Survivors

Name of investigator: Suzilawati Binti Mohamed Ariffin

I have been asked taking part in the Intensive Care Experience. I have read the informed consent document for this survey. I have received an explanation of the nature, purpose and duration of this survey.

I, _____ (name of participant) hereby consent to participate in this survey.

I understand that:

- a. my participation is voluntary. I can stop participating in this survey at any time and I am free to not answer any particular question(s).
- b. while information gained in this study may be used in a conference presentation, and may also be published in a journal article, I will not be identified. Information concerning me will remain strictly confidential.
- c. I may not directly benefit from taking part in this survey.
- d. I can ask the researcher, at any time for any additional information.

Name of person taking cosent:

Participant's name:

Role:

I/C no:

Date:

Signature:

I/C no:

Date:

Signature:

Appendix B

Information Sheet and Consent for Research Participants (Malay Version)

Lampiran Informasi Pesakit

Pengenalan dan Objektif

Saya, Suzilawati Mohamed Ariffin, nombor pelajar 561235811, nombor kajian (Malaysia): NMRR-14-1615-23580, merupakan pelajar sarjana di Faculty of Nursing, Chiang Mai University, Thailand dan sedang melaksanakan kajian bertajuk “Intensive Care Experience among Intensive Care Unit Survivors”. Kajian ini adalah kursus wajib bagi saya untuk memenuhi kriteria graduasi. Kajian ini mempunyai objektif seperti berikut:

1. Untuk mengetahui/mendalami pengalaman semasa menerima rawatan rapi dalam kalangan pesakit di unit rawatan rapi.

Anda dijemput untuk turut serta dalam kajian ini kerana mempunyai kualiti dan karakter yang amat diperlukan untuk kajian ini. Sila baca lampiran informasi ini dengan teliti bagi memastikan anda memahami kajian ini dan mengetahui apa yang perlu anda lakukan sekiranya diminta berbuat sedemikian. Sekiranya ada sebarang pertanyaan berkenaan kajian ini atau anda memerlukan seseorang untuk memberi penerangan, anda dipersilakan untuk berbuat demikian. Selepas anda memahami dan bersetuju untuk turut serta, anda akan diminta untuk menandatangani lampiran ini atau membuat sebarang tanda dihadapan petugas kajian. Pihak kami akan memberikan salinan lampiran sekiranya anda mahu.

Tujuan Kajian

Kajian ini bertujuan untuk mengumpul maklumat berkaitan dengan pengalaman pesakit semasa menerima rawatan di Unit Rawatan Rapi (ICU). Informasi dari kajian ini boleh digunakan untuk membantu petugas rawatan kesihatan dalam membentuk plan

rawatan dan memberikan servis rawatan terbaik untuk pesakit yang menerima rawatan di ICU.

Peserta Kajian

Kajian ini mensasarkan wanita dan lelaki berumur di antara 18 hingga 64 tahun. Jumlah peserta kajian yang diperlukan adalah seramai 142 orang. Kami menyasarkan 3 hospital untuk mencapai jumlah sasaran ini dimana setiap hospital memerlukan sejumlah peserta yang ditentukan berdasarkan pecahan jumlah kemasukan pesakit ke ICU menjadikan setiap hospital memerlukan, 32 orang dari Hospital Tengku Ampuan Afzan, 47 orang dari Hospital Raja Permaisuri Bainun, dan 63 orang dari Hospital Taiping.

Prosedur Kajian

Sekiranya anda bersetuju untuk turut serta di dalam kajian ini dan didapati anda memenuhi kriteria kajian, maka anda boleh memulakan prosedur ini sekarang. Sesetengah pesakit mungkin tidak dapat untuk turut serta disebabkan mereka tidak memenuhi kriteria yang diperlukan. Tetapi, anda juga akan ditolak dari menyertai kajian ini sekiranya didapati: kesihatan anda semakin merudum, anda tidak menjawab terlalu banyak soalan yang ditanyakan, anda tidak meletakkan nama mahupun menandatangani surat kebenaran untuk menyertai kajian ini.

Tanggungjawab Peserta

Kesemua peserta diminta untuk menjawab 2 set soalan. Peserta diberi masa sehingga satu hari untuk menjawab soalan sekiranya perlu. Walaubagaimanapun, kami amat mengharapkan anda selesa menjawab semua soalan dengan hati yang terbuka, dan diingatkan bahawa anda mempunyai hak untuk menolak dari menjawab sebarang soalan, mahupun berhenti dari terus menyertai kajian ini pada bila-bila masa. Anda juga boleh meminta masa untuk berehat dari menjawab soalan. Selepas selesai menjawab kesemua soalan, anda diminta memulangkannya kepada individu yang bertanggungjawab dalam mengambil kebenaran anda untuk menyertai kajian ini.

Berapa lama harus saya terlibat dalam kajian ini?

Anda hanya terlibat dalam satu sesi sahaja. Dua set soalan (ICEQ dan soalan tambahan) akan diberikan dan anda diberi masa sehingga satu hari untuk melengkapkan jawapan sebelum memulangkannya pada individu yang bertanggungjawab. Kesemua soalan memerlukan anda untuk menjawabnya sendiri di atas helaian yang sama. Namun, anda boleh bertanya kepada penyelidik atau pembantu penyelidik sekiranya ada persoalan berkaitan set soalan yang diberikan.

Risiko dan/atau Ketidakselesaan

Semasa sesi pengambilan data, kami akan mengambil informasi berkaitan tahap kesihatan anda. Risiko bagi anda dalam kajian ini mungkin datang dari segi terdapat soalan yang anda rasakan tidak selesa untuk dijawab. Sekiranya ada soalan yang membuatkan anda tidak selesa, anda boleh meninggalkan soalan tersebut dan beralih ke soalan yang berikutnya. Anda tidak perlu menjawab soalan yang dirasakan tidak selesa. Namun, kami memberikan masa sehingga satu hari untuk anda memikirkan jawapan sekaligus membantu dalam membuang rasa tidak selesa semasa menjawab soalan. Kami akan memastikan privasi dan kerahsiaan anda akan dipelihara sepanjang kaji selidik ini berjalan.

Manfaat Kajian

Kajian ini adalah sebahagian dari keperluan saya untuk graduasi. Berkemungkinan kajian ini tidak memberikan manfaat secara terus kepada anda. Namun, pengetahuan dan maklumat yang diperolehi dari kajian ini mungkin dapat membantu dalam memberikan informasi berkenaan dengan pengalaman pesakit lain yang mengalami situasi yang sama seperti anda.

Kerahsiaan Data

Rekod medical dan data kajian anda hanya diakses oleh penyelidik atau pembantu penyelidik. Data anda akan diletakkan di dalam sampul bertutup dan diletakkan di dalam pejabat Kuliah Kejururawatan, Universiti Islam Antarabangsa oleh penyelidik selepas kesemua data peserta dianalisa. Kesemua data akan disimpan selama lima tahun dan akan dimusnahkan oleh penyelidik selepas sampai waktu limitasi. Sebarang

publikasi kajian ini tidak akan menggunakan nama serta identiti anda secara individu. Bagaimanapun, rekod anda mungkin akan disemak oleh Kumpulan Etika Kajian, Fakulti Kejururawatan, Universiti Chiang Mai, Thailand. Informasi peribadi anda juga akan disemak sekiranya benar-benar diperlukan dari segi perundangan.

Kos dalam Menyertai Kajian

Tiada kos bagi anda dalam menyertai kaji selidik ini.

Bayaran

Anda tidak akan menerima sebarang bentuk bayaran dalam menyertai kaji selidik ini. Namun, anda akan diberikan cenderahati dari penyelidik atas dasar menghargai pembabitan secara sukarela anda dalam kajian ini.

Hak Peserta

Penyertaan dalam kajian adalah bergantung kepada diri anda sendiri. Anda mempunyai hak untuk turut serta mahupun menolak dari menyertai kajian ini. Sekiranya anda bersetuju untuk turut serta, namun membuat keputusan untuk tidak lagi menyertai kajian ini, anda berhak untuk berbuat sedemikian pada bila-bila masa. Sekiranya anda memutuskan untuk tidak lagi turut serta, sukacita dimaklumkan bahawa hak anda untuk mendapatkan servis rawatan medikal atau apa-apa jua jenis rawatan tidak akan terganggu/dihalang.

Anda mempunyai hak untuk mengakses informasi anda yang diambil untuk kajian ini. Sekiranya anda mahu mengakses informasi anda, sila maklumkan kepada penyelidik dan anda akan diberikan maklumat berdasarkan syarat dan regulasi yang telah ditetapkan oleh Universiti Chiang Mai.

Siapa yang Boleh Anda Hubungi Sekiranya Mempunyai Soalan atau Masalah Berkaitan Kajian ini?

Sebarang soalan berkaitan kajian boleh menghubungi:

Suzilawati Mohamed Ariffin

Penyelidik Utama

Chiang Mai University Faculty of Nursing

110 Intavaroros Road, Chiang Mai 50200

Tel: 019-5244573 (24 jam)

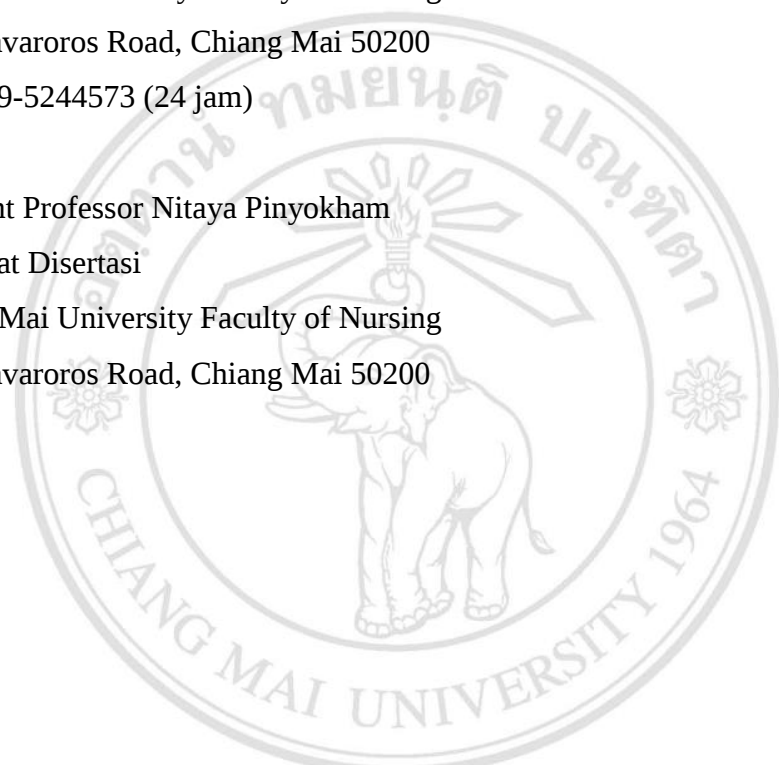
Atau

Assistant Professor Nitaya Pinyokham

Penasihat Disertasi

Chiang Mai University Faculty of Nursing

110 Intavaroros Road, Chiang Mai 50200

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Borang Kebenaran Pesakit

Kebenaran untuk Menyertai Kajian di Unit Rawatan Rapi dalam Kalangan Pesakit yang Pernah Menerima Rawatan di Unit Rawatan Rapi (ICU)

Saya telah dipelawa untuk menyertai kaji selidik berkenaan pengalaman menerima rawatan di unit rawatan rapi. Saya telah membaca dokumen kebenaran untuk menyertai kaji selidik ini. Saya juga telah menerima penjelasan berkenaan dengan kaji selidik, tujuan ia dilakukan dan masa yang diberikan untuk melengkapinya kajian ini.

Saya, _____ (nama peserta) dengan ini memberi kebenaran untuk turut serta dalam kaji selidik ini.

Saya memahami bahawa:

a. penyertaan saya adalah secara sukarela. Saya mempunyai pilihan untuk berhenti dari menyertai kaji selidik ini pada bila-bila masa dan saya bebas untuk tidak menjawab mana-mana soalan yang ditanya.

b. sekiranya informasi dari kaji selidik ini digunakan di dalam perbincangan di persidangan, dan mungkin akan dibukukan di dalam jurnal artikel, informasi berkaitan dengan saya tidak akan dibocorkan. Informasi berkaitan dengan saya akan kekal dirahsiakan.

c. saya mungkin tidak akan mendapat keuntungan secara terus daripada penyertaan kaji selidik ini.

d. saya boleh bertanya kepada penyelidik pada bila-bila masa untuk mendapatkan maklumat tambahan.

Nama individu yang mengambil kebenaran:

Nama peserta:

Tugas:

No. I/C:

Tarikh:

Tandatangan:

No. I/C:

Tarikh:

Tandatangan:

Appendix C

Questionnaire (English Version)

This questionnaires consists of two (2) parts: Demographic data, Intensive Care Experience Questionnaires (ICEQ) with additional questions.

Part I: Demographic data

This questions asking about demographic data of the patient. It consists of 12 questions.

1. Gender
2. Age
3. ...
4. ...
5. ...
12. Types of admission

Part II: Intensive care experience questionnaire (ICEQ)

This questionnaire is designed to find out what you felt and remember about your intensive care experience.

1. AWARENESS OF SURROUNDING (9 ITEMS)

Please tick the box that best describes what you think about each of the statements below. How much do you agree:

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1	I have no recollection of being in intensive care	1	2	3	4	5
2						

Please tick the box that best describes how often these happened:

		All of the time	Most of the time	Some of the time	Rarely	Never
3						
4						
5						
6						
7						
8						
9	I felt safe	5	4	3	2	1

Additional questions for this domain:

a) Presence of whom (health personnel/ family members) that make you felt safe? Please state the reason.

.....

b)

2. FRIGHTENING EXPERIENCES (6 ITEMS)

Please tick the box that best describes what you think about each of the statements below. How much do you agree:

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1	I thought I would die	5	4	3	2	1

Please tick the box that best describes how often these happened:

		All of the time	Most of the time	Some of the time	Rarely	Never
2						
3						
4						
5						
6	I seemed to have bad dreams	5	4	3	2	1

Additional questions for this domain:

a) What were the events that make you felt helpless, scared, felt like dying, or pain? Please describe those events.

.....

b)

c)

3. RECALL OF EXPERIENCES (5 ITEMS)

Please tick the box that best describes what you think about each of the statements below. How much do you agree:

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1	Most of my memories of intensive care are blurred	1	2	3	4	5
2						
3						
4						
5	I seemed to sleep too much	1	2	3	4	5

Additional questions for this domain:

a) What are the events that you remember the most during your stay in ICU?

.....

b)

c)

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4. SATISFACTION WITH CARE (4 ITEMS)

Please tick the box that best describes what you think about each of the statements below. How much do you agree:

		Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
1	My care could have been better	1	2	3	4	5
2						
3						
4	I thought my care was as good as it could have been	5	4	3	2	1

Additional questions for this domain:

a) How did you feel about care service during your stay in ICU? Why were you think so?

.....

b)

.....

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Appendix D

Questionnaire (Malay Version)

Set soalan ini mengandungi dua (2) bahagian: Data demografik, *Intensive Care Experience Questionnaires* (ICEQ) dan soalan tambahan.

1. Data demografik

Bahagian ini menanyakan berkenaan data demografik pesakit. Bahagian ini mengandungi 12 soalan.

1. Jantina
2. Umur
3. ...
4. ...
5. ...
12. Jenis kemasukan

2. Intensive care experience questionnaire (ICEQ)

Soalan kaji selidik ini dibentuk untuk mengetahui perasaan dan ingatan anda semasa menerima rawatan di unit rawatan rapi (ICU).

1. KESEDARAN TERHADAP SEKELILING (9 SOALAN)

Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sejauh mana anda bersetuju:

		Sangat setuju	Setuju	Sama ada setuju atau tidak setuju	Tidak setuju	Sangat tidak setuju
1	Saya tidak mengingati langsung tentang kehadiran saya di unit rawatan rapi	1	2	3	4	5
2	...					

Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sekerap mana anda mengalami perkara berikut:

		Sepanjang masa	Hampir setiap masa	Kadang-kadang	Sangat jarang	Tidak pernah
3	...					
4						
5						
6						
7						
8						
9	Saya rasa selamat	5	4	3	2	1

Soalan tambahan untuk domain ini:

a) Kehadiran siapakah (staf kesihatan/ ahli keluarga) yang membuatkan anda rasa selamat? Silakan berikan alasan anda.

.....

b)

2. PENGALAMAN YANG MENAKUTKAN (6 SOALAN)

Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sejauh mana anda bersetuju:

		Sangat setuju	Setuju	Sama ada setuju atau tidak setuju	Tidak setuju	Sangat tidak setuju
1	Saya rasa saya akan mati	5	4	3	2	1

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Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sekerap mana anda mengalami perkara berikut:

		Sepanjang g masa	Hampir setiap masa	Kadang- kadang	Sangat jarang	Tidak pernah
2						
3						
4						
5						
6	Saya seperti mengalami mimpi buruk	5	4	3	2	1

Soalan tambahan untuk domain ini:

a) Apakah kejadian yang membuatkan anda merasa tidak berdaya, takut, rasa seperti mati, atau sakit? Sila perelaskan kejadian tersebut.

.....

b)

c)

3. MENINGATI SEMULA PENGALAMAN (5 SOALAN)

Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sejauh mana anda bersetuju:

		Sangat setuju	Setuju	Sama ada setuju atau tidak setuju	Tidak setuju	Sangat tidak setuju
1	Hampir semua memori saya berkenaan dengan rawatan rapi adalah tidak jelas	1	2	3	4	5
2						
3						
4						
5	Saya tidur secara berlebihan	1	2	3	4	5

Soalan tambahan untuk domain ini:

a) Apakah kejadian/perkara yang paling anda ingati semasa tinggal di ICU?

.....

b)

c)

4. TAHAP KEPUASAN DENGAN JAGAAN (4 SOALAN)

Sila bulatkan jawapan yang bersesuaian dengan keadaan anda mengikut pernyataan-pernyataan di bawah. Sejauh mana anda bersetuju:

		Sangat setuju	Setuju	Sama ada setuju atau tidak setuju	Tidak setuju	Sangat tidak setuju
1	Jagaan terhadap saya seharusnya lebih baik	1	2	3	4	5
2						
3						
4	Saya fikir jagaan terhadap saya bagus seperti yang sepatutnya	5	4	3	2	1

Soalan tambahan bagi domain ini:

a) Bagaimanakah perasaan anda terhadap perkhidmatan kesihatan yang anda terima semasa tinggal di ICU? Mengapa anda berfikir sedemikian?

.....

b)

Appendix E

Certificate of Ethical Clearance



Certificate of Approval

No. 027/2015

Name of Ethics Committee : Ethics Committee, Faculty of Nursing, Chiang Mai University Address of Ethics Committee : 110 Inthawaroros road., SriPhum, Chiang Mai 50200	
Principal Investigator : Miss Suzilawati Mohamed Ariffin Master of Nursing Science Program (International Program) Faculty of Nursing, Chiang Mai University	
Protocol title : Intensive Care Experience Among Intensive Care Unit Survivors STUDY CODE : EXP – 022 – 2558 Sponsor : -	
Documents filed	Document reference
Research protocol	- Version date April 7, 2015
Informed consent documents /Patient information sheet	- Version date April 7, 2015
Case Record Form	- Version date April 7, 2015
Principal Investigator Curriculum vitae	- Version date April 7, 2015

Opinion of the Ethics Committee/Institutional Review Board : Expedited Review

The Ethics Committee has reviewed the protocol and documents above and give the favorable opinion

Date of Approval : April 7, 2015 **Expiration Date :** April 6, 2016

Progress report is required to be submitted to the Ethics Committee for continuing review

☐ at 3 month interval

☐ at 6 month interval

☒ annually (in this case please submit at least 60 days prior to expiration date)

This Ethics Committee is organized and operates according to GCPs and relevant international ethical guidelines, the applicable laws and regulations.

Signed : Wichit Srisuphan

(Professor Emerita Dr. Wichit Srisuphan)

Chairperson, Faculty of Nursing, Chiang Mai University

Signed : Wipada Kunaviktikul

(Professor Dr. Wipada Kunaviktikul)

Dean, Faculty of Nursing, Chiang Mai University

GENERAL CONDITION OF APPROVAL:

- Prior Research Ethics Committee approval is required before implementing any changes in the consent documents or protocol unless those changes are required urgently for the safety of subjects.
- Any event or new information that may affect the benefit/risk ratio of the study must be reported to the REC promptly.
- Any protocol deviation/violation must be reported to the REC.

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Appendix F

Permission for Used ICEQ

Janice Rattray <j.z.rattray@dundee.ac.uk> 3/31/14

Dear Suzilawati,

Thank you for your email. I am attaching the ICEQ, please feel free to use this in your study.

Janice

From: Suzilawati Ariffin [mailto:1204smaj@gmail.com]

Sent: 31 March 2014 11:43

To: Janice Rattray

Subject: ICEQ

The University of Dundee is a registered Scottish Charity, No: SC015096



Appendix G

Permission of Data Collection Letters



JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Tel : 03 2282 0491
Faks : 03 2282 8072 / 03 2282 0015

Ruj. Kami : (9)KKM/NIHSEC/ P15-237
Tarikh : 10 Jun 2015

Suzilawati Binti Mohamed Ariffin
Universiti Islam Antarabangsa
Kampus Kuantan

Tuan/ Puan,

NMRR-14-1615-23580

Intensive care experience among intensive care unit survivors

Dengan hormatnya perkara di atas adalah dirujuk.

2. Bersama dengan surat ini dilampirkan surat kelulusan saintifik dan etika bagi projek ini. Segala rekod dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah Hospital/Institusi di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Dato'/ Tuan/ Puan perlu akur dan mematuhi keputusan tersebut.

3. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga 10 Jun 2016. Tuan/Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web Jawatankuasa Etika & Penyelidikan Perubatan (JEPP) (<http://www.nih.gov.my/mrec>).

- i. **Continuing Review Form** selewat-lewatnya 2 bulan sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.
- ii. **Study Final Report** pada penghujung kajian.
- iii. Mendapat kelulusan etika sekiranya terdapat pindaan ke atas sebarang dokumen kajian/ lokasi kajian/ penyelidik.
- iv. Kajian berkenaan intervensi klinikal sahaja: Laporan mengenai **all Serious Adverse Events (SAEs)**, **Suspected Unexpected Serious Adverse Reaction (SUSARs)** dan **Protocol Deviation/Violation** di lokasi kajian yang diluluskan oleh JEPP jika berkenaan. **SAE** perlu dilaporkan dalam tempoh 15 hari kalender dari *awareness of event* oleh penyelidik. Laporan awal **SUSAR** perlu dikemukakan seawal mungkin tapi tidak melewati 7 hari calendar dari *awareness of event* oleh penyelidik, disusuli dengan laporan lengkap dalam tempoh tambahan 8 hari kalender.

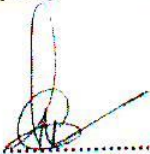
4. Bilangan subjek/ pesakit/ responden yang disasarkan untuk menyertai kajian ini di Malaysia adalah 142 orang.

5. Sila ambil maklum bahawa sebarang urusan surat-menyurat berkaitan dengan penyelidikan ini haruslah dinyatakan nombor rujukan surat ini untuk melicinkan urusan yang berkaitan.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang menurut perintah,



DATO' DR CHANG KIAN MENG

Pengerusi

Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia

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JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Tel : 03 2282 0491
Faks : 03 2282 8072 / 03 2282 0015

Ruj. Kami : (10)KKM/NIHSEC/ P15-237
Date 10 June 2015

Protocol Title :

NMRR-14-1615-23580

Intensive care experience among intensive care unit survivors

Principal Investigator/s :

Suzilawati Binti Mohamed Ariffin
Universiti Islam Antarabangsa
Kampus Kuantan

Documents received and reviewed with reference to the above study:

1. Study Protocol Version 3 Version Date 15-05-2015
2. Patient information sheet (English) & Informed Consent Form (English)
Version 2 Version Date 15-05-2015
3. Patient information sheet (BM) & Informed Consent Form (BM) Version 2
Version Date 15-05-2015
4. Questionnaire version 2 Date 18-02-2015.
5. Curriculum vitae of :
 - Suzilawati Binti Mohamed Ariffin

Please note that the approval is valid until **10 June 2016**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (<http://www.nih.gov.my/mrec>).

- v. **Continuing Review Form** has to be submitted to MREC at least 2 months before the expiry of the approval.
- vi. **Study Final Report** upon study completion to the MREC.
- vii. Ethical approval is required in the case of **amendments/ changes** to the **study documents/ study sites/ study team**.
- viii. **Applicable for Clinical interventional Studies only:** Report occurrences of all **Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from

awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.

3. **142** number of subjects/ patients/ respondents are targeted to enroll this study in Malaysia.

Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any):

Project Sites:

Hospital Raja Permaisuri Bainun, Ipoh

Hospital Taiping

Hospital Tengku Ampuan Afzan, Kuantan

Decision by Medical Research & Ethics Committee:

(☒) Approved

(☐) Disapproved

Date of Approval : 10 June 2015



DATO' DR CHANG KIAN MENG

Chairperson

Medical Research & Ethics Committee

Ministry of Health Malaysia

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Appendix H

The Cronbach's Alpha Coefficient of Instrument

The Cronbach's Alpha Coefficient of Instrument

Instrument	α
Intensive care experience questionnaire (ICEQ)	
Awareness of surrounding	0.914
Frightening experiences	0.821
Recall of experiences	0.797
Satisfaction with care	0.841

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Appendix I

The Responses of Opened End Questions

Experienced Among the Survivors in the Intensive Care Unit

Questions	Response	n	%
Awareness of surrounding			
Presence of whom (health personnel/ family member) that makes you felt safe? Please state the reason.	Presence of my family. I feel safe since I know them well.	72	50.7
	Presence of staffs and family members. I feel safe when I felt someone nearby.	31	21.8
	Unconscious/ No comment	15	10.6
	Presence of staff (doctors, nurses). They encourage me for my speed recovery. They always be my side whenever I need help.	14	9.9
	I do not care whoever come. The feeling of afraid about dying are taking over.	6	4.2
	Presence of staff, family members, and friends. They always give me encouragement.	3	2.1
	Presence of friends. I feel happy when they come to visit.	1	0.7
Do you aware about place (being in ICU, hospital, etc.), person (health personnel, family members, etc.) or time (during treatment/procedure, after treatment /procedure, during	Not notice about anything because it is to painful to bear with (illness)	54	38.0
	I know the place, time and people after received an explanation from the staffs	25	17.6
	I am fully conscious about people, time and place	23	16.2
	I am fully conscious about place and people.	16	11.3
	Sometime I know that: I am in ICU, surrounded with staff and family members, and receiving treatment.	16	11.3

Questions	Response	n	%
admission, day and night, etc.) during your stay in the ICU? Please specify it.	No comment	8	5.6
Frightening experiences			
What do you feel during stay in ICU?	Afraid	75	53.0
	No comment	22	15.5
	Unexplained feeling	16	11.2
	Calm and eager to get well as soon as possible	9	6.3
	Sad because cannot eat and cannot go home	5	3.5
	I think I am death	3	2.1
	Painful	3	2.1
	Phobia and stress	3	2.1
	I want to go home	2	1.4
	Impressed with the ICU's environment	1	0.7
	Uncomfortable, seemed like everybody watching me	1	0.7
	I want to discharged right away	1	0.7
	Acceptance since it is a the way to treat my illness	1	0.7
What were the events that make you felt helpless, scared, felt like dying, or pain? Please describe those events.	Scared: Seeing 'things'/ scary things/ ghost or spirits (try to take out my ETT), feel afraid of either life or death, afraid about my illness either can be cured or not, blood taking procedure always makes me afraid, nightmares	46	32.4

Questions	Response	n	%
	Pain at the affected side of my body, pain resulted from the procedures, painful feeling/ can not move my own body, positioning caused my body felt pain especially at the affected site	29	20.4
	Felt helpless when whole of my body felt weak	21	14.8
	I cannot remember/ No comment	15	10.6
	Ventilator: Intubation and suctioning via ETT, breathing via ventilator	12	8.5
	Environment in ICU Confuse with the environment, I am trauma been in ICU, admitted to the ICU, my body surrounded by wires, fierceful staff/ Staff who always nagging, to be left alone	11	7.7
	Noises Sound from machines, loudness in the ICU	5	3.5
	Not afraid because I am vibrant for my recovery	2	1.4
	Felt like dying when having shortness of breath	1	0.7
What is the most frightening events/moment during your stay in ICU? Please explain.	Nightmares (black shadows/ staff want to kill me/ seeing something scary)	35	24.7
	Nothing happen	19	13.4
	Noises: Scary and weird sound, loud sound from machines and equipments	16	11.3
	Seeing others patients dying/death	15	10.6
	ETT or ventilator not functioning	11	7.75
	Cannot remember	11	7.75
	Pain that come from procedures, illness, post operation/ Extubation that speechlessly painful	9	6.3
	Feel afraid about dying	8	5.6

Questions	Response	n	%
	Cannot move my body	5	3.5
	To be left alone	5	3.5
	Surrounded with unknown peoples	3	2.1
	Body full with wires and tubes	3	2.1
	Seeing blood	2	1.4
Recall of experiences			
What are the events that you remember the most during your stay in ICU?	Nothing	30	21.1
	ETT and ventilator: suctioning, intubation, extubation	21	14.8
	Seeing scary things (shadows/ creatures)	20	14.1
	Loud sound from the machines	14	10.0
	Extremely painful feeling, pain at affected site	12	8.5
	Loudness in ICU makes me happy/ happy with the services/ good encouragement from the staff/ safe environment in ICU	11	7.7
	Treatment procedures	8	5.6
	Seeing another patients death	5	3.5
	Full of sophisticated equipment	4	2.8
	Admission of another patients	3	2.1
	Family members/ friends come to visit	3	2.1
	Been scold by the staff	2	1.4
	Cannot move my body	2	1.4
	Bathed by female staff nurse. Feel embarrassed.	2	1.4
	Experiencing CPR	1	0.7
	Seeing blood come from my nostril	1	0.7
	When tranfered out from ICU	1	0.7
	Shortness of breath	1	0.7
	Long febrile	1	0.7

Questions	Response	n	%
What are the things that you desperately want to forget? Please state the reason.	Been in ICU	55	38.7
	Pain result from illness, suctioning is painful and uncomfortable	24	16.9
	Nothing to forget	21	14.9
	Seeing 'things' and witnessed a dead of other patients	12	8.5
	Intubation via oral/nostril	8	5.6
	Loud sound (terrible/ scary)	6	4.2
	Nightmares	6	4.2
	Blood taking procedures makes me uncomfortable	2	1.4
	Cannot move my body. Felt helpless	2	1.4
	Feel shame when younger staff changing my attires	1	0.7
	Extubation	1	0.7
	Felt extremely thirsty	1	0.7
	A lot of tubes and wires on and inside my body	1	0.7
	Was restrained on the bed	1	0.7
	Cannot eat	1	0.7
Do you think that you get enough sleep during your stay in ICU? State the reason why you feel so.	Yes. I get enough sleep without being disturbed (sedation, pain killer)	97	68.3
	No. Cannot get enough sleep because of loud sound from machines	10	7.0
	No. Cannot get enough sleep because of feeling uncomfortable	9	6.3
	No. Cannot get enough sleep because of the pain	8	5.6

Questions	Response	n	%
	No. Cannot get enough sleep. I cannot figured why it's happen	7	5.0
	No. Cannot get enough sleep because of afraid (not able to wake up again/ weird things comes and do harm to me)	7	5.0
	Not sure	4	2.8
Satisfaction with care			
How did you feel about care service during your stay in ICU? Why were you thinkso?	Good The staffs give the best services to the patients (eventhough they are busy/ soft spoken), feel happy with the services, staff are very disciplines and concerned with patient's conditions	89	62.7
	Satisfy Satisfy with the services. Thankful because able to overcome the illness, It is okay but feel shame when procedures are conducted by the staffs	26	18.3
	Not good Need to improved the professional attitudes when handling patients, Hate been treated in ICU and the bad services, I have been restrained by the staff and it is hurt	14	9.9
	Mixed feeling. Sometimes the services are good, but sometimes are not (clumsy staff, noises)	9	6.3
	No comment	4	2.8

Questions	Response	n	%
What are the things/events that disturbed you the most when receiving care service in ICU?	No comment/ nothing happen	38	27.0
	Noises from the machines and visitors	32	22.5
	Pain	22	15.5
	Feel pain and seeing shadows in the ICU, Suctioning, Pain at operation site/ illness site		
	Seeing patient who are next to me, who are critically ill/ dead	10	7.0
	Environment in ICU	5	3.5
	Bad services from the staff (CPR was done in rough manner)	5	3.5
	Been disturbed when I sleep	5	3.5
	No issues, I received the best services here in ICU	4	2.8
	Nightmares	4	2.8
	Afraid of not getting good services	2	1.4
	Received bad news about my health conditions	2	1.4
	Need improvement about the dress code. It is untidy	2	1.4
	To be left alone	2	1.4
	Cannot communicate/ speak	2	1.4
	Cannot move until I get bed sore	1	0.7
	Been restrained. Staff claimed that I try to pull out the ETT	1	0.7
	Seeing other patients received the visitor while I am alone	1	0.7
	No one tell me about another step of my treatment	1	0.7
	Feel shame when bathed by younger staff	1	0.7
	Blood taking procedure every morning	1	0.7
	All the wires and tubes	1	0.7

CURRICULUM VITAE

Name Ms. Suzilawati Mohamed Ariffin

Date of Birth April 12, 1985

Educational Background

1998-2002 Certificate, High School, SMK Gunung Rapat
2002-2003 Certificate, Matriculation Level,
Kulim Matriculation College
2004-2008 Degree in Health Sciences, Nursing,
University Science of Malaysia

Professional Experiences

Three years training in government hospital



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