



APPENDICES

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APPENDIX A

Study Participant Informed Consent

I, _____, voluntarily consent to taking part in the research study entitled “Dietary Behavior, Perceived Benefits and Barriers Among Persons Undergone Urinary Tract Stone Removal”.

Prior to signing this informed consent, I have read (or had read to me) the information sheet for participants during the study and have received a detailed explanation of the objectives, risks and benefits of the study. I understand the information thoroughly. I was given the chance to ask questions and study staff answered all questions to my satisfaction. I have taken enough time to understand the information on the study participant information sheet and was given enough time to decide whether I want to take part in this study.

I have the right to withdraw from the study at any time and I am taking part voluntarily. If I decide to leave the study, my rights to medical or other services will not be affected.

I sign this Informed Consent voluntarily to show my intent to take part in this study and understand that I will be offered a copy of this consent to keep. By signing this document I am not giving up any of my legal rights.

Participant's Signature _____ Date _____
Name ()

Researcher's Signature _____ Date _____
Name ()

APPENDIX B

Study Participant Information Sheet

Study Introduction and Objectives

I, Suhana bin Muhamad, Student ID 561235810, Research ID (Malaysian): 23581, I am a master student at the Faculty of Nursing, Chiang Mai University, and conducting a study entitled “Dietary behavior, Perceived benefits and Barriers Among Persons Undergone Urinary Tract Stone Removal”. This study will fulfill my thesis study requirement for my degree. This study has the following objectives:

1. To examine level of dietary behavior, perceived benefits and barriers among persons undergone urinary tract stone removal
2. To examine relationship between perceived benefits, perceived barriers and dietary behavior among persons undergone urinary tract stone removal

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 the objectives of this study and agreed to participate, 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 be kept for your reference.

Study Purpose

This study is being conducted to gather the information necessary to see dietary behavior among persons after stone removal and what benefits and barriers that perceived by this population in practicing those behavior to prevent stone recurrence. Dietary behavior is important risk for the development of recurrence stones especially among affected population. This information from this study may be used to help

persons especially after stones removal to prevent the recurrence of urinary tract stones by emphasizing importance of recommended dietary behavior.

Study Participants

This study is for women and men age 18 to 64. There will be a total of 88 participants in the study. Participants will be recruited from outpatient's clinic in Hospital Kuala Lumpur (38 participants), Hospital Selayang (25 participants) and Hospital Tengku Ampuan Afzan (25 participants).

Study Procedures

You may begin today if you are found to be eligible for this study and if you voluntarily agree to take part in the study. Some people may not be able to join the study because they do not meet all of the requirements.

All participants will be asked to complete 4 parts of the questionnaires. These questionnaires will take about 40 minutes to one (1) hour to complete. Although we hope that you will be comfortable answering all of the questions openly and honestly, please remember that the participation in this study is completely voluntary and 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.

How Long Must I Take Part in this Study

You will be asked to take part only in one session of answering the questionnaires for this study.

Risks and/or Discomforts

This study will bring no risks or discomforts to participants.

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 regarding dietary behavior, benefits and barriers that perceived by peoples who are suffering from the same condition/illness as

you in order to prevent recurrence stone event after urinary stone removal. Knowledge gained from this study also can be used to develop an effective health education program in order to prevent the recurrence of the urinary tract stones among Malaysian population.

Protecting Data Confidentiality

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 any payment for taking part in this study. However, you will receive souvenir (stationery-pen) as token of appreciation to take part in 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. Should 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. "Other study rights and privileges as mandated by Chiang Mai University rules and regulations."

Who Do You Call if You Have Questions or Problems?

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

Suhana binti Muhamad, Principal Investigator
Chiang Mai University Faculty of Nursing
110 Intavaroros Road
Chiang Mai 50200
Tel: 012-2984127 (24 hours access)

Or

Assistant Prof. Dr. Khanokporn Sucamvang, Thesis Advisor
Chiang Mai University Faculty of Nursing
110 Intavaroros Road
Chiang Mai 50200
Tel: 66-53949049, 66-53945017 (Office hour)

If you would like information related to your rights as a study participant, you can contact:

Secretariat
Medical Research and Ethics Committee
Ministry of Health, Malaysia
Tel: 03-2287 4032 (Office hour)

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APPENDIX C

Research Instrument

Part I: Personal Profile Data

This part contains question related to your personal data. Please respond to each item by (√) inside the selected box.

- 1) Gender: Male Female
- 2) Age: _____, Height: _____ cm, Weight: _____ kg (BMI = _____)
- 3) Race: Malay Chinese Indian Others: _____
- 4) Marital status : Single Married Others: _____

.....

.....

.....

12) Main source of information regarding urinary tract stones prevention

- Physician Nurse Family member/friend
- Internet/ mass media Health campaign
- Others: _____

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Part II: Dietary Behavior Questionnaire

This questionnaire contains statement about your present dietary behavior after removal of urinary tract stones. Please give respond to each item by (√) inside the box.

Dietary intake	Daily	4-5 days per week	2-3 days per week	Monthly	Never
1. Eat dairy product such as 1 slice cheese or 1 cup yogurt					
2. Eat no more than 1 serving of red meat					
3. Eat no more than 1-2 serving of white meat					
.....					
.....					
.....					
14. Drink at least 6-8 glasses of water					
.....					
.....					
.....					
18. Drink no more than 1 glass of grape juice					

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Part III: Perceived Benefits Questionnaire

This questionnaire contains statement about benefits of following recommended healthy diet that perceived by you in order to prevent recurrence of urinary tract stones. Please give respond to each item by circle the following number.

Benefit items	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)
1. Help to prevent the recurrence of urinary tract stones	1	2	3	4
2. Help to prevent from pain	1	2	3	4
3. Help to prevent from repeated surgery procedure	1	2	3	4
.....				
.....				
.....				
10. Prevent from long term intake of medication	1	2	3	4

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Part IV : Perceived Barriers Questionnaire

This questionnaire contains statement about barriers that perceived by you in order to follow recommended diet to prevent recurrence of urinary tract stones. Please give respond to each item by circle the following number.

Barrier items	Strongly Disagree (1)	Disagree (2)	Agree (3)	Strongly Agree (4)
1. Recommended food is expensive	1	2	3	4
2. Have limited choice of recommended food when I eat out	1	2	3	4
3. Do not have enough motivation to follow the recommended diet regime	1	2	3	4
4. Busy lifestyle make it difficult to follow the recommended diet regime	1	2	3	4
.....				
.....				
.....				
14. Family member/friends influences me to eat unhealthy food	1	2	3	4

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APPENDIX D

Ethical Approval from Faculty of Nursing, Chiang Mai University



Certificate of Approval

No. 050/2015

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 : Mrs. Suhana Muhamad Master of Nursing Science Program (Internatioanl Program) Faculty of Nursing Chiang Mai University	
Protocol title : Dietary Behavior, Perceived Benefits and Barriers Among Persons Udergone Urinary Tract Stone Removal STUDY CODE : EXP – 037 – 2558 Sponsor : -	
Documents filed	Document reference
Research protocol	- Version date May 11, 2015
Informed consent documents /Patient information sheet	- Version date May 11, 2015
Case Record Form	- Version date May 11, 2015
Principal Investigator Curriculum vitae	- Version date May 11, 2015

<p>Opinion of the Ethics Committee/Institutional Review Board : Expedited Review</p> <p>The Ethics Committee has reviewed the protocol and documents above and give the favorable opinion</p> <p>Date of Approval : May 11, 2015 Expiration Date : May 10, 2016</p>
--

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 E

Ethical Approval from Medical Research and Ethics Committee, Malaysia



JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(*Medical Research & Ethics Committee*)
KEMENTERIAN KESIHATAN MALAYSIA
d/Institut Pengurusan Kesihatan Tel. : 03 2282 9082/03 2282 9085
Jalan Rumah Sakit, Bangsar 03 2287 4032/03 2282 0491
59000 Kuala Lumpur Faks: 03 22828072/03 2282 0015

Ruj. Kami : (5) KKM/NIHSEC/P15-531
Tarikh : 8hb Jun 2015

Suhana binti Muhamad
Kulliyah Kejururawatan
Universiti Islam Antarabangsa , Malaysia

Tuan/Puan

NMRR-14-1736-23581 (IIR)

Dietary behavior, perceived benefits and barriers among persons after urinary tract stones removal

Lokasi Kajian:

Bil	Lokasi Kajian
1	Hospital Kuala Lumpur
2	Hospital Selayang
3	Hospital Tengku Ampuan Afzan, Kuantan

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) mengambil maklum bahawa projek tersebut adalah untuk memenuhi keperluan akademik Sarjana Sains Kejururawatan.

3. Sehubungan dengan ini, dimaklumkan bahawa pihak JEPP KKM tiada halangan dari segi etika ke atas pelaksanaan projek tersebut. JEPP mengambil maklum bahawa kajian ini tidak melibatkan intervensi terhadap subjek dan hanya menggunakan **borang kaji selidik** dalam pengumpulan data kajian. Segala rekod dan data adalah **SULIT** dan hanya digunakan untuk tujuan kajian ini dan semua isu serta prosedur mengenai **data confidentiality** mesti dipatuhi. Kebenaran daripada Pegawai Kesihatan Daerah/Pengarah Hospital/ Pengarah Jabatan Kesihatan Negeri dan Ketua-Ketua Jabatan atau pegawai yang bertanggung jawab disetiap lokasi kajian di mana kajian akan dijalankan mesti diperolehi sebelum kajian dijalankan. Tuan/Puan perlu akur dan mematuhi keputusan tersebut.

4. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **8hb Jun 2016**. Tuan/Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web MREC (<http://www.nih.gov.my/mrec>).


- I. 'Continuing Review Form' selewat-lewatnya 2 bulan sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.
- II. Laporan tamat kajian pada penghujung kajian.
- III. Laporan mengenai "All adverse events, both serious and unexpected"/Protocol Deviation atau Violation kepada Jawatankuasa Etika & Penyelidikan Perubatan, KKM jika berkenaan.
- IV. Memaklumkan jika terdapat pindaan keatas sebarang dokumen kajian

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

Cc

Pengarah
Hospital Tengku Ampuan Afzan, Kuantan

Clinical Research Centre
Hospital Tengku Ampuan Afzan, Kuantan

Pengarah
Hospital Kuala Lumpur

Clinical Research Centre
Hospital Kuala Lumpur

Pengarah
Hospital Selayang

Clinical Research Centre
Hospital Selayang

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APPENDIX F

Validity Results for Dietary Behavior, Perceived Benefits and Barriers

Table F1

Validity of Dietary Behavior Questionnaire

Item	Score	
	I-CVI (rating 3 or 4)	S-CVI (rating 3 or 4)
Item 1	1.00	√
Item 2	1.00	√
Item 3	1.00	√
Item 4	1.00	√
Item 5	1.00	√
Item 6	1.00	√
Item 7	1.00	√
Item 8	1.00	√
Item 9	1.00	√
Item 10	1.00	√
Item 11	1.00	√
Item 12	1.00	√
Item 13	1.00	√
Item 14	1.00	√
Item 15	1.00	√
Item 16	1.00	√
Item 17	0.83	×
Item 18	1.00	√
		17/18=0.94

Table F2

Validity of Perceived Benefit Questionnaire

Item	Score	
	I-CVI (rating 3 or 4)	S-CVI (rating 3 or 4)
Item 1	1.00	√
Item 2	1.00	√
Item 3	1.00	√
Item 4	0.83	×
Item 5	1.00	√
Item 6	1.00	√
Item 7	1.00	√
Item 8	1.00	√
Item 9	1.00	√
Item 10	1.00	√
		9/10=0.90

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Table F3

Validity of Perceived Barriers Questionnaire

Items	Score	
	I-CVI (rating 3 or 4)	S-CVI (rating 3 or 4)
Item 1	1.00	√
Item 2	1.00	√
Item 3	1.00	√
Item 4	1.00	√
Item 5	1.00	√
Item 6	1.00	√
Item 7	1.00	√
Item 8	1.00	√
Item 9	1.00	√
Item 10	1.00	√
Item 11	1.00	√
Item 12	1.00	√
Item 13	1.00	√
Item 14	0.83	×
		13/14=0.93

Content validity index of the items (I-CVI) and of the scale (S-CVI) was calculated as follows;

$$I-CVI = \text{Number of items rated as 3 or 4} / \text{Total number of experts}$$

$$CVI = \text{Number of items rated as 3 or 4} / \text{Total number of items}$$

APPENDIX G

Additional Analysis of Dietary Behavior

Table G1

Frequency and Percentage Distribution of Participants' Dietary Behavior (n = 88)

Dietary behavior	Daily	4-5 days per week	2-3 days per week	Monthly	Never
	n (%)	n (%)	n (%)	n (%)	n (%)
<i>Calcium intake behavior</i>					
Eat dairy product	1(1.1)	5(5.7)	6(6.8)	28(31.8)	48 (54.6)
Drink at least 1 glass of milk	11(12.5)	6(6.8)	17(19.3)	20(22.7)	34(38.7)
<i>Protein intake behavior</i>					
Eat no more than 1 serving of red meat	4(4.5)	5(5.7)	29(33.0)	41(46.6)	9(10.2)
Eat no more than 1-2 serving of white meat	31(35.2)	8(9.1)	44(50.0)	3(3.4)	2(2.3)
Eat at least 1 serving of legumes	4(4.5)	8(9.1)	26(29.6)	38(43.2)	12(13.6)
Eat animal's internal organs	2(2.3)	4(4.5)	11(12.5)	42(47.7)	29(33.0)
Eat seafood	4(4.5)	7(8.0)	27(30.7)	41(46.6)	9(10.2)
<i>Fruits and vegetables intake behavior</i>					
Eat vegetables	51(58.0)	9(10.2)	27(30.7)	1(1.1)	0(0)
Eat fruits	29(33.0)	15(17.0)	36(40.9)	8(9.1)	0(0)
<i>Oxalate intake behavior</i>					
Eat food contain high oxalate	16(18.1)	10(11.4)	43(48.9)	17(19.3)	2(2.3)

Table G1

Dietary behavior	Daily	4-5 days per week	2-3 days per week	Monthly	Never
	n (%)	n (%)	n (%)	n (%)	n (%)
<i>Sodium intake behavior</i>					
Add seasoning or salty sauce in every dish/meal	23(26.1)	11(12.5)	19(21.6)	11(12.5)	24(27.3)
Eat salty food	3(3.4)	6(6.8)	18(20.5)	38(43.2)	23(26.1)
Add more salt to my meal at the table	2(2.3)	1(1.1)	6(6.8)	7(8.0)	72(81.8)
Eat fast food	1(1.1)	9(10.2)	14(15.9)	50(56.8)	14(15.9)
<i>Fluids intake behavior</i>					
Drink at least 6-8 glasses of water	64(72.7)	8(9.1)	14(15.9)	2(2.3)	0 (0)
Drink at least 1 cup of coffee or tea	54(61.4)	10(11.4)	14(15.9)	7(7.9)	3(3.4)
Drink at least I glass of orange juice or lemonade juice	11(12.5)	10(11.4)	27(30.7)	22(25.0)	18(20.4)
Drink no more than 1 glass of grape juice	0(0)	3(3.4)	6(6.8)	15(17.1)	64(72.7)

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APPENDIX H

Additional Analysis of Perceived Benefits

Table H1

Mean, Standard Deviation, Frequency and Percentage of Perceived Benefits (n = 88)

Benefits items	Mean	SD	Answered, n (%)	
			1-2	3-4
1. Prevent the recurrence of urinary tract stones	3.02	.567	9 (10.2)	79 (89.8)
2. Prevent from pain	3.00	.695	17 (19.3)	71 (80.7)
3. Prevent from repeated surgery procedure	3.09	.560	10 (11.4)	78 (88.6)
4. Increase control over my own health	3.25	.552	5 (5.7)	83 (94.3)
5. Stay healthy	3.19	.476	3 (3.4)	85 (96.6)
6. Control weight	3.02	.660	18 (20.5)	70 (79.5)
7. Feel better	3.25	.531	4 (4.5)	84 (95.5)
8. Prevent from disease complication	3.16	.623	11 (12.5)	77 (87.5)
9. Save cost	3.20	.483	3 (3.4)	85 (96.6)
10. Prevent from long term intake of medication	3.02	.678	19 (21.6)	69 (78.4)

*1 = strongly disagree, 2 = Disagree, 3 = Agree, 4 = Strongly agree

Table H2

Percentages of Participants' Total Responses in Agreement ('agree' and 'strongly agree') and Rank of Perceived Benefit Items (n =88)

Benefits items	Percentage	Rank
Help to stay healthy	96.6	1
Save cost	96.6	1
Feel better	95.5	2
Increase control over my own health	94.3	3
Prevent the recurrence of urinary tract stones	89.8	4
Prevent from repeated surgery procedure	88.6	5
Prevent from disease complication	87.5	6
Prevent from pain	80.7	7
Control weight	79.5	8
Prevent from long term intake of medication	78.4	9

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Table H3

Frequency, Percentage, Mean, Standard Deviation of Perceived Benefits According to BMI

BMI	Perceived benefit item (reduce weight)		
	N (%)	Mean	SD
Slim (< 18.5)	4 (4.5)	3.00	.816
Normal (18.5 - 24.9)	40 (45.5)	3.13	.607
Overweight (25 - 29.9)	30 (34.1)	3.03	.669
Obese (>30)	14 (15.9)	2.71	.726
Total mean = 3.02, SD = .660			

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APPENDIX I

Additional Analysis of Perceived Barriers

Table I1

Mean, Standard Deviation, Frequency and Percentage of Perceived Barriers (n = 88)

Barrier items	Mean	SD	Answered, n (%)	
			1-2	3-4
1. Recommended diet is expensive	2.34	.659	55 (62.5)	33 (37.5)
2. Limited choice of diet when I eat out	2.85	.635	17 (19.3)	71 (80.7)
3. Lack motivation	2.73	.601	27 (30.7)	61 (69.3)
4. Busy lifestyle	2.51	.661	47 (53.4)	41 (46.6)
5. Forget	2.63	.631	34 (38.6)	54 (61.4)
6. Recommended diet regime is complicated	2.49	.661	49 (55.7)	39 (44.3)
7. Prepare recommended diet is time consuming	2.23	.707	64 (72.7)	24 (27.3)
8. Recommended diet is tasteless	2.40	.704	48 (54.6)	40 (45.4)
9. Eat whatever diet prepared by family members	2.58	.707	40 (45.4)	48 (54.6)
10. Lack of family/friends support	2.17	.647	65 (73.9)	23 (26.2)
11. Drink more water cause to pass urine frequently	2.94	.488	13 (14.8)	75 (85.2)
12. Drink more water only when feel thirsty	2.53	.694	41 (46.6)	47 (53.4)
13. Not enough money to buy recommended diet regime	2.19	.641	64 (72.7)	24 (27.3)
14. Family members/friends influence me to eat unhealthy diet	2.01	.491	79 (89.8)	9 (10.2)

*1 = strongly disagree, 2 = Disagree, 3 = Agree, 4 = Strongly agree

Table I2

Percentages of Participants' Total Responses in Agreement ('agree' and 'strongly agree') and Rank of Perceived Barrier Items (n =88)

Barriers items	Percentage	Rank
Drink more water cause to pass urine frequently	85.2	1
Have limited choice diet when I eat out	80.7	2
Lack motivation	69.3	3
Forget	61.3	4
Eat whatever diet prepared by family members	54.6	5
Drink more water only when feel thirsty	53.4	6
Busy lifestyle	46.6	7
Recommended diet regime is tasteless	45.4	8
Recommended diet regime is complicated	44.3	9
Recommended diet regime is expensive	37.5	10
Prepare the recommended diet is time consuming	27.3	11
Not enough money to buy recommended diet	27.3	11
Lack of family/friends support	26.2	12
Family members/friends influence me to eat unhealthy diet	10.2	13

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CURRICULUM VITAE

Name Mrs. Suhana Muhamad

Date of Birth July 12, 1985

Educational Background

2008 Bachelor of Health Sciences (Hons),
Nursing Universiti Sains Malaysia (USM)

Professional Experiences

2008-present Registered nurse with Nursing Board Malaysia



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