The Effect of Person-centred Diabetic Foot Care Education on Self-efficacy and Foot Care Behavior in People with Diabetes: A Randomized Control Trial

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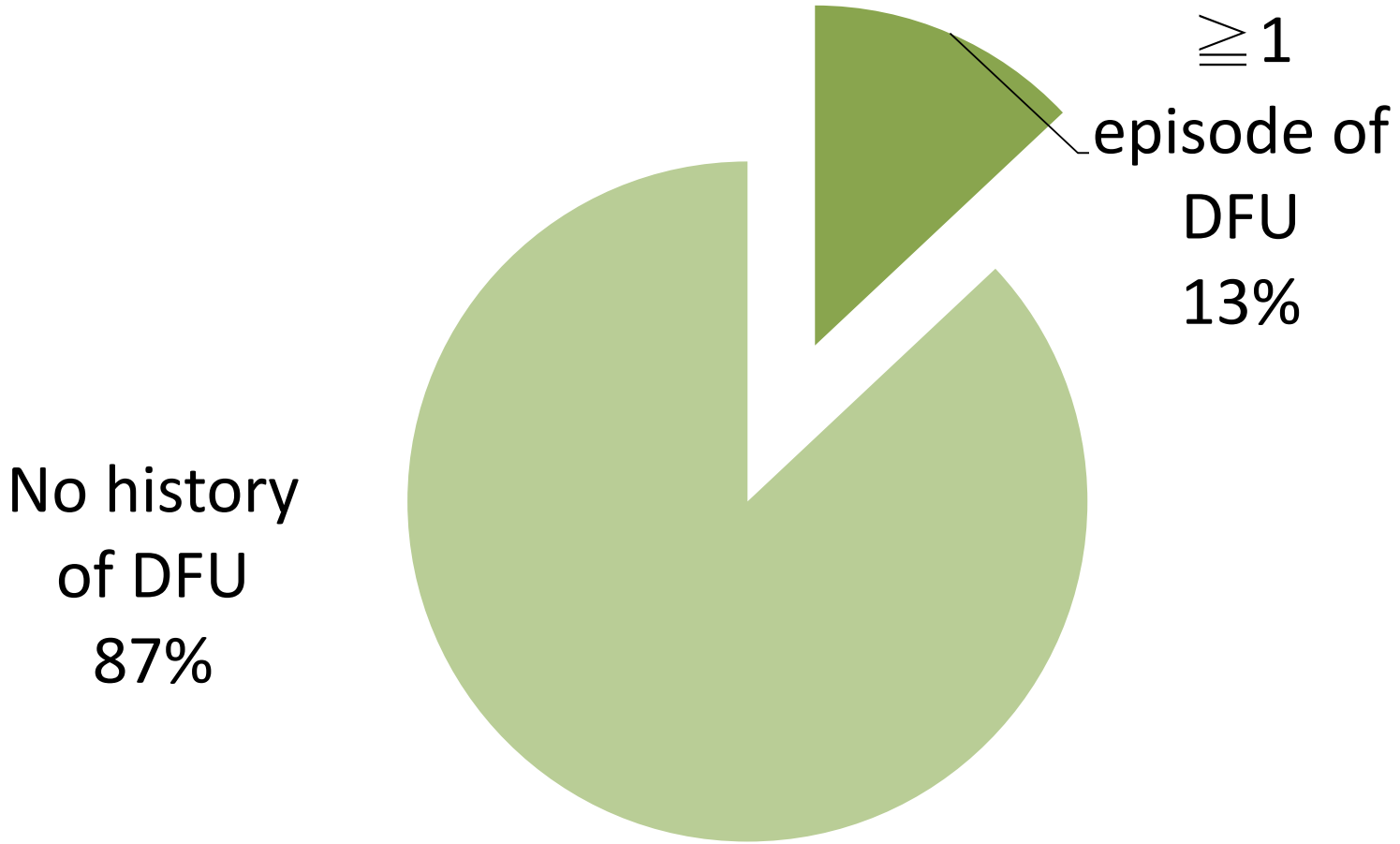
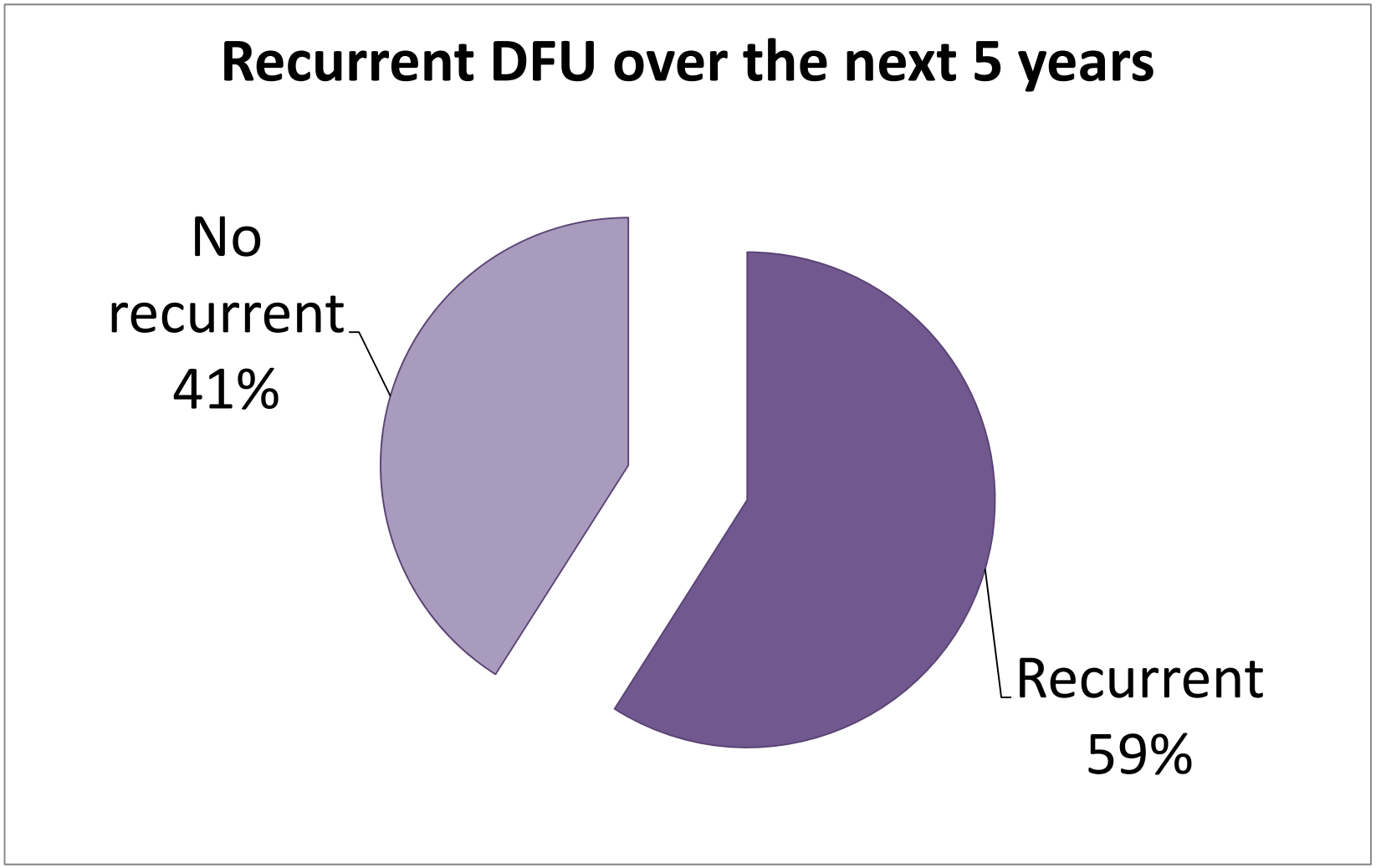
Content

- Background to the study
- Objectives
- Study method
- Results
- Discussion
- Conclusion and Recommendation

Prevalence of diabetic foot ulceration (DFU) in the world



(Al-Rubeaan et al., 2015; Danmusa et al., 2016; Dubsky et al., 2013; Mariam et al., 2017; Rice et al., 2014; Sarinnapakam et al., 2016; Sinharay et al., 2012; Zhang et al., 2016)



(Al-Rubeaan et al., 2015; Danmusa et al., 2016; Dubsky et al., 2013; Mariam et al., 2017; Rice et al., 2014; Sarinnapakam et al., 2016; Sinharay et al., 2012; Zhang et al., 2016)

- The risk of death for people with DFU is two folds higher than those who do not have an ulcerated foot in the diabetic population (Chammas et al., 2016).
- The five-year mortality rate is 40%-55% after the first occurrence of DFU (Jupiter et al., 2015; Robbins et al., 2008)

Impact of DFU

The occurrence of DFU is considered to distress the health related quality of life

- Negative impact in physical and psychosocial aspects in people with diabetes and their caregivers.

Enormous healthcare cost in managing DFU, diabetic related lower extremity amputation (LEA):

- ↑medical and financial burden to our healthcare system

(Driver *et al.*, 2010; Stockl *et al.*, 2004)

International guidelines on DFU prevention

NICE National Institute for Health and Care Excellence

Diabetic foot problems: prevention and management

NICE guideline
Published: 26 August 2015
nice.org.uk/guidance/ng19

NICE, 2015

IWGDF Guidance on the prevention of foot ulcers in at-risk patients with diabetes

Prepared by the IWGDF Working Group on Prevention of Foot Ulcers

Recommendations
Introduction
Recommendations and Rationale
Key contri
Reference

Authors
S. A. Bus[1]; J. J. van Netten[2]; L. A. Lavery[3]; M. Monteiro-Soares[4]; A. Rasmussen[5]; Y. Jubiz[6]; P. E. Price[7]; on behalf of the International Working Group on the Diabetic Foot (IWGDF)

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International Workgroup on the Diabetic Foot, 2015

Reviews/Commentaries/ADA Statements
TASK FORCE REPORT

Comprehensive Foot Examination and Risk Assessment

A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists

Andrew J.M. Boulton, MD, FRCP[1,2]
David G. Armstrong, DPM, PhD[3]
Stephen F. Albert, DPM, CFED[4]
Lawrence A. Lavery, DPM, MPH[9]
Joseph W. LeMaster, MD, MPH[10]
Joseph L. Mills, Sr., MD[11]

foot problems is the first step in preventing such complications, this report will focus on key components of the foot

American Diabetes Association, 2008

Clinical trigger

Low risk DM foot:
- Annual / biennial DM foot screening
- DM foot care education

At risk DM foot:
- Annual DM foot screening
- DM foot care education
- Preventive treatment

High risk DM foot:
- Specialized care for foot ulceration (advanced wound care technologies and products) / foot protection (orthotics etc)
- DM foot care education

(NICE, 2015)

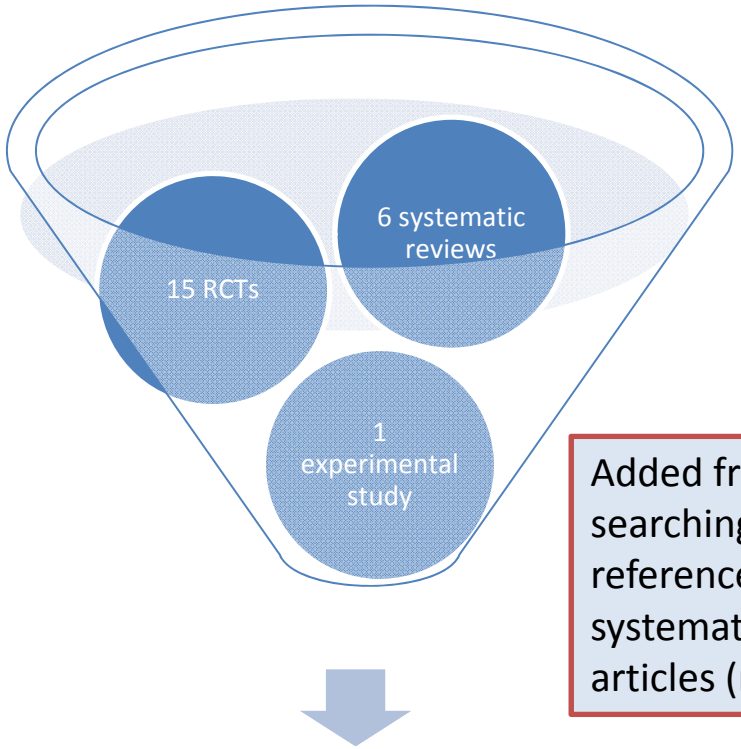
Despite the availability of various national guidelines, clinical pathway and protocol of managing DM foot → **Still high DFU or LEA rate** 2005 vs 2010)

(Hicks et al., 2014)

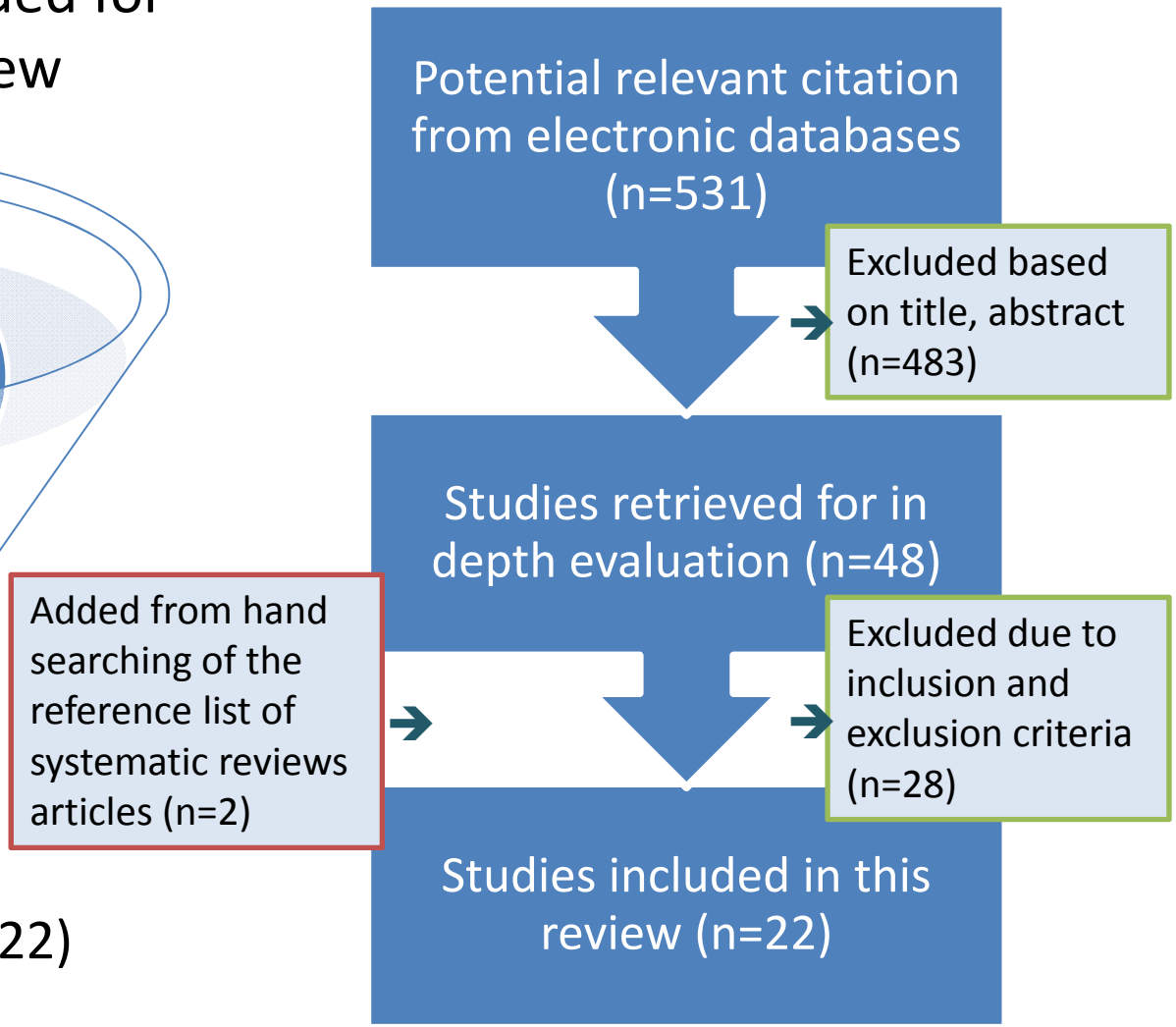
Diabetic foot care (DFC) education is considered as one of cornerstone of DM foot protection…

Summary of existing knowledge – Effectiveness of diabetic foot care education

22 articles were included for integrated review



Included studies (n=22)



Summary of existing knowledge – Effectiveness of diabetic foot care education

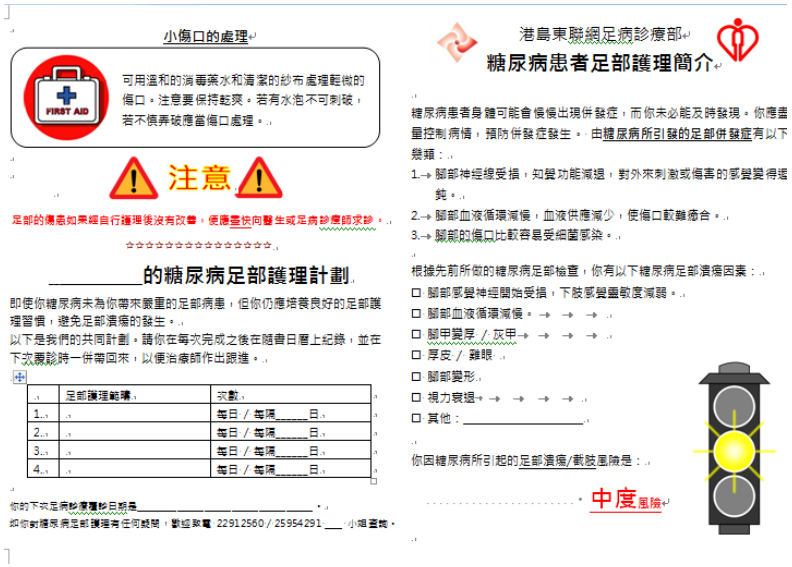
- Key components and delivery format of DFC education identified from current available evidence
  - Contents based on national guidelines, e.g., NICE, ADA, IWGDF
    - Delivery format: Individual counseling (n=10) session VS group educational class (n=5) (class size 6 to 30).
    - Professional involvement: depending on the availability of resources and expertise of staff e.g., nurse, podiatrist.

- Key outcome parameters for evaluating DFC education interventions:
  - improving diabetic foot care knowledge,
  - promoting self-care behavior,
  - enhancing self-efficacy,
  - reduction in DFU and LEA in people with diabetes

- However, effectiveness on DFC outcomes among reviewed studies varied and are inconsistent

Still lack of robust evidence to support the effectiveness of diabetic foot care education in various systematic reviews

(Dorresteijn *et al.*, 2014; Singh *et al.*, 2005; Valk *et al.*, 2002)



小傷口的處理

可用溫和的消毒藥水和清潔的紗布處理輕微的傷口。注意要保持乾爽。若有水泡不可刺破，若不慎弄破應當傷口處理。

注意

足部的傷患如果經自行護理後沒有改善，便應盡快向醫生或足病診療師求診。

_____的糖尿病足部護理計劃

即使你糖尿病未為你帶來嚴重的足部病患，但你仍應培養良好的足部護理習慣，避免足部潰瘍的發生。

以下是我們的共同計劃。請你在每次完成之後在隨書日曆上紀錄，並在下次覆診時一併帶回來，以便治療師作出跟進。

	足部護理範疇	次數
1.		每日 / 每隔_____日
2.		每日 / 每隔_____日
3.		每日 / 每隔_____日
4.		每日 / 每隔_____日

你的下次足病診療覆診日期是_____。

如你的糖尿病足部護理有任何疑問，歡迎聯電 22912560 / 25954291 ___ 小姐查詢。

港島東聯網足病診療部

糖尿病患者足部護理簡介

糖尿病患者身體可能會慢慢出現併發症，而你未必能及時發現。你應盡量控制病情，預防併發症發生。由糖尿病所引發的足部併發症有以下幾種：

1. 腳部神經線受損，知覺功能減退，對外來刺激或傷害的感覺變得遲鈍。
2. 腳部血液循環減慢，血液供應減少，使傷口較難癒合。
3. 腳部的傷口比較容易受細菌感染。

根據先前所做的糖尿病足部檢查，你有以下糖尿病足部潰瘍因素：

- □ 腳部感覺神經開始受損，下肢感覺靈敏度減弱。
- □ 腳部血液循環減慢。→ → → →
- □ 腳甲變厚 / 灰甲 → → → →
- □ 厚皮 / 雞眼
- □ 腳部變形
- □ 視力衰退 → → → → →
- □ 其他：_____

你因糖尿病所引起的足部潰瘍/截肢風險是：

中度風險

良好的足部護理是日常生活中的重要一環，方法非常簡易，每天只要花幾分鐘時間便可完成。

腳甲

平日剪腳甲時，要沿著趾頭的形狀直剪，不要剪腳甲兩旁的角落下去。再用指甲銼磨滿兩旁的角位。

雞眼/ 厚皮

若發現腳上有雞眼或厚皮的情況，可用厚皮銼/浮水石輕薄，並向足病診療師求診。切勿用雞眼藥水/雞眼膠布或自行處理，以免做成損傷。

每天應小心檢查雙腳有否損傷，以便及早作出適當的處理。若視力欠佳可請他人協助。

每天用溫水(大約 40℃)及中性肥皂清潔雙腳，用手肘或溫度計測試水溫。

糖尿病患者雙腳皮膚較燥，應塗上潤膚膏以保持皮膚柔滑。腳跟部位要特別注意，慎防爆裂。

清潔後應用柔軟的毛巾將雙腳及腳趾縫徹底抹乾。

任何時間都不可赤腳走路。廚房、浴室等室內地方都應穿著拖鞋。

足癬(即香港腳)，足癬是皮膚的真菌感染，需及早找醫生或足病診療師治理，以免變成潰爛。

合適的鞋

- 鞋底有抗紋，能吸震與防跳
- 鞋頭深且闊，容許腳趾有足夠空間，避免腳趾壓損
- 鞋襯或腳墊貼設計，增加走路時的穩定性
- 鞋頭柔軟舒適，乾爽透氣
- 鞋底有抗紋，能吸震與防跳

買新鞋之後應每天只穿一段短時間，檢查雙腳有否因磨擦而紅腫。若雙腳給新鞋弄傷，表示鞋型並不適合，不宜再穿。

襪子不可太緊或彈力過強，以免影響血液循環；夏天要穿棉襪，冬天則穿羊毛襪保暖；每天應更換襪子。破爛的襪子不宜修補，以免擦傷皮膚。

A new person-centred DFC education guided by health-belief model was therefore designed with its effectiveness being evaluated.

Health belief model based DFC

糖尿病患者身體可能會慢慢出現併發症，而你未必能及時發現。你應盡量控制病情，預防併發症發生。 由糖尿病所引發的足部併發症有以下幾類：

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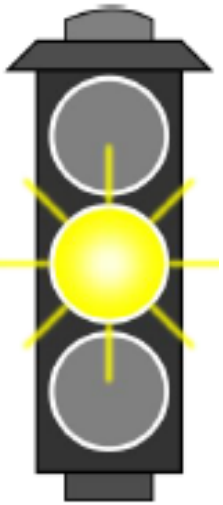
❶ Perceived susceptibility

根據先前所做的糖尿病足部檢查，你有以下糖尿病足部潰瘍因素：

- ☐ 腳部感覺神經開始受損，下肢感覺靈敏度減弱。
- ☐ 腳部血液循環減慢。
- ☐ 腳部變形
- ☐ 腳甲變厚 / 灰甲
- ☐ 視力衰退
- ☐ 厚皮 / 雞眼
- ☐ 其他：_____

❷ Perceived threats

如你有吸煙的習慣，請你盡早戒煙。尼古丁會影響你的下肢血液循環，嚴重者有可能要截肢。



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❸ Perceived severity

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- 鞋籠柔軟舒適，乾爽透氣
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每天應更換襪子。破爛的襪子不宜修補，以免補口刮傷皮膚。

4 Cues to action

小傷口的處理

可用溫和的消毒藥水和清潔的紗布處理輕微的傷口。注意要保持乾爽。若有水泡不可刺破，若不慎弄破應當傷口處理。

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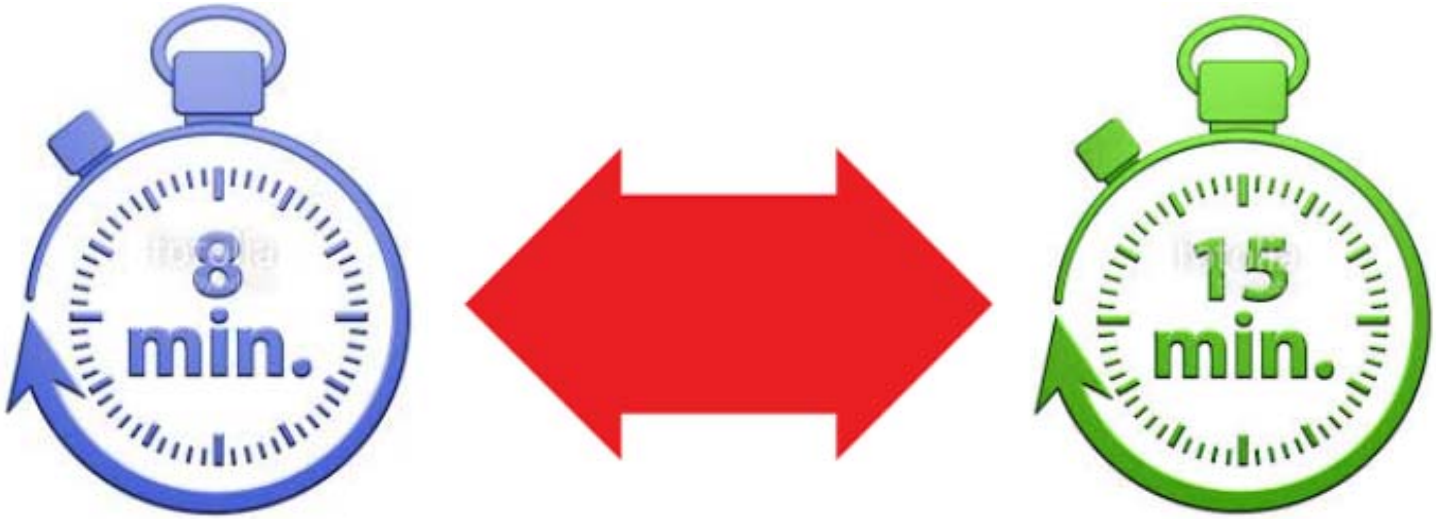
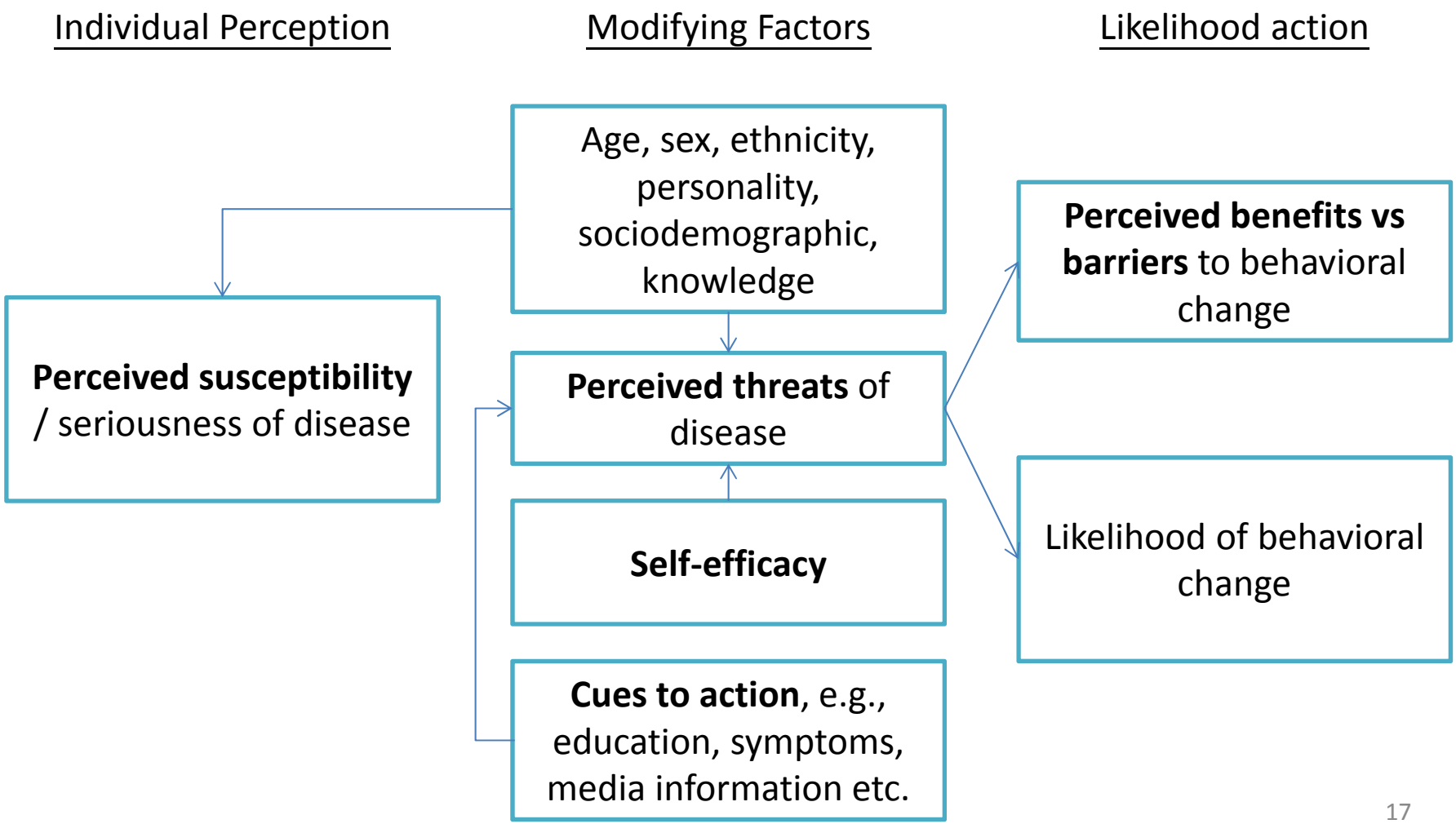
❺

Self-efficacy (Mutually agreed DFC plan by participants and podiatrist)



Individualized DFC education session lasts 8 to 15 minutes.
Conducted by podiatrist.

Health-belief Model (Rosenstock and Becker, 1988)



Objectives:

- To evaluate the effect of DFC education programme which is guided by health-belief model on self-efficacy and foot care behavior in people with diabetes.

Hypothesis (H_0):

- There is no significant difference on self-efficacy in diabetic foot care between experimental and control group.
- There is no significant difference on diabetic foot care behavior between experimental and control group.

Study methods

- Study design: multi-sites, 2-arm randomized control trial.
- Subjects recruitment:
  - New out-patient of Podiatry Department, Hong Kong East Cluster.
- Eligible participants were randomly assigned to one of the below groups:
  - Experimental Group (EG):
    - Receiving diabetic foot care education based on health-belief model
  - Control Group (CG):
    - Usual diabetic foot care education (Conventional didactic approach)

Study methods (continue)

- Randomization and allocation concealment:
  - Computer-generated random numbers in sealed opaque envelops to assign control / intervention sequence in blocks of two by an independent personnel
- Researchers' blinding
  - Outcome measurements were collected by trained data collectors who were blinded to group assignment

Sample size calculation

- Corbett (2003):
  - Effect size for evaluating the self-efficacy in diabetic foot care behavior and foot care behavioral change were 0.37 and 0.43 respectively.

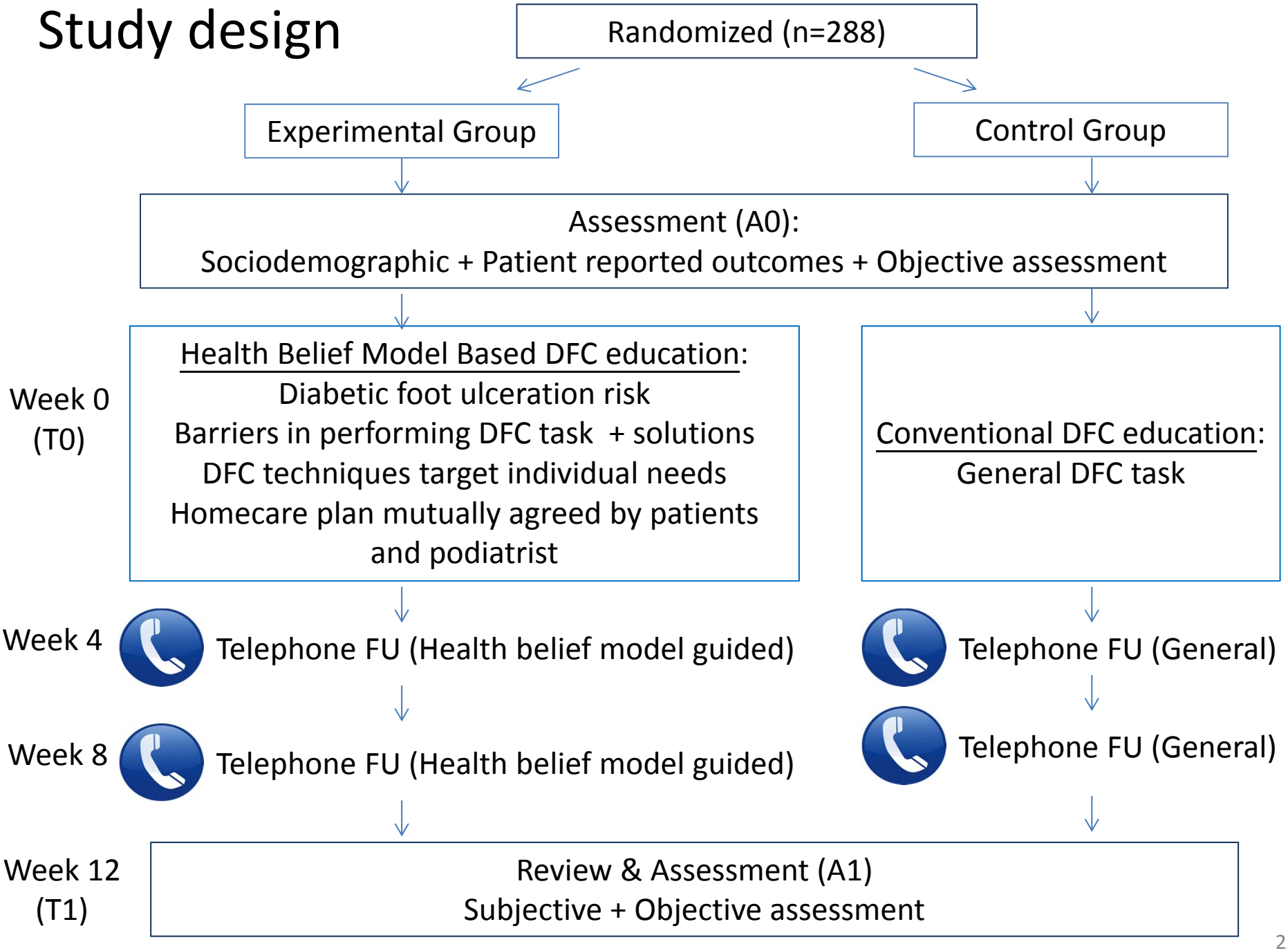
→ Estimation: 115 participants per group

  - effect size of at least 0.37 on any outcome between the intervention and control groups at a post intervention time point with 80% power at 5% level of significance, assuming there is no between-group difference on the outcomes at the baseline after randomization.

- Attrition rate of 20% (Corbett, 2003)

144 participants per group

Study design



Sampling

Inclusion criteria:

- **Never** attend Podiatry Service before
- Age 18 or above
- **Type 2 diabetes** (on drugs / insulin / mixed)
- Able to read Chinese and speak Cantonese
- ADL independent (Modified BI $\geqq$ 85)

Exclusion criteria:

- **Acute foot and ankle conditions** includes ingrown toenail, paronychia, cellulitis
- **Any lower extremities amputation**
- Old aged home residents
- Cognitive impairments (AMT <6)
- Known psychiatric illness
- Both hands unable to reach feet
- Visual impairments that inhibit individuals to perform foot care independently
- Currently undergoing anti-cancer treatment
- On haemodialysis / peritoneal dialysis

Outcome measures (1)

- Sociodemographic data
- Clinical data including diabetes related data and co-morbidities.
- Subjective assessments (Patient reported outcomes)
  - Chinese Foot Care Confidence Scale (Chan & Sit, 2015)
  - Chinese Diabetic Foot Care Behavior Assessment (Chan & Sit, 2015)

Outcome measures (2)

Objective assessment: conducted by blinded assessor

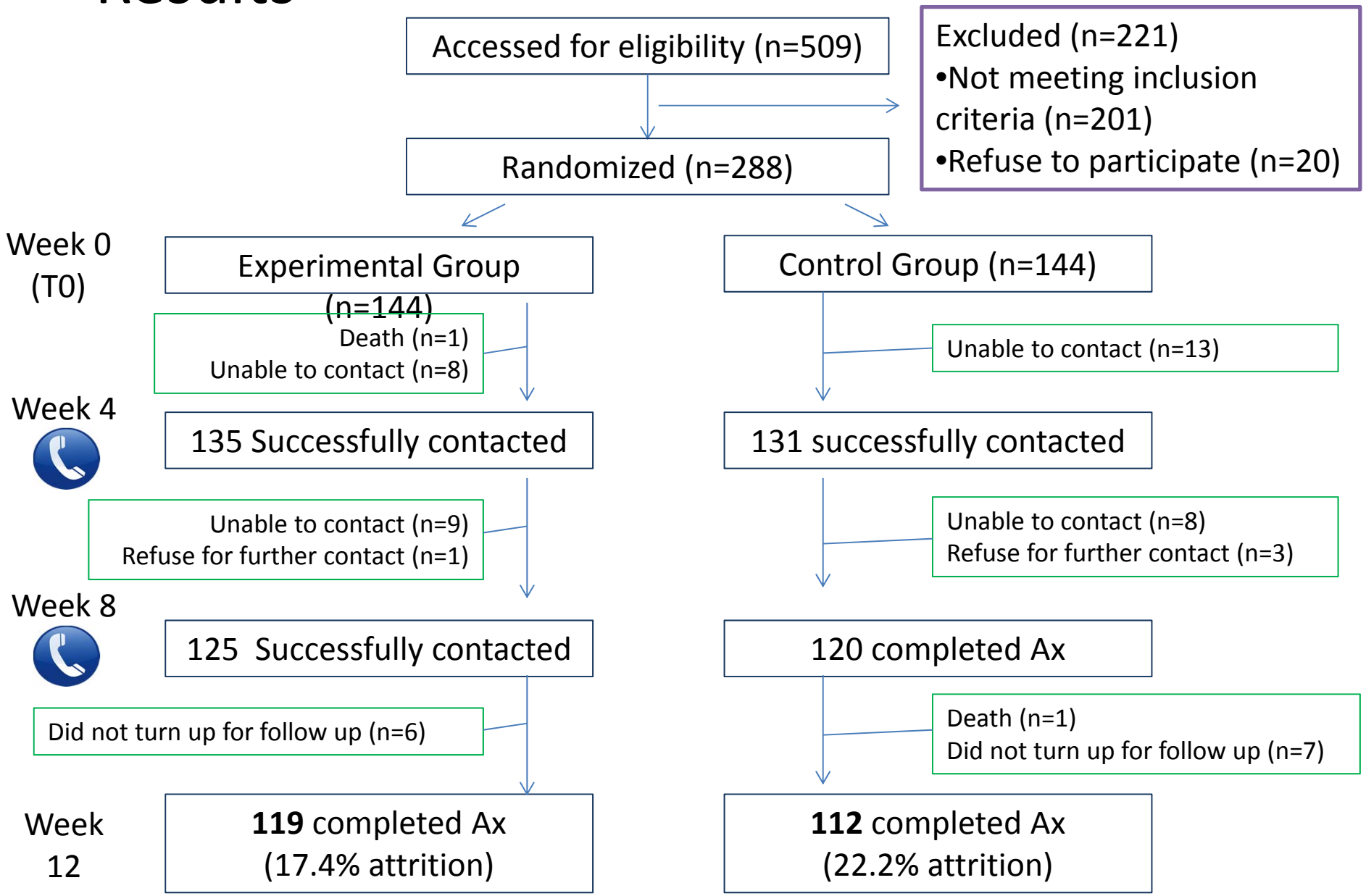
Hallux toenail cuticle to free edge index

Hallux toenail relative thickness index

Xerosis severity scale

Tinea Pedis Clinical Score

Results


Accessed for eligibility (n=509)
Excluded (n=221)
•Not meeting inclusion criteria (n=201)
•Refuse to participate (n=20)
Randomized (n=288)
Week 0 (T0)
Experimental Group (n=144)
Control Group (n=144)
Death (n=1)
Unable to contact (n=8)
Unable to contact (n=13)
Week 4
135 Successfully contacted
131 successfully contacted
Unable to contact (n=9)
Refuse for further contact (n=1)
Unable to contact (n=8)
Refuse for further contact (n=3)
Week 8
125 Successfully contacted
120 completed Ax
Did not turn up for follow up (n=6)
Death (n=1)
Did not turn up for follow up (n=7)
Week 12
119 completed Ax (17.4% attrition)
112 completed Ax (22.2% attrition)

Baseline Characteristics of patients: Sociodemographic data (1)

	Control Group (N=144)	Experimental Group (n=144)	*p*
Mean age (years)	69.3 (11.3)	69.3 (10.5)	0.36[T]
Sex			
Female	74 (51.4%)	66 (45.8%)	0.35[c]
Male	70 (48.6%)	78 (54.2)	
Education level			
Primary or below	59 (41.0%)	46 (31.9%)	0.28[c]
Secondary	63 (43.8%)	73 (50.7%)	
Tertiary or above	22 (15.3%)	25 (17.4%)	
Employment status			
Not working	104 (72.2%)	95 (66.0%)	0.51[c]
Part time	9 (6.3%)	12 (8.3%)	
Full time	31 (21.5%)	37 (25.7%)	

T=*T*-test was used ; C: Chi square was used.

Baseline characteristics of patients: Sociodemographic data (2)

	Control Group (N=144)	Experimental Group (n=144)	*p*
Cohabitation			
Lives alone	16 (11.1%)	27 (18.8%)	0.13[c]
Lives with family	128 (88.9%)	117 (81.3%)	
Mobility			
Walks unaided	119 (82.6%)	127 (88.2%)	0.17[c]
Walks with aids	25 (17.4%)	17 (11.8%)	
Smoking			
Yes	6 (4.2%)	9 (6.3%)	0.23[c]
Quitted	19 (13.2%)	28 (19.4%)	
Never	119 (82.6%)	107 (74.3%)	

C: Chi square was used.

Baseline characteristics of patients: Clinical data

	Control Group (n=144)	Experimental group (n=144)	*p*
Duration of DM (years)	10.5 (8.8)	10.9 (8.0)	0.56[T]
HbA1C (%)	7.2 (1.1)	7.2 (1.2)	0.43[T]
Diabetes treatment			
Insulin	2 (1.4%)	2 (1.4%)	0.94[c]
OHA	111 (77.1%)	113 (78.5%)	
Diet control	15 (10.4%)	12 (8.3%)	
Insulin + OHA	16 (11.1%)	17 (11.8%)	
Diabetes Foot Risk (American Diabetes Association, 2008)			
No LOPS, No PAD, No deformity	128 (88.9%)	126 (87.5%)	0.93[c]
LOPS ± deformity	15 (10.4%)	17 (11.8%)	
PAD ± LOPS	1 (0.7%)	1 (0.7%)	

T: *T*-test was used ; C: Chi square was used.

Baseline data of outcome measures

		Control Group (n=144)	Experimental Group (n=144)	p^T
Subjective Assessment				
Foot Care Confidence Scale		43.95 (8.34)	44.07 (8.17)	0.66
Diabetic Foot Care Behavior (Preventive)		0.60 (0.12)	0.60 (0.11)	0.50
Diabetic Foot Care Behavior (Damaging)		0.86 (0.09)	0.86 (0.10)	0.20
Objective Assessment				
Hallux toenail length (mm)	Right	14.34 (2.31)	14.32 (3.32)	0.74
	Left	14.35 (2.38)	14.34 (3.19)	0.46
Hallux toenail thickness (mm)	Right	18.28 (1.73)	18.59 (2.19)	0.14
	Left	18.22 (1.94)	18.51 (1.97)	0.52
Xerosis Severity Score	Right	1.69 (1.58)	1.97 (1.45)	0.43
	Left	1.68 (1.54)	1.97 (1.54)	0.87
Tinea Pedis Clinical Score		5.57 (4.67)	5.65 (4.69)	0.43

T: T-test was used .

Outcome measures at pre-test and post test between the control and experimental group (Subjective assessment)

	Control Group (mean)	Experimental Group (mean)
Foot Care Confidence Scale (Possible range: 12 to 60)		
Pre-test	43.95	44.07
Post-test	44.78	47.24
Change	0.84	3.17
Diabetic Foot Care Behavior Scale - Preventive (Possible range 0-1)		
Pre-test	0.60	0.60
Post-test	0.53	0.48
Change	-0.07	-0.12
Diabetic Foot Care Behavior Scale – Damaging (Possible range 0-1)		
Pre-test	0.86	0.86
Post-test	0.86	0.88
Change	0.01	0.02

Outcome measures at pre-test and post test between the control and experimental group (Objective assessment)

	Control Group (mean)		Experimental Group (mean)	
	Right	Left	Right	Left
Hallux toenail cuticle to free edge index (mm)				
Pre-test	14.35	14.35	14.32	14.34
Post-test	13.67	13.93	12.82	13.08
Change	-0.68	-0.42	-1.50	-1.26
Hallux toenail relative thickness index (mm)				
Pre-test	18.28	18.28	18.59	18.59
Post-test	18.13	18.07	18.01	18.05
Change	-0.15	-0.21	-0.58	-0.54
Xerosis Severity Scale (Possible range: 0 to 8)				
Pre-test	1.69	1.97	1.68	1.97
Post-test	1.18	1.28	1.18	1.24
Change	-0.51	-0.69	-0.50	-0.73

Outcome measures at pre-test and post test between the control and experimental group (Objective assessment) - Continue

	Control Group (mean)	Experimental Group (mean)
Tinea Pedis Clinical Score (Possible range: 0 to 20)		
Pre-test	5.57	5.65
Post-test	5.25	5.04
Change	-0.32	-0.61

	Control Group	Experimental Group	P^c
No. of participants reported foot wound developed during the study period:			
Tinea pedis related	1	3	
Eczema	2	2	
Cut during toenail care	2	0	
Total	5	5	0.92

C: Chi square was used.

Generalized estimating equation (GEE) models for the comparison of the outcome across time between experimental and control group

		B(95%CI)	*P*
Subjective Assessment			
Foot Care Confidence Scale		3.75 (1.52, 5.98)	0.001*
Diabetic Foot Care Behavior (Preventive)		-0.05 (-0.07, -0.02)	0.001*
Diabetic Foot Care Behavior (Damaging)		0.30 (0.01, 0.06)	0.018*
Objective Assessment			
Hallux toenail cuticle to free edge index	Right	-0.75 (-1.40, -0.10)	0.024*
	Left	-0.65 (-1.29, -0.01)	0.045*
Hallux toenail relative thickness index	Right	-0.44 (-0.88, 0.01)	0.057
	Left	-0.31 (-0.71, 0.10)	0.143
Xerosis Severity Score	Right	-0.18 (-0.55, 0.19)	0.347
	Left	-0.23 (-0.61, 0.15)	0.244
Tinea Pedis Clinical Score		-0.30 (-1.39, 0.80)	0.597

P<0.05 denotes statistically significant result

Diabetic foot care education using Health-belief model has:

Statistically significant effect:

- ↑ Self efficacy in DFC
- ↑ Preventive DFC behavior
- ↓ Damaging DFC behavior
- ↓ Toenail cuticle to free edge index

No statistically significant effect:

- Relative toenail thickness index
- Skin dryness on feet
- Tinea Pedis
- Foot wounds / ulcerations development

- Consistent with previous studies:
  - ↑Self efficacy in DFC (Corbet, 2003)
  - ↑DFC behavior (Borges & Ostwald, 2008; Lincoln et al., 2008)
- Inconsistent with previous studies:
  - Foot appearance (Bloomgarden et al., 1987)

- Possible reasons for no significant difference in objective assessment:
  - No gold standard in measuring toenail thickness
  - Management of dry skin:
    - Relative humidity varies across the year
    - Take time
  - Management of tinea pedis
    - ? Efficacy of topical antifungal available
    - Usually takes >12weeks for improvement shown.

Clinical significance

- Health-belief model and diabetic foot care education:
  - Easy and quick to adopt in busy clinical setting
  - Emphasize on person centered
  - Identify the individual perception and modifiable factors → intervene accordingly
  - Not much extra resources are required

- The results of this study could shed light to existing diabetic foot protection, not only limited to diabetic nurses and podiatrists, but also other professions in the trans-disciplinary team could benefit from this.

Conclusion

- The person-centred diabetic foot care education using health belief model was found beneficial to people with diabetes in terms of DFC efficacy and behavior.
- Clinician should review their current DFC education program and consider to adopt person-centred approach to advocate the importance of DFC and DFU prevention.

Way forward

- Worth to evaluate the lasting effect of this person-centred based DFC education.
- Implement in high risk group of diabetic foot ulceration
- ?Train Patient Care Assistants to deliver the education content.

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