Effectiveness of Home-based Family Caregiver-delivered Aromatherapy Programme for Older Persons with Behavioural and Psychological Symptoms of Dementia: Study Protocol of Randomized Controlled Trial

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Contents

Introduction

Introduction

BPSD

- Behavioural and Psychological Symptoms of Dementia (BPSD) is an umbrella term refers to a diverse range of signs and symptoms of "disturbed perception, thought content, mood, or behaviour that frequently occur in patients with dementia" (Finkel et al., 1997, p. 1060)
- Up to 100% of older persons with dementia (PWD) exhibit at least one sign and symptom of BPSD at any stage and any form of their illness (Haibo et al., 2013; Huang et al., 2017; Makimoto et al., 2019; Mukherjee et al., 2017; Vaingankar et al., 2017)

Adverse Impacts to PWD	Adverse Impacts to Caregivers
• ↓ social function and QoL (Wu et al., 2017) • ↑ susceptibility to abuse and neglect (Cooper & Livingston, 2014) • ↑ risk for physical harm (Feil et al., 2007) • Lead to hospital admissions and ultimately institutionalization (Beeri et al., 2002) • ↑ risk of mortality (Bransvik et al., 2020)	• ↑ caregiver burden (Baharudin et al., 2019) • ↑ caregiver distress (Hiyoshi-Taniguchi et al., 2018; Kales et al., 2015; Liu et al., 2017) More serious for informal/ family caregivers for PWD living at home

Effective management of BPSD could benefit both the PWD and the Caregivers !

Introduction

Aromatherapy

- Aromatherapy is one type of sensory stimulation interventions in the non-pharmacological strategies (Strom et al., 2016)
- A natural treatment uses essential oils through different approaches to balance, harmonize and promote the health of body, mind and spirit (International Federation of Aromatherapists, n.d.-a; Kusmerik, 1992; Price & Price, 1999)

Essential Oils

- The major components of aromatherapy
- Aromatic, volatile substance extracted from aromatic plants (Farrar & Farrar, 2020; International Federation of Aromatherapists, n.d.-b, n.d.-c).
- With complex chemical components → form chemical groups → produce therapeutic effects (Kayne, 2008)

圖片來源：https://www.nealsyardremedies.com/organic-lemon-essential-oil/12560628.html

Aromatherapy for BPSD Management

Introduction

- Has been clinically used for the management of BPSD for more than 20 years.
- Ranked with highest strength of recommendation due to good-quality patient-oriented evidence (Raetz, 2013)
- Improve PWD's BPSD symptoms, e.g. sleep and night-time behaviour (Takeda et al., 2017; Wolfe & Herzberg, 1996), agitation (Forrester et al., 2014; Yang, Wang, et al., 2016), depression (Yang et al., 2017; Yang, Wang, et al., 2016) , and aggressive behaviours (Alzheimer's Society, 2020; Lee, 2005)
- Improve PWD's QoL (Ballard et al., 2002)
- Decrease caregivers' burden (Turten Kaymaz & Ozdemir, 2017) and distress (Mascherona et al., 2020; Turten Kaymaz & Ozdemir, 2017)

Aromatherapy for BPSD Management

Introduction

Dementia and Geriatric Cognitive Disorders Extra

Systematic Review

Dement Geriatr Cogn Disord Extra 2021;11:273–297
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Effectiveness and Safety of Aromatherapy in Managing Behavioral and Psychological Symptoms of Dementia: A Mixed-Methods Systematic Review

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- 22 Quantitative Studies
  - 12 RCTs
  - 10 quasi-experimental studies
- 2 Qualitative Studies

Aromatherapy, especially in the inhalation approach, is a potentially safe and effective strategy for BPSD management.

More structuralized and comparable studies with sufficient sample size, adherence monitoring, and a sound theoretical basis could be conducted to obtain conclusive findings regarding the effectiveness of aromatherapy in BPSD management.

(Li et al., 2021)

Service Gap in Hong Kong

以愛心服事關懷 | With Love, We Serve and Care

新聞稿 2013 年 10 月 24 日

香薰治療與認知障礙症

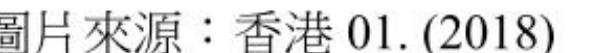
隨着人口持續老化，香港人人均壽命延長，估計在 2039 年，本港認知障礙症患者數目料急增至 33 萬人。

目前，醫學界仍未有任何方法可完全根治腦退化症疾病，對於預防認知障礙症的方法亦不多。基督教靈實協會(靈實)一直希望引入多方面的自然療法來幫助患有認知障礙症的長者，當中包括有香薰治療。靈實的臨床香薰治療師認為，香薰精油有助平靜患有認知障礙症長者的不安情緒。

圖片來源：基督教靈實協會. (2013)

【認知障礙症】香薰療法助患病長者改善情緒　保良局納入安老服務

圖片來源：香港 01. (2018)



渣打香港 150 週年慈善基金長者智晴坊

香薰精油應用有效
改善情緒及幫助睡眠

香薰治療對於認知障礙症患者心身療效最為顯著。透過吸入天然香氣分子，可令腦神經釋放開心荷爾蒙，從而提升或安撫情緒，令用者在日

香健會香薰治療文憑導師
葉香薰治療創辦人

Settings	Deliverers
☑ Some residential homes	☑ Aromatherapist
☑ Some day care centers for elderly	☑ Trained healthcare worker and nurses
☒ Home-based setting	☒ Family caregivers

(Po Leung Kuk, 2019, 2020; The Hong Kong Polytechnic University, 2019)

> 80% HK dementia population living at home (Yu et al., 2012)

→ A need for a **home-based family caregiver-delivered** aromatherapy programme for PWD with BPSD

Study Protocol

Aim and Objectives

Aim

Develop and evaluate the effectiveness of a home-based family caregiver-delivered aromatherapy programme for BPSD management.

Objectives

Evaluate the effectiveness of the aromatherapy programme in:

1. Reducing the severity of BPSD symptoms for PWD
2. Improving quality of life (QoL) for PWD
3. Decreasing family caregivers' distress
4. Decreasing family caregivers' burden

Study Design

RCT
(2-armed parallel design)

Process Evaluation

PWD and Family Caregiver Dyads

Randomization

Intervention Group | Control Group
1 : 1

Assessments: Baseline + Post intervention/ control period

Process evaluation during and after intervention

Consecutive Process

Participants

Target Population

PWD living at homes in Hong Kong, and their family caregivers.

Sampling Criteria - Inclusion Criteria

PWD	Family Caregiver
1) 60-year-old or above 2) Residence at home 3) Diagnosis of dementia of any type and stage of severity 4) Presenting with at least one symptom of BPSD in previous one month before the study 5) Understand Cantonese or Mandarin	1) Relative provide unpaid daily care to PWD at home 2) Without change in caregiver for the previous one month and during the study period 3) Literate in Chinese, able to communicate with Cantonese or Mandarin

Participants

Sampling Criteria - Exclusion Criteria

Either PWD or Family Caregivers
1) PWD have received aromatherapy in the past one month 2) With other neurological or psychological diseases 3) Hate the smell of Lavender or Lavender essential oil 4) Allergy or discomfort after using Lavender essential oil 5) With a condition that is a contraindication to the use of Lavender essential oil (e.g. pregnant, breastfeeding, hypotension, exacerbation of asthma, epilepsy, G6PD etc.)

Participants

Study Protocol

Sample Size

- Previous similar studies:
  - Effect sizes (d_{ppc2}) = 0.674 - 0.763
  - Attrition = 0% -9%

(Fujii et al., 2008; Lin et al., 2007; Mascherona et al., 2020)

- This study:
  - d_{ppc2}= 0.674
  - Significance level = 0.05
  - Power = 80%
  - Attrition = 9%

Main Study: 80 PWD and 80 Caregivers

Pilot and Feasibility Study: 8 PWD and 8 Caregivers

G*Power 3.1.9.7

File Edit View Tests Calculator Help

Central and noncentral distributions | Protocol of power analyses

critical t = 1.99444

Test family: t tests

Statistical test: Means: Difference between two independent means (two groups)

Type of power analysis: A priori: Compute required sample size – given α, power, and effect size

Input Parameters	
Tail(s)	Two
Effect size d	0.674
α err prob	0.05
Power (1–β err prob)	0.8
Allocation ratio N2/N1	1

Output Parameters	
Noncentrality parameter δ	2.8595398
Critical t	1.9944371
Df	70
Sample size group 1	36
Sample size group 2	36
Total sample size	72
Actual power	0.8051448

Participants

Sampling Method

Voluntary sampling

- Non-probability sampling design (Setia, 2016)
- Study is advertised by the researcher, individuals who volunteer to participate and meet the sampling criteria are recruited (Murairwa, 2015; Setia, 2016)

家居香薰治療研究

香港中文大學研究團隊現誠邀患有認知障礙症／腦退化症的長者和家屬照顧者參與家居香薰治療研究，以探討家居香薰治療於改善認知障礙症／腦退化症的行為和心理症狀(BPSD)的效果。

研究形式：

- ❖ 由註冊護士香薰治療師上門進行評估，提供家居香薰治療指導和香薰治療物品
- ❖ 研究為期大約1個月, 費用全免
- ❖ 完成研究後, 可獲得禮券共面值港幣100元

參與者：

長者	家屬照顧者
✓ 60歲或以上	✓ 與長者同住的親人
✓ 於家裡居住	✓ 持續為長者提供免費的日常家居照顧
✓ 經醫生確診為患有認知障礙症/腦退化症	✓ 能讀寫中文，和以廣東話或國語溝通
✓ 能以廣東話或國語溝通	✓ 沒有任何不適合香薰治療的情況
✓ 沒有任何不適合香薰治療的情況	

了解詳情和報名:

https://cloud.itsc.cuhk.edu.hk/mycuform/view.php?id=1108866

Recruitment Poster

本研究已通過香港中文大學－新界東醫院聯網臨床研究倫理聯席委員會之審查

Participants

Recruitment Method

Recruitment poster with researcher' contact information and link/ QR code of online application form are used to advertise and recruit samples in different settings and media:

- Different social media, online communication tools
- Online support groups for the PWD's family caregivers.
- University mass mail
- Day care centers for the elderly or other organizations related to dementia care

- Consecutive samples are contacted by researcher for screening to confirm they have met sampling criteria

Recruited into the study

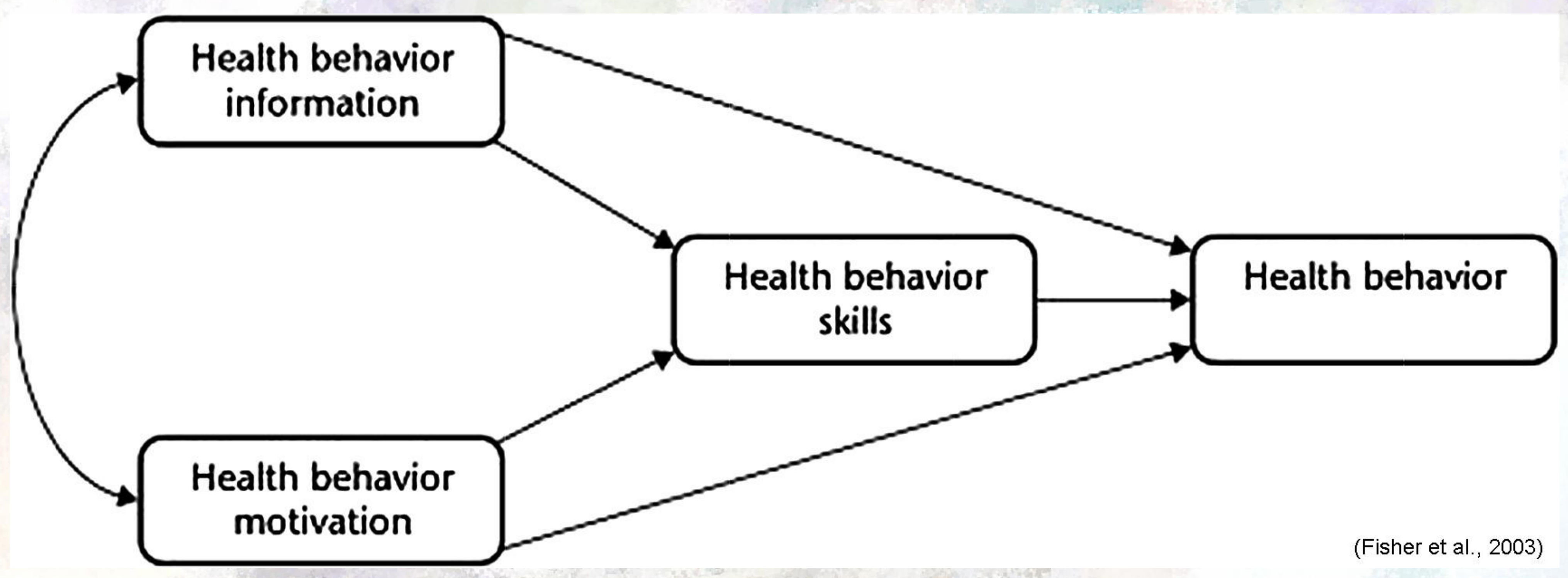
Intervention

Home-based Family Caregiver-delivered Aromatherapy Programme

Theoretical Framework of the Programme

Information-motivation-behavioural skills (IMB) model (Fisher & Fisher, 1992; Fisher et al., 2003)

- 3 fundamental psychological determinants associated with initiation and maintenance of health-related behaviour:



(Fisher et al., 2003)

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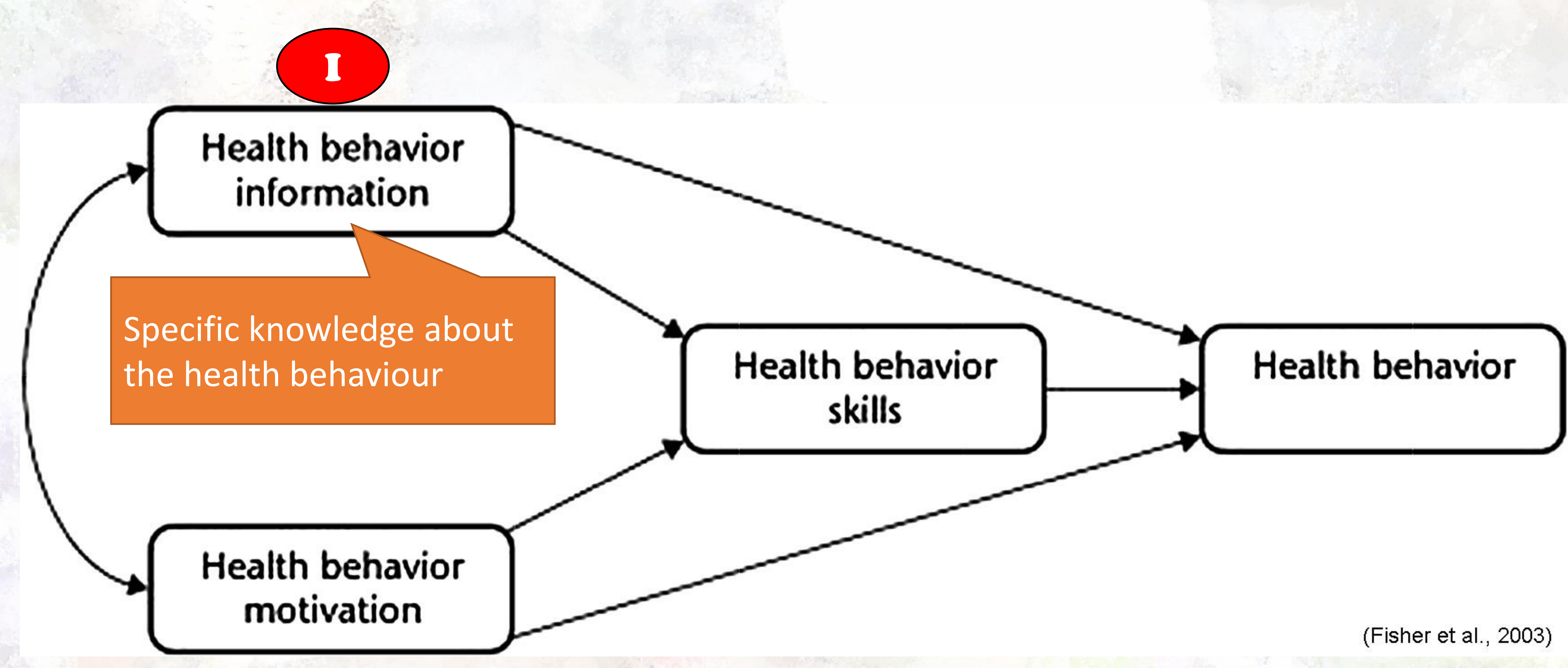
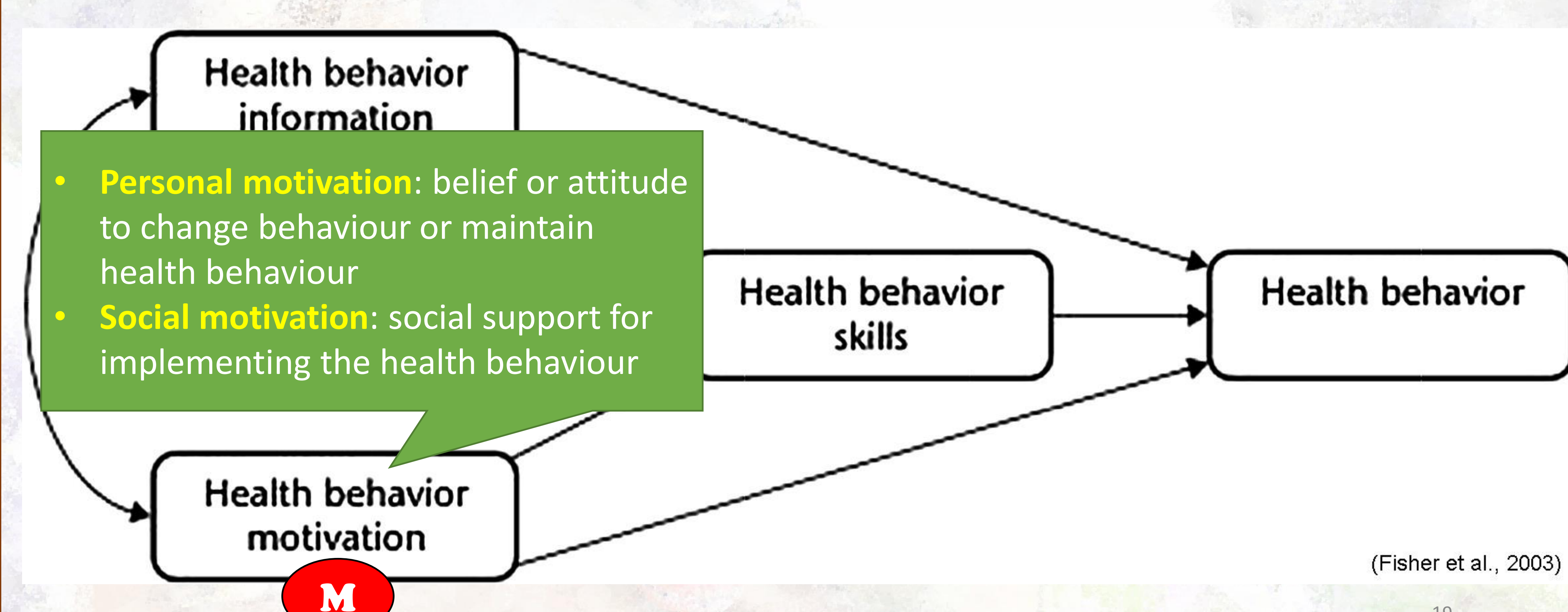
Study Protocol

Theoretical Framework of the Programme



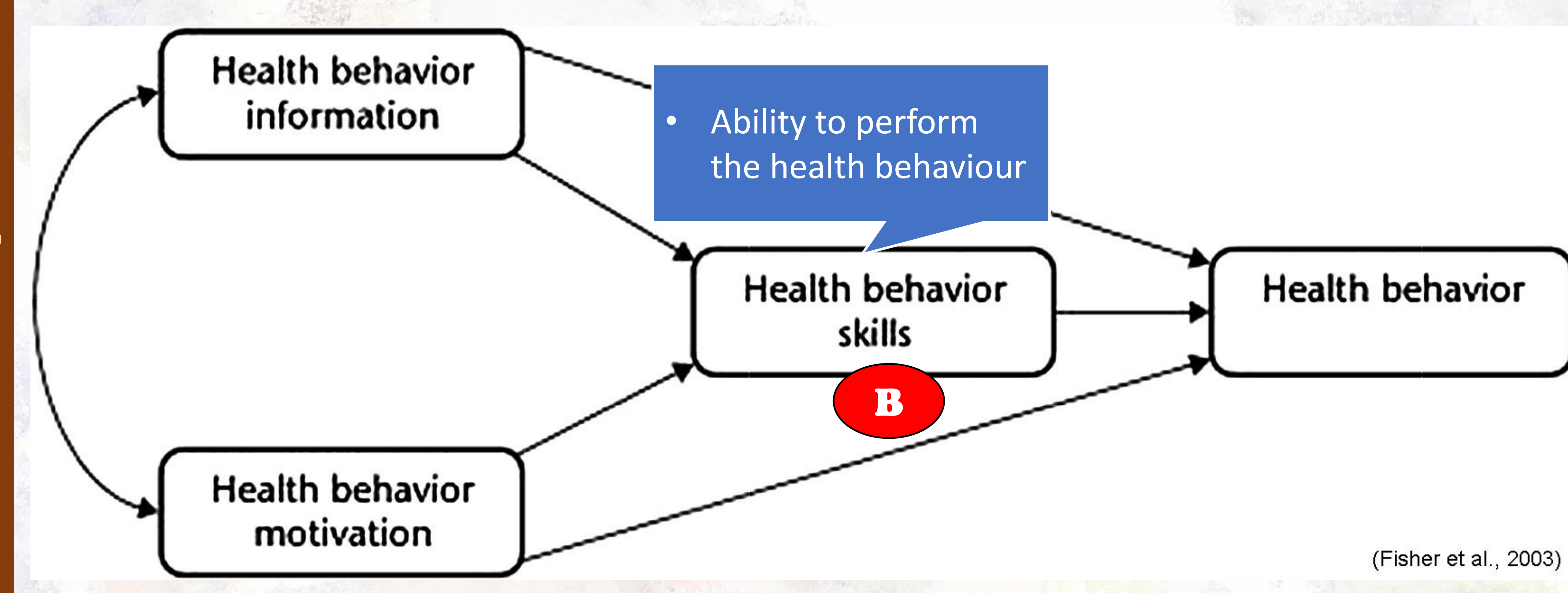
Intervention

Theoretical Framework of the Programme



Intervention

Theoretical Framework of the Programme



Intervention

Components of the Programme

Individualized face-to-face training to family caregivers (1 hr)

Aromatherapy intervention
Delivered by family caregivers
(3 weeks)

- Conducted in the participants' homes
- Written materials used in the programme are reviewed by aromatherapists, medical officers, registered nurses (Gen + Psy), and PWD's family caregivers.

Intervention

Individualized face-to-face training to family caregivers

By the researcher (RN [Gen], Aromatherapist [IFA, UK; NAHA 2019, USA; IAAMA 2019, Australia])

1) 30-minute education on BPSD and aromatherapy (IMB: I & Personal M)

香薰治療於 BPSD 的應用方法

經過對本地和海外相關研究報告的分析，總結出以下最簡單安全和易於應用的方法以供照顧者在家中為患有認知障礙症的長者施行香薰治療：

A. 治療方法

直接吸聞未經稀釋的精油，每日 2 次(相隔最少 4 小時)，每次吸聞 1 小時，為期 3 週。

B. 使用精油：薰衣草精油(*Lavandula angustifolia*)

俗名	薰衣草/ 真正薰衣草
植物學名	*Lavandula angustifolia*
別名	*Lavandula officinalis, Lavandula vera.*
主要化學成份和作用	➢ 乙酸沉香酯(~40%) →改善睡眠，安撫情緒，放鬆神經，抗痙攣 ➢ 沉香醇(~40%)→鎮定神經，改善睡眠
提取方法	以蒸餾法提取自花朵或整株植物
使用禁忌和注意事項	☹ 懷孕頭三個月避免使用，懷孕三個月後和哺乳媽媽要在香薰治療師指導下使用 ☹ 有降血壓效果，低血壓患者避免使用 ☹ 含有少量樟腦成份，蠶豆症和癲癇患者避免使用 ☹ 含有少量香豆素，使用薄血藥或阿士匹靈的人士避免使用

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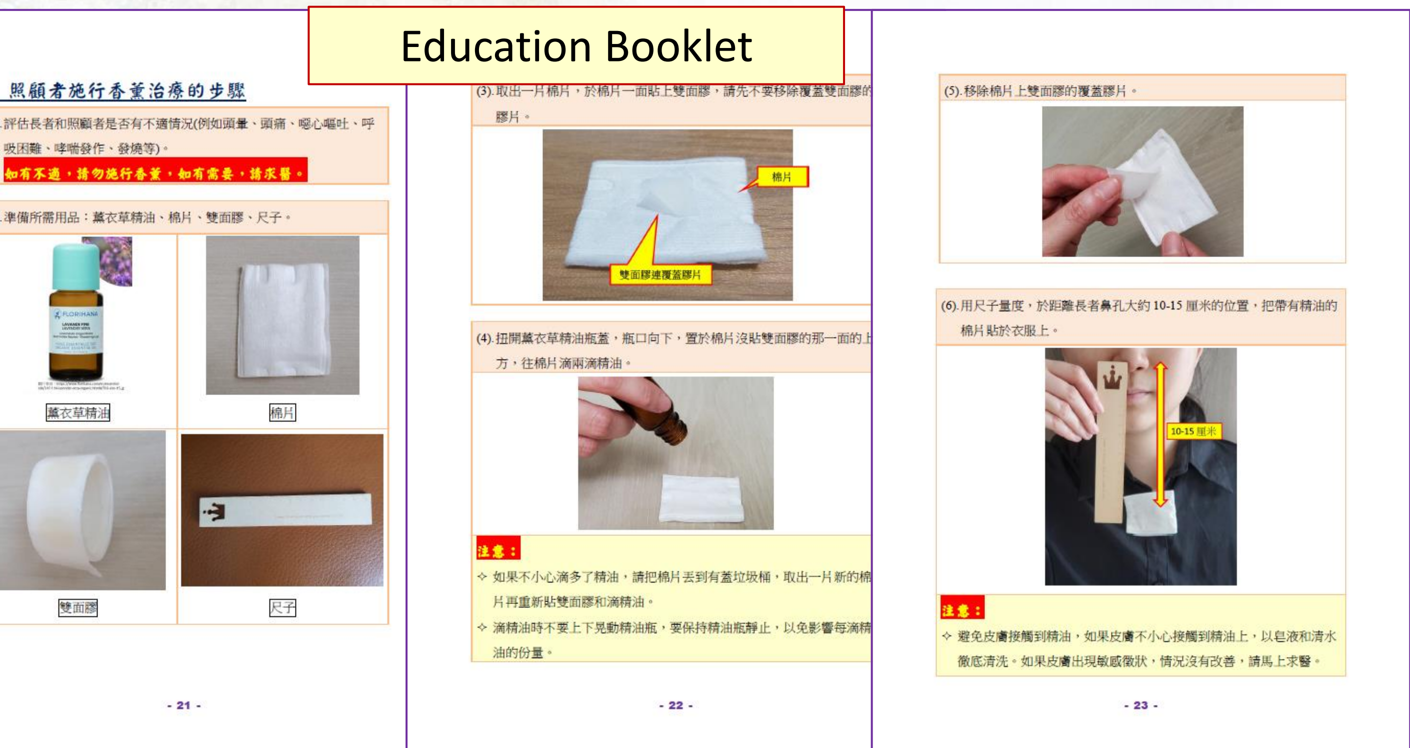
Intervention

Individualized face-to-face training to family caregivers

2) 15-minute skill demonstration by researcher and 15-minute return-demonstration by the family caregivers (IMB: B)
   - Skill assessment form is used to assess family caregivers' skill until all the items are passed

Education Booklet



Skill Assessment Form

理症狀的效果」研究

估表

參與者編號：________________ 評估日期：________________

- 照顧者必須要做到每一個技巧，總成績才能達到合格的要求
- 照顧者可作多次評估，直到合格
- ✓: 能夠做到/ ×: 未能做*

技巧 ＼ 評估次數			
(1). 評估長者和照顧者是否有不適情況(例如頭暈、頭痛、噁心嘔吐、呼吸困難、哮喘發作、發燒等)。			
(2). 準備所需用品：薰衣草精油、棉片、雙面膠、尺子。			
(3). 取出一片棉片，於棉片一面貼上雙面膠，先不要移除覆蓋雙面膠的膠片。			
(4). 扭開薰衣草精油瓶蓋，瓶口向下，置於棉片沒貼雙面膠的那一面的上方，往棉片滴兩滴精油。			
(5). 移除棉片上雙面膠的覆蓋膠片。			
(6). 用尺子量度，於距離長者鼻孔大約 10-15 厘米的位置，把帶有精油的棉片貼於衣服上。			
(7). 大約每 15 分鐘觀察一次長者的情況，以確認棉片沒有脫落，長者和照顧者都沒有不適情況出現。			
(8). 1 小時後，把棉片除下丟到有蓋垃圾桶，並確保已移除長者衣服上的雙面膠。			
(9). 正確填寫治療紀錄。			
總成績	☐合格 ☐再評估	☐合格 ☐再評估	☐合格 ☐再評估

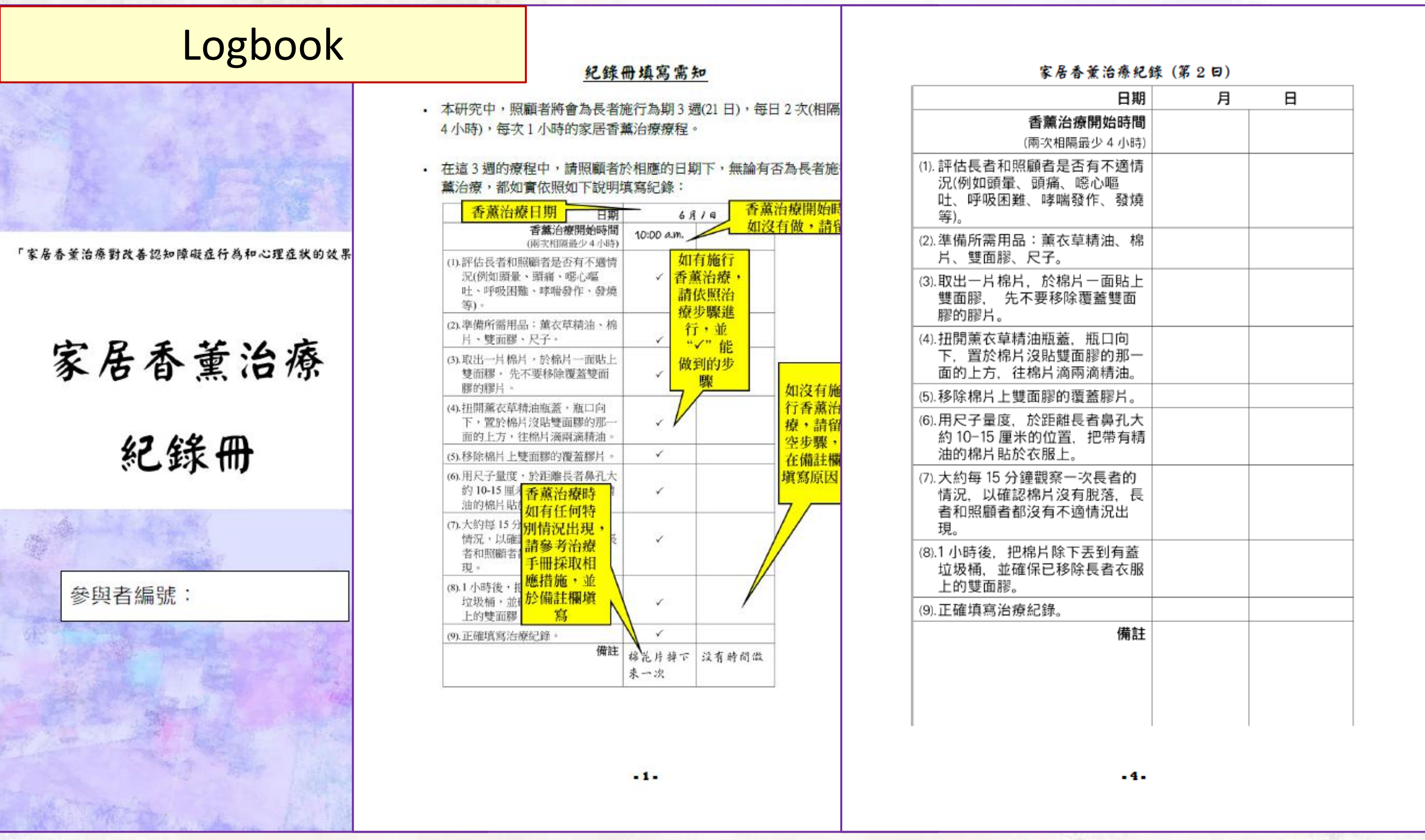
評核員姓名及簽署：________________

Intervention

Aromatherapy intervention delivered by family caregivers

- Education booklet, logbook, researcher’ contact information, and aromatherapy materials are provided to family caregiver to deliver and record 3-week aromatherapy intervention
- Regular consultation (IMB: Social M)

Logbook



「家居香薰治療對改善認知障礙症行為和心理症狀的效果

家居香薰治療

紀錄冊

參與者編號：

紀錄冊填寫需知

- 本研究中，照顧者將會為長者施行為期 3 週(21 日)，每日 2 次(相隔 4 小時)，每次 1 小時的家居香薰治療療程。
- 在這 3 週的療程中，請照顧者於相應的日期下，無論有否為長者施行香薰治療，都如實依照如下說明填寫紀錄：

香薰治療日期 日期	6月1日	
香薰治療開始時間 (兩次相隔最少 4 小時)	10:00 a.m.	
(1).評估長者和照顧者是否有不適情況(例如頭暈、頭痛、噁心嘔吐、呼吸困難、哮喘發作、發燒等)。	✓	
(2).準備所需用品：薰衣草精油、棉片、雙面膠、尺子。	✓	
(3).取出一片棉片，於棉片一面貼上雙面膠，先不要移除覆蓋雙面膠的膠片。	✓	
(4).扭開薰衣草精油瓶蓋，瓶口向下，置於棉片沒貼雙面膠的那一面的上方，往棉片滴兩滴精油。	✓	
(5).移除棉片上雙面膠的覆蓋膠片。	✓	
(6).用尺子量度，於距離長者鼻孔大約 10-15 厘米的位置，把帶有精油的棉片貼於衣服上。	✓	
(7).大約每 15 分鐘觀察一次長者的情況，以確認棉片沒有脫落，長者和照顧者都沒有不適情況出現。	✓	
(8).1 小時後，把棉片除下丟到有蓋垃圾桶，並確保已移除長者衣服上的雙面膠。	✓	
(9).正確填寫治療紀錄。	✓	
備註	棉花片掉下來一次	沒有時間做

香薰治療開始時間如沒有做，請留空

如有施行香薰治療，請依照治療步驟進行，並"✓"能做到的步驟

如沒有施行香薰治療，請留空步驟，在備註欄填寫原因

香薰治療時如有任何特別情況出現，請參考治療手冊採取相應措施，並於備註欄填寫

-1-

家居香薰治療紀錄（第 2 日）

日期	月	日
香薰治療開始時間 (兩次相隔最少 4 小時)		
(1).評估長者和照顧者是否有不適情況(例如頭暈、頭痛、噁心嘔吐、呼吸困難、哮喘發作、發燒等)。		
(2).準備所需用品：薰衣草精油、棉片、雙面膠、尺子。		
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(8).1 小時後，把棉片除下丟到有蓋垃圾桶，並確保已移除長者衣服上的雙面膠。		
(9).正確填寫治療紀錄。		
備註		

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Aromatherapy Materials

Intervention

Design of Aromatherapy Intervention for the Programme

Based on previous research evidence and guidelines

Intervention Approach - Inhalation

- Most common in previous studies (12 quantitative and 1 qualitative studies)
- 77%, n=10 → reduction in the severity of BPSD symptoms → n=6 (50%) reach statistical significance
- No adverse effect was reported

Essential Oil - Lavender (*Lavandula angustifolia*)

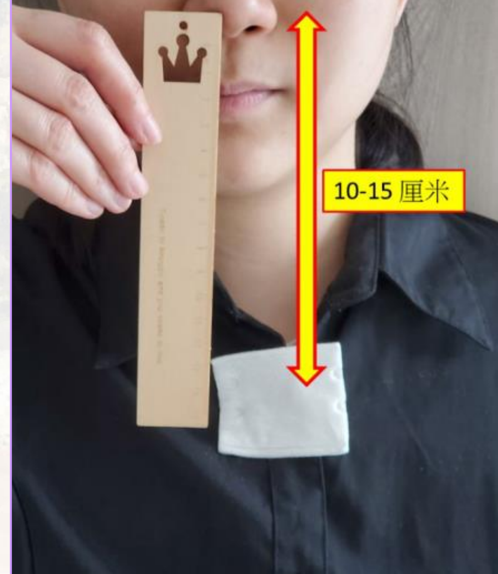
- Almost all previous studies with aromatherapy inhalation used Lavender essential oil (92%, n=12)

(Beshara & Giddings, 2002; Fu et al., 2013; Fujii et al., 2008; Gray & Clair, 2002; Holmes et al., 2002; Johannessen, 2013; Lin et al., 2007; Mascherona et al., 2020; Moorman Li et al., 2017; Ogun-Semore, 2019; Smallwood et al., 2001; Snow et al., 2004; Takeda et al., 2017)

Design of Aromatherapy Intervention for the Programme

Delivery Methods, Concentration and Dosage	
Direct inhalation	**Indirect inhalation**
▪ 10-15 cm from nose ▪ 2 drops undiluted essential oil ▪ No need to consider the size of area for dosage (Fujii et al., 2008; International Federation of Aromatherapists, n.d.; Snow et al., 2004)	▪ Use diffuser ▪ Concentration and dosage depends on the size of the area the participants stayed in, and the manufacturer's instruction (Holmes et al., 2002; Johannessen, 2013; Lin et al., 2007; Mascherona et al., 2020; Moorman Li et al., 2017; Smallwood et al., 2001)

More feasible and easy to control



- ✓ Direct inhalation
- ✓ 2 drops 100% Lavender essential oil in cotton pad/ clothes
- ✓ 10-15cm near the nose

Intervention

Design of Aromatherapy Intervention for the Programme

Frequency and Duration

Previous aromatherapy inhalation studies with significant improvement in BPSD	
Frequencies	4 / week - 4 / day
Each session	20 min - 2 hr
Duration	8 days – 8 weeks

This study	
Frequency	2 / day (at least 4 hr interval)
Each session	1 hr
Duration	3 weeks

Further Considerations:

- Aromatherapy inhalation up to 1 hr each time could provide significant and safe effect without causing harm to the cardiovascular system (European Society of Cardiology, 2012)
- Total elimination of essential oil chemicals from the body takes less than 4 hr (Kohlert et al., 2002; Kohlert et al., 2000; Li et al., 2018; Pavan et al., 2018)
- Prolonged use of same essential oil should be avoided to prevent overexposure and sensitization, and a break of at least 1 week was suggested after using the same essential oil for 2-3 wks (Becco, 2019; International Federation of Aromatherapists, 2018; Missouri Poison Center, 2017; Moore, 2016; National Association for Holistic Aromatherapy, 2021)

Control

Wait List Control

Baseline Assessment

No Intervention x 3 wks

Post-control Assessment

Aromatherapy Education
and Materials

Data Collection

For both Intervention and Control Group

Baseline Assessment (T0) (by researcher)

- PWD and Family Caregivers' Demographic and Clinical Data
- PWD's Severity of Dementia (HK-MoCA) (Wong et al., 2009)

- **Primary Outcomes:** PWD's Severity of BPSD (CNPI) (Leung et al., 2001)
- **Secondary Outcomes:** PWD's QoL (C-DEMQoL-Proxy) (Kuo et al., 2021) + Family Caregivers' Distress (CNPI) (Leung et al., 2001) + Family Caregivers' Burden (CZBI) (Chan et al., 2005)

Intervention/ Control (3 wks)

Post Assessment (T1) (by blinded research assistant nurse)

- **Primary Outcomes**
- **Secondary Outcomes**

HK-MoCA: Montreal Cognitive Assessment Hong Kong Version; CNPI: Chinese Versions of Neuropsychiatric Inventory; C-DEMQoLProxy: Chinese Version of Dementia Quality of Life Measure – Proxy; CZBI: Chinese version of Zarit Burden Interview

Data Collection

Process Evaluation for Intervention Group

During Face-to-face Training to Family Caregivers

Skill assessment form

During 3-week Family Caregiver-delivered Aromatherapy

Logbook	Regular Consultation

After 3-week Family Caregiver-delivered Aromatherapy

Semi-structured individual interview to family caregivers

Data Analysis

Quantitative Data

- Obtained from baseline and outcome assessments
- Statistical Package for Social Sciences (SPSS)
- Intention-to-treat (ITT), two-tailed tests, significance level 0.05 are employed
- Data-cleaning to identify and correct the error in data file
- Assess normality by skewness and kurtosis statistics and normal Q-Q plot
- Assess homogeneity of baseline data by independent-sample t-test, Mann–Whitney U test, Pearson chi-square test, or Fisher’s exact test depending on the type and normality of the data
- Assess effectiveness of intervention by generalized estimating equation (GEE) model

Data Analysis

Qualitative Data

- Obtained from consultation records, the remarks of the logbooks, and the post-intervention interviews of process evaluation
- The post-intervention individual interviews are audiotaped and transcribed verbatim
- Content analysis using Nvivo for coding and analysis

Ethical Considerations

- Have obtained ethics approval from the Joint CUHK-NTEC CREC
- Have clinical trial registration in ClinicalTrials.gov
- The participants are covered by clinical trial insurance
- In compliance with different ethical principles and guidelines
  - Respect for human dignity
  - Beneficence
  - Justice
  - Declaration of Helsinki (World Medical Association, 2018)
  - International Conference on Harmonisation-Good Clinical Practice (Good Clinical Practice Network, n.d.)
- Incentive (HK$100 coupons provide to each PWD-family caregivers dyads) is provided after completing all data collection to increase retention rate and compensate for the time spent

Significance & Progress

Significance of the Study

- Address the service gap in the use of aromatherapy for BPSD management in home-based setting
- Develop evidence-based aromatherapy programme for the community-dwelling PWD with BPSD in home-based setting, and to evaluate its effectiveness on both the PWD and the family caregivers
- The findings will serve as basis for recommendations on home-based aromatherapy intervention, and contribute to future research and practice related to aromatherapy for BPSD management.

Current Progress of the Study

This study is ongoing at the stage of consecutive participant recruitment and intervention delivery

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Thank you !