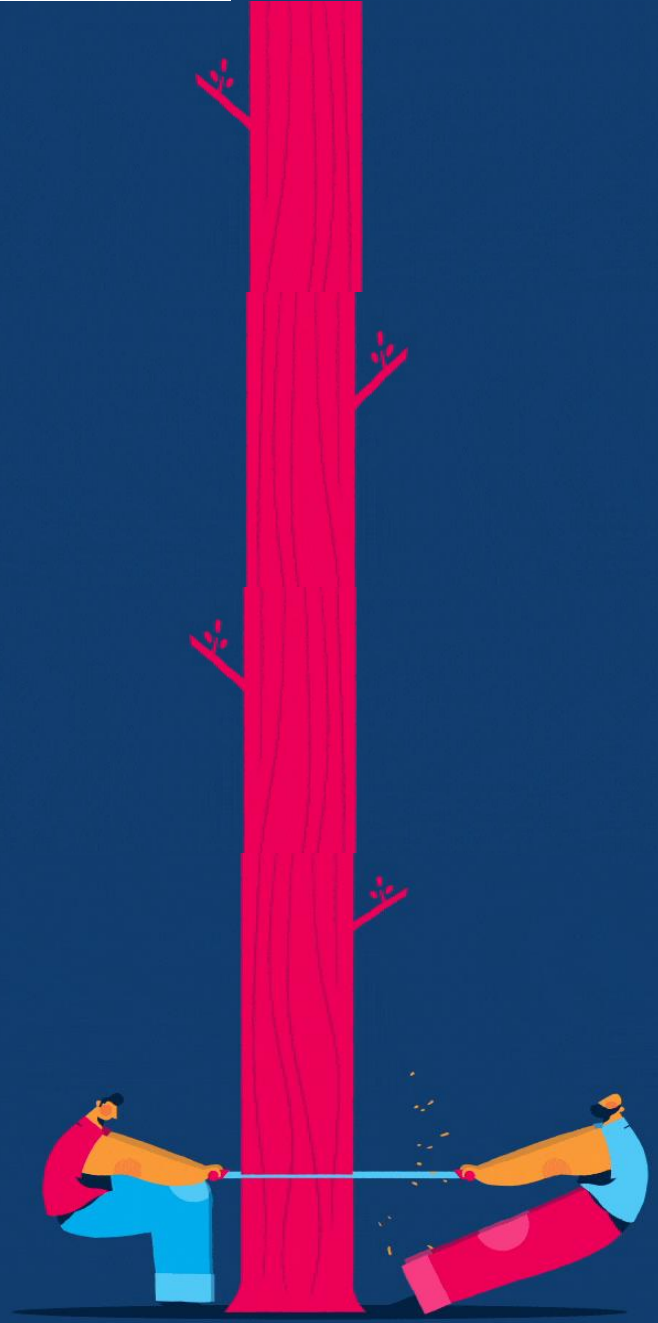
臨床試驗登記的重要性

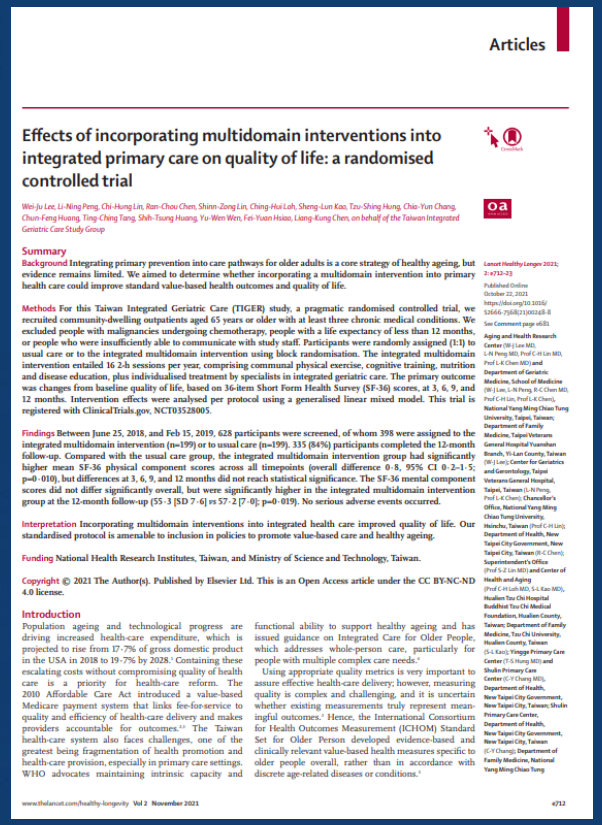
陳亮恭特聘教授

台北市立關渡醫院（北榮經營）院長

國立陽明交通大學醫學系特聘教授

Taiwan Integrated GERiatric Care Study (TIGER)





Articles

Effects of incorporating multidomain interventions into integrated primary care on quality of life: a randomised controlled trial

Wei-Ju Lee, Li-Ning Peng, Chi-Hung Lin, Ran-Chou Chen, Shinn-Zong Lin, Ching-Hui Loh, Sheng-Lun Kao, Tzu-Shing Hung, Chia-Yun Chang, Chun-Feng Huang, Ting-Ching Tang, Shih-Tsung Huang, Yu-Wen Wen, Fei-Yuan Hsiao, Liang-Kung Chen, on behalf of the Taiwan Integrated Geriatric Care Study Group

Summary

Background Integrating primary prevention into care pathways for older adults is a core strategy of healthy ageing, but evidence remains limited. We aimed to determine whether incorporating a multidomain intervention into primary health care could improve standard value-based health outcomes and quality of life.

Methods For this Taiwan Integrated Geriatric Care (TIGER) study, a pragmatic randomised controlled trial, we recruited community-dwelling outpatients aged 65 years or older with at least three chronic medical conditions. We excluded people with malignancies undergoing chemotherapy, people with a life expectancy of less than 12 months, or people who were insufficiently able to communicate with study staff. Participants were randomly assigned (1:1) to usual care or to the integrated multidomain intervention using block randomisation. The integrated multidomain intervention entailed 16 2-h sessions per year, comprising communal physical exercise, cognitive training, nutrition and disease education, plus individualised treatment by specialists in integrated geriatric care. The primary outcome was changes from baseline quality of life, based on 36-item Short Form Health Survey (SF-36) scores, at 3, 6, 9, and 12 months. Intervention effects were analysed per protocol using a generalised linear mixed model. This trial is registered with ClinicalTrials.gov, NCT03528005.

Findings Between June 25, 2018, and Feb 15, 2019, 628 participants were screened, of whom 398 were assigned to the integrated multidomain intervention (n=199) or to usual care (n=199). 335 (84%) participants completed the 12-month follow-up. Compared with the usual care group, the integrated multidomain intervention group had significantly higher mean SF-36 physical component scores across all timepoints (overall difference 0·8, 95% CI 0·2–1·5; p=0·010), but differences at 3, 6, 9, and 12 months did not reach statistical significance. The SF-36 mental component scores did not differ significantly overall, but were significantly higher in the integrated multidomain intervention group at the 12-month follow-up (55·3 [SD 7·6] vs 57·2 [7·0]; p=0·019). No serious adverse events occurred.

Interpretation Incorporating multidomain interventions into integrated health care improved quality of life. Our standardised protocol is amenable to inclusion in policies to promote value-based care and healthy ageing.

Funding National Health Research Institutes, Taiwan, and Ministry of Science and Technology, Taiwan.

Lancet Healthy Longev 2021; 2: e712–23

Published Online October 22, 2021 https://doi.org/10.1016/S2666-7568(21)00248-8

See Comment page e681

Aging and Health Research Center (W-J Lee MD, L-N Peng MD, Prof C-H Lin MD, Prof L-K Chen MD) and Department of Geriatric Medicine, School of Medicine (W-J Lee, L-N Peng, R-C Chen MD, Prof C-H Lin, Prof L-K Chen), National Yang Ming Chiao Tung University, Taipei, Taiwan; Department of Family Medicine, Taipei Veterans General Hospital Yuanshan Branch, Yi-Lan County, Taiwan (W-J Lee); Center for Geriatrics and Gerontology, Taipei Veterans General Hospital, Taipei, Taiwan (L-N Peng, Prof L-K Chen); Chancellor's Office, National Yang Ming Chiao Tung University, Hsinchu, Taiwan (Prof C-H Lin); Department of Health, New Taipei City Government, New Taipei City, Taiwan (R-C Chen); Superintendent's Office (Prof S-Z Lin MD) and Center of Health and Aging (Prof C-H Loh MD, S-L Kao MD), Hualien Tzu Chi Hospital Buddhist Tzu Chi Medical Foundation, Hualien County, Taiwan; Department of Family Medicine, Tzu Chi University, Hualien County, Taiwan (S-L Kao); Yongye Primary Care Center (T-S Hung MD) and Shulin Primary Care Center (C-Y Chang MD), Department of Health, New Taipei City Government, New Taipei City, Taiwan; Shulin Primary Care Center, Department of Health, New Taipei City Government, New Taipei City, Taiwan (C-Y Chang); Department of Family Medicine, National Yang Ming Chiao Tung

Introduction

Population ageing and technological progress are driving increased health-care expenditure, which is projected to rise from 17·7% of gross domestic product in the USA in 2018 to 19·7% by 2028.[1] Containing these escalating costs without compromising quality of health care is a priority for health-care reforms. The 2010 Affordable Care Act introduced a value-based Medicare payment system that links fee-for-service to quality and efficiency of health-care delivery and makes providers accountable for outcomes.[2,3] The Taiwan health-care system also faces challenges, one of the greatest being fragmentation of health promotion and health-care provision, especially in primary care settings. WHO advocates maintaining intrinsic capacity and functional ability to support healthy ageing and has issued guidance on Integrated Care for Older People, which addresses whole-person care, particularly for people with multiple complex care needs.[4]

Using appropriate quality metrics is very important to assure effective health-care delivery; however, measuring quality is complex and challenging, and it is uncertain whether existing measurements truly represent meaningful outcomes.[5] Hence, the International Consortium for Health Outcomes Measurement (ICHOM) Standard Set for Older Person developed evidence-based and clinically relevant value-based health measures specific to older people overall, rather than in accordance with discrete age-related diseases or conditions.[5]

樹林衛生所 鶯歌衛生所 鄭骨科診所

陽明交大附醫 北榮員山分院 花蓮慈濟門診

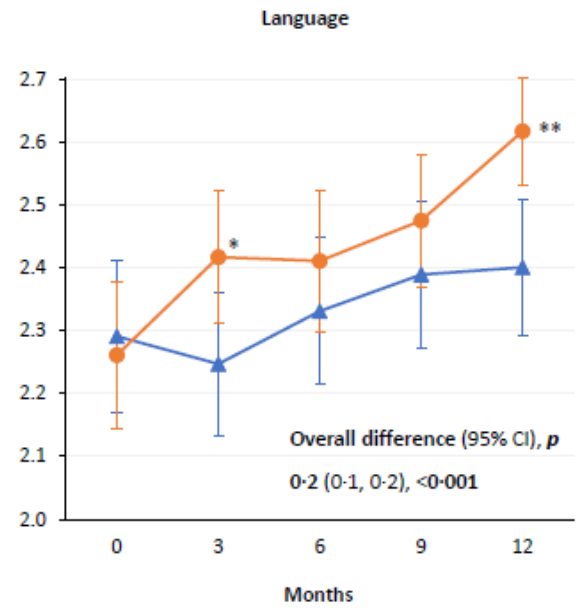
Lee WJ, et al. Lancet Healthy Longev. 2021;2(11):e712-e723.

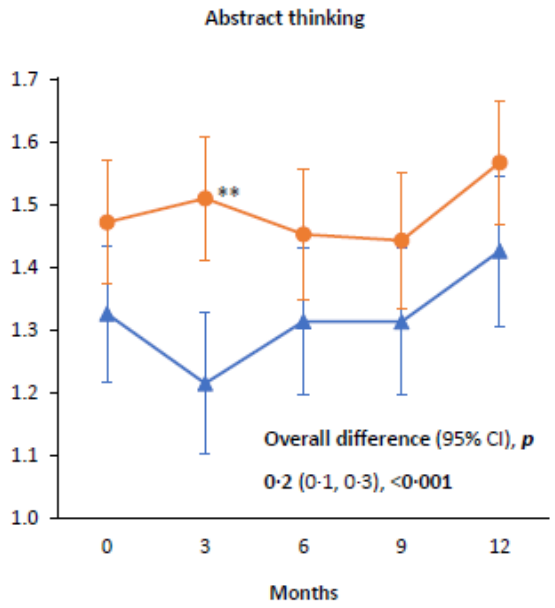
	Usual care		Integrated multidomain		p value for difference at follow-up timepoints	Overall difference	
	n/N (%) or mean (SD)	Change from baseline (95% CI)	n/N (%) or mean (SD)	Change from baseline (95% CI)		Between-group comparison*	p value
Global cognitive impairment (MoCA$_{ss}$ <26)							
Baseline	120/199 (60%)	..	114/199 (57%)	-	-	-	..
3 months	100/190 (53%)	..	78/194 (40%)	-	0·015	-	..
6 months	93/181 (51%)	..	73/192 (38%)	-	0·0060	-	..
9 months	77/171 (45%)	..	64/185 (35%)	-	0·049	-	..
12 months	59/157 (38%)	..	47/178 (26%)	-	0·028	0·5 (0·4 to 0·7)	<0·0001†
Individual MoCA domain scores							
Visuospatial							
Baseline	3·2 (1·6)	..	3·8 (1·3)	-	-	-	..
3 months	3·4 (1·5)	−0·2 (−0·4 to −0·1)	3·7 (1·4)	−0·1 (−0·3 to 0·0)	0·0088	-	..
6 months	3·3 (1·5)	−0·3 (−0·4 to −0·2)	3·7 (1·4)	−0·1 (−0·3 to 0·0)	0·013	-	..
9 months	3·6 (1·3)	−0·2 (−0·3 to −0·1)	3·8 (1·3)	−0·1 (−0·3 to 0·1)	0·10	-	..
12 months	3·8 (1·3)	0·3 (0·1 to 0·5)	3·9 (1·1)	0·1 (0·0 to 0·3)	0·36	0·0 (0·0 to 0·1)	0·29‡
Naming							
Baseline							
3 months							
6 months							
9 months							
12 months							0·0003†
Concentration							
Baseline							
3 months							
6 months							
9 months							
12 months							0·0001†
Language							
Baseline							
3 months							
6 months							
9 months							
12 months							0·0001†
Abstract thinking							
Baseline							
3 months							
6 months							
9 months							
12 months	1·4 (0·8)	0·0 (−0·1 to 0·1)	1·6 (0·7)	0·1 (0·0 to 0·2)	0·0074	0·2 (0·1 to 0·3)	<0·0001†
Delayed recall							
Baseline	2·3 (1·8)	..	2·3 (1·7)	-	-	-	..
3 months	2·9 (1·8)	−0·1 (−0·4 to 0·1)	3·4 (1·6)	−0·4 (−0·6 to −0·2)	0·012	-	..
6 months	3·1 (1·7)	−0·1 (−0·3 to 0·2)	3·4 (1·6)	−0·3 (−0·5 to −0·2)	0·036	-	..
9 months	3·3 (1·6)	0·1 (−0·1 to 0·3)	3·8 (1·4)	0·0 (−0·1 to 0·2)	0·0006	-	..
12 months	3·3 (1·7)	1·0 (0·7 to 1·2)	3·8 (1·5)	1·5 (1·2 to 1·7)	0·0016	0·6 (0·4 to 0·7)	<0·0001†

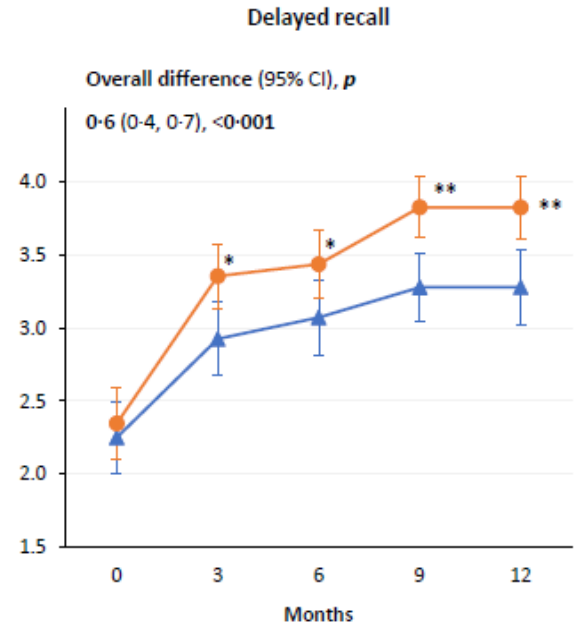
(Table 3 continues on next page)

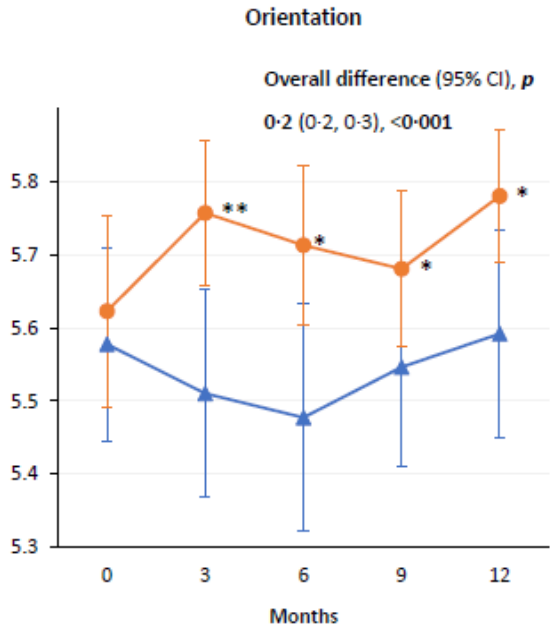
Cognitive function

- ⬆ Global function
- ⬆ Naming
- ⬆ Concentration
- ⬆ Language
- ⬆ Abstract thinking
- ⬆ Delayed recall



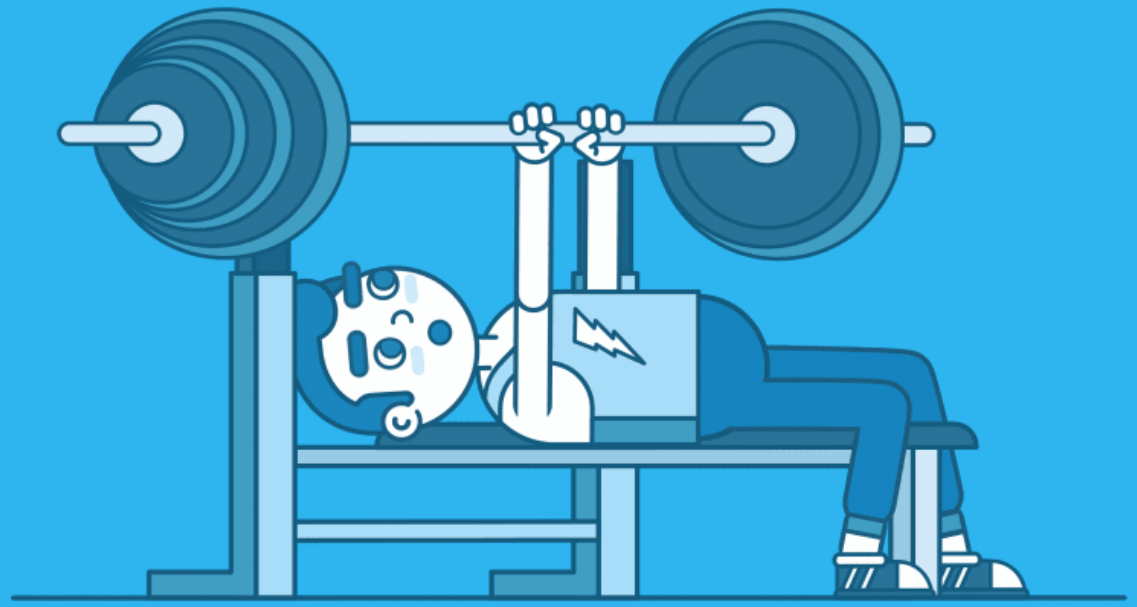


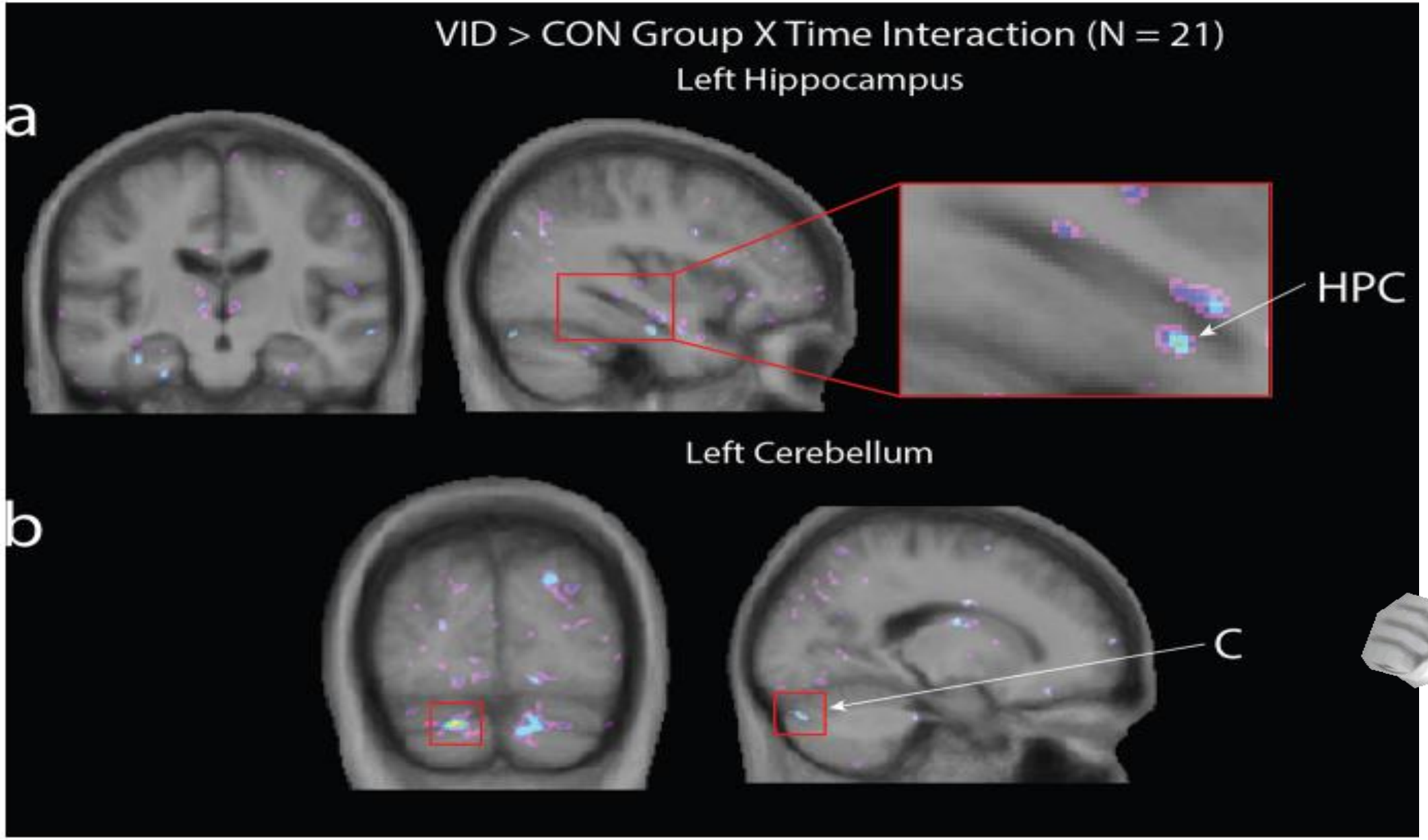




Lee WJ, et al., Lancet Healthy Longev 2021;2:E712-E723

健康促進有效
執行難以持續

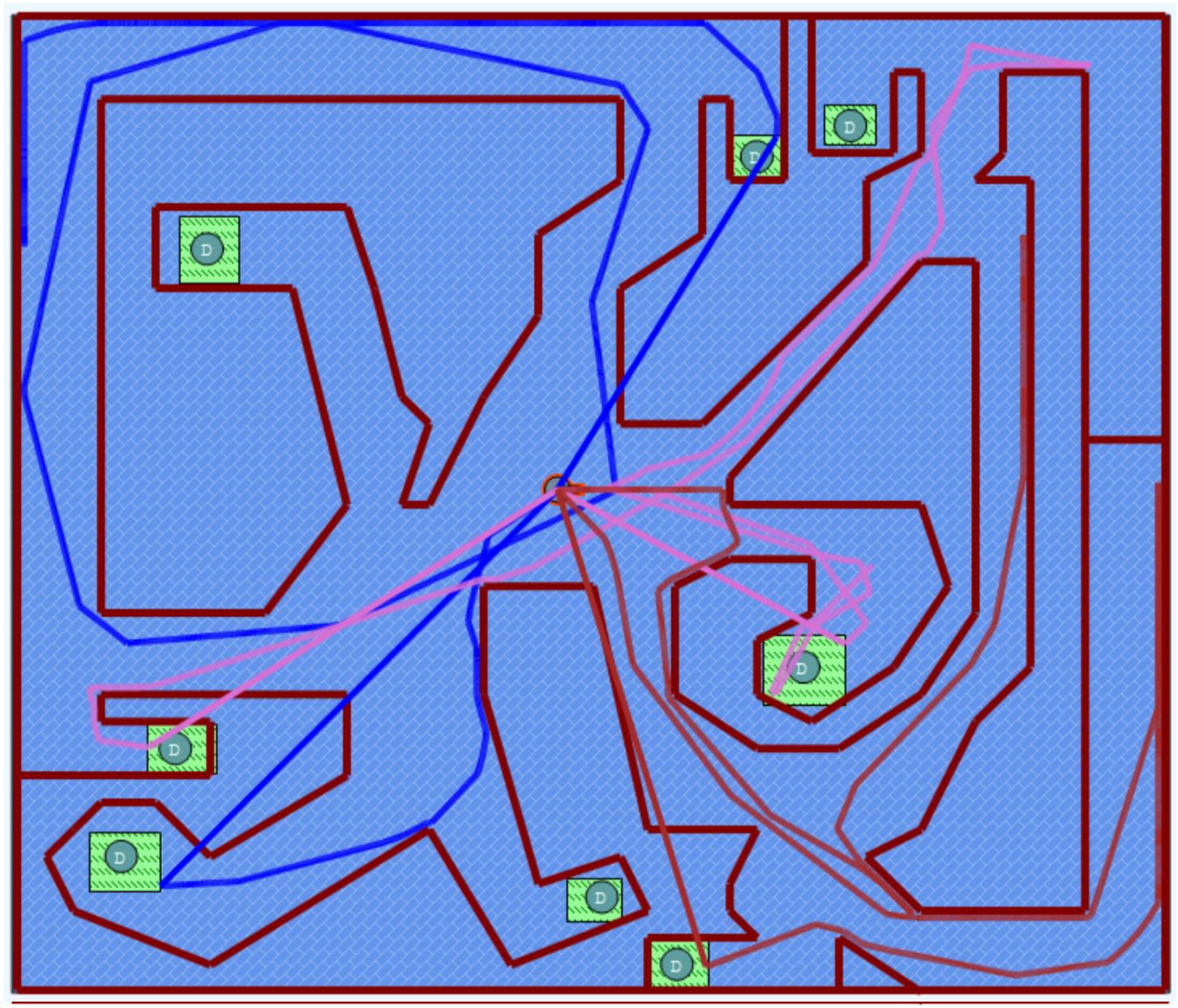




半年馬利歐遊戲相對增加海馬迴與小腦體積

West GL, et al., PLoS One 2017;12:0187770


x 4
x 0
gifs.com


D
D
D
D
D
D
D
D


A


C


E


R


Happy
OK
Jazzy
OK
Crazy
GOOD
Funky
OK
Fancy
GOOD
Baby
GOOD

Original Paper

Efficacy of Digital Dance on Brain Imagery, Cognition, and Health: Randomized Controlled Trial

Heng-Hsin Tung[1,2,3], PhD; Chen-Yuan Kuo[4], PhD; Pei-Lin Lee[3], PhD; Chih-Wen Chang[3], MPH; Kun-Hsien Chou[4,5], PhD; Ching-Po Lin[4,5,6], PhD; Liang-Kung Chen[3,7,8], PhD

[1]Department of Nursing, National Yang Ming Chiao Tung University, Taipei, Taiwan

[2]Tungs' Taichung MetroHarbor Hospital, Taichung, Taiwan

[3]Center for Healthy Longevity and Aging Sciences, National Yang Ming Chiao Tung University, Taipei, Taiwan

[4]Institute of Neuroscience, National Yang Ming Chiao Tung University, Taipei, Taiwan

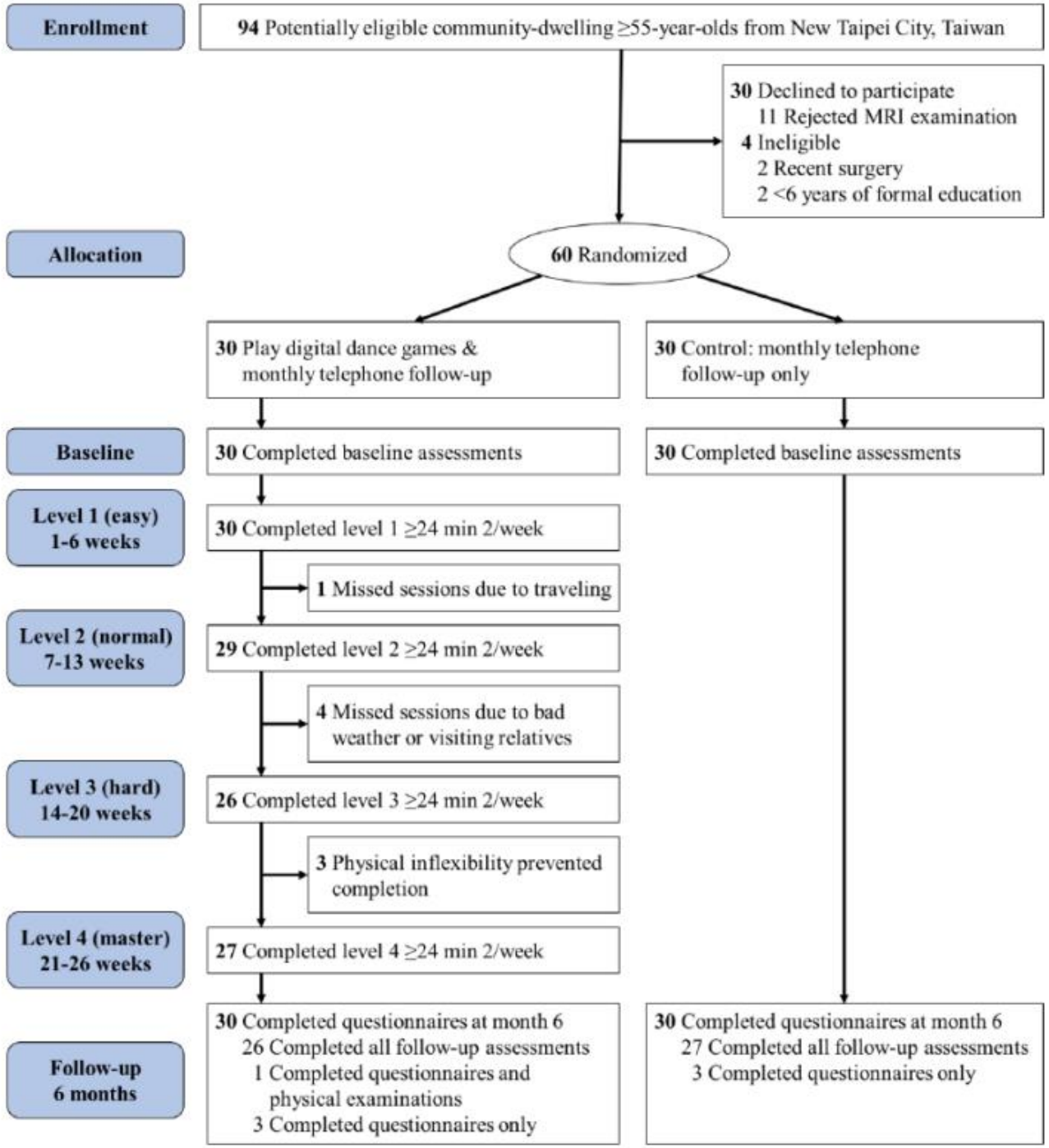
[5]Brain Research Center, National Yang Ming Chiao Tung University, Taipei, Taiwan

[6]Department of Education and Research, Taipei City Hospital, Taipei, Taiwan

[7]Center for Geriatrics and Gerontology, Taipei Veterans General Hospital, Taipei, Taiwan

[8]Taipei Municipal Gan-Dau Hospital, Taipei, Taiwan

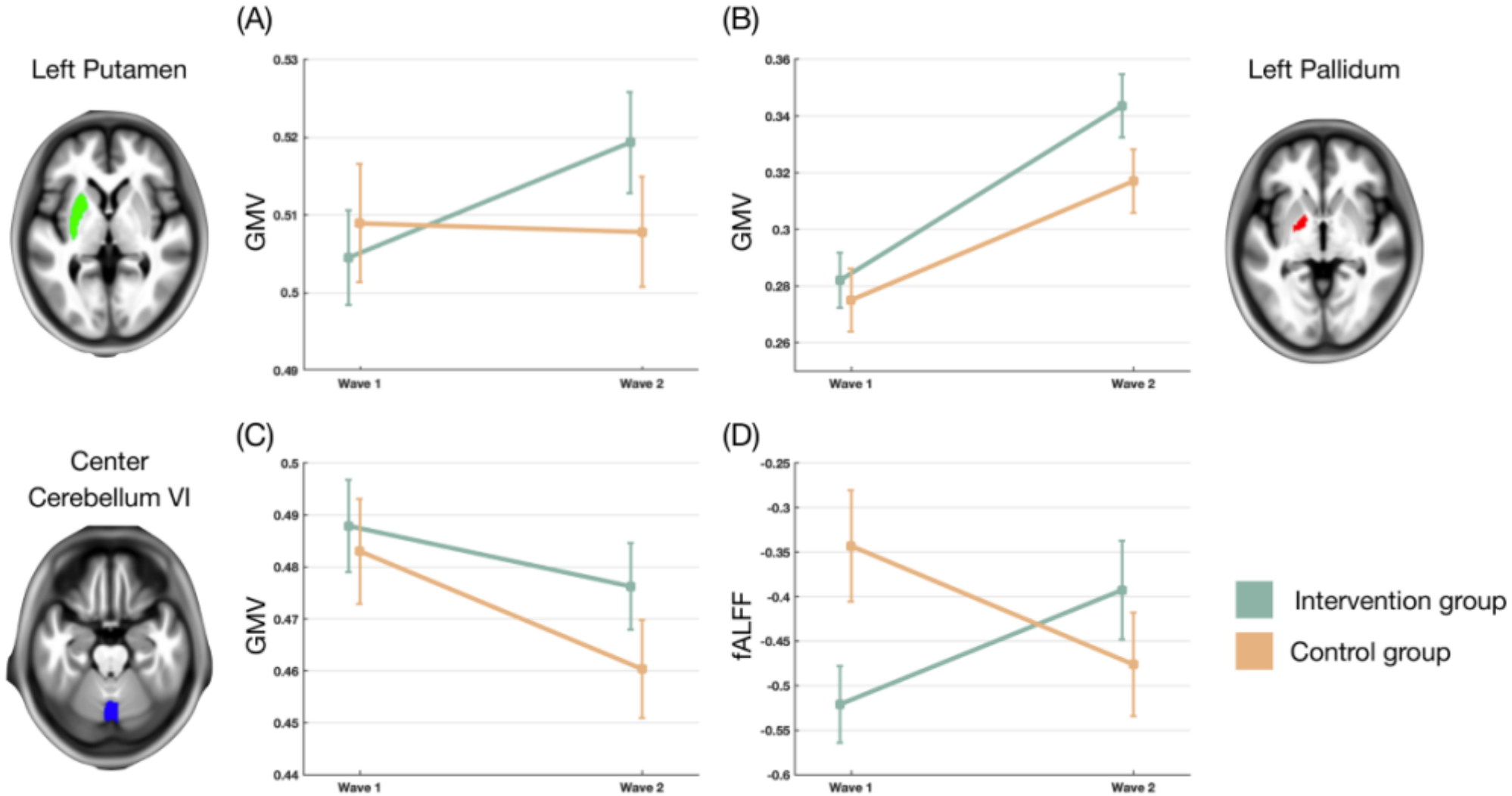
Tung HH, et al. J Med Internet Res. 2024;26:e57694.



Tung HH, et al. Lancet Digit Health (under review)

Tung HH, et al. J Med Internet Res. 2024;26:e57694.

Figure 2. Comparison between the intervention and control groups of the slopes of the (A) left putamen gray matter volume (GMV), (B) left pallidum GMV, (C) center cerebellum VI GMV, and (D) left pallidum fractional amplitude of low frequency fluctuations (fALFF).



Tung HH, et al. J Med Internet Res. 2024;26:e57694.

Table 4. Associations between dance intervention performance and secondary outcomes (n=30).

Outcomes	Unstandardized B (SE)	Standardized β	*t* test (*df*)	*P* value
Increased cognitive function (MoCA[a])				
Completion rate of interventions for >24 minutes per session	0.647 (0.264)	0.394	2.453 (4)	.02
Correct rate for assigned dance with level 2 difficulty	0.937 (0.356)	0.420	2.633 (4)	.01
Correct rate for assigned dance with level 3 difficulty	0.955 (0.295)	0.417	3.237 (4)	.003
Increased self-rated daily health status (EQ-VAS[b])				
Completion rate of interventions for >24 minutes per session	–1.159 (0.399)	–0.455	–2.905 (4)	.008
Correct rate for assigned dance with level 3 difficulty	–1.177 (0.446)	–0.331	–2.638 (4)	.01
Affecting increased resilience (BRS[c])				
Correct rate for assigned dance with level 3 difficulty	–5.629 (1.903)	–0.415	–2.958 (4)	.007
Affecting decreased demoralization level (DS-MV[d])				
Correct rate for assigned dance with level 1 difficulty	–0.382 (0.124)	–0.622	–3.081 (4)	.005
Correct rate for assigned dance with level 2 difficulty	–0.370 (0.105)	–0.628	–3.529 (4)	.002
Correct rate for assigned dance with level 3 difficulty	–0.351 (0.087)	–0.579	–4.030 (4)	<.001

[a]MoCA: Montreal Cognitive Assessment.

[b]VAS: visual analogue scale.

Tung HH, et al. J Med Internet Res. 2024;26:e57694.


nature aging
Aging well for Aus
nature
Brain mitophagy
systemic aging
nature aging
Single-cell epigen
www.nature.com/nataging / January 2021
nature aging
Aging in unity
www.nature.com/nataging / May 2023 Vol. 3 No. 5
nature aging
Focus on demer
Dr. Anna Kriebs
Senior Editor, Nature Aging

U.S. National Library of Medicine

ClinicalTrials.gov

COMPLETED

Benefits of Digital Dance Game

ClinicalTrials.gov ID NCT05411042

Study Record Dates

These dates track the progress of study record a
reported results are reviewed by the National Lib
standards before being posted on the public we

Study Registration Dates	
First Submitted	2022-06-06
First Submitted that Met QC Criteria	2022-06-06
First Posted	2022-06-08

Methods

Participants

This RCT enrolled community residents aged ≥55 years in Taipei, Taiwan, from August 31, 2020, to June 27, 2021 and followed them for 6 months; however, the trial was interrupted for approximately 3 months due to the COVID-19 pandemic (Figure 1). Participant inclusion criteria were as follows: (1) age ≥55 years, (2) ≥6 years of formal education, (3) spoke Mandarin and Taiwanese, (4) engagement in digital dance games <3 times per year during the past 3 years and not within the past 3 months, (5) ability to understand the research procedures and adhere to the prescribed study activities and assessments, and (6) provision of written informed consent. Participants meeting any of the following criteria were excluded from the study: (1) inability to communicate effectively with study staff, (2) undergoing active chemotherapy for malignancy, (3) life expectancy <12 months, and (4) presence of contraindications for magnetic resonance imaging (MRI) such as ferromagnetic foreign bodies or metal implants.

RETROSPECTIVE REGISTRATION

COMPLETED

Effectiveness of Integrated Care

ClinicalTrials.gov ID NCT03528005

Study Record Dates

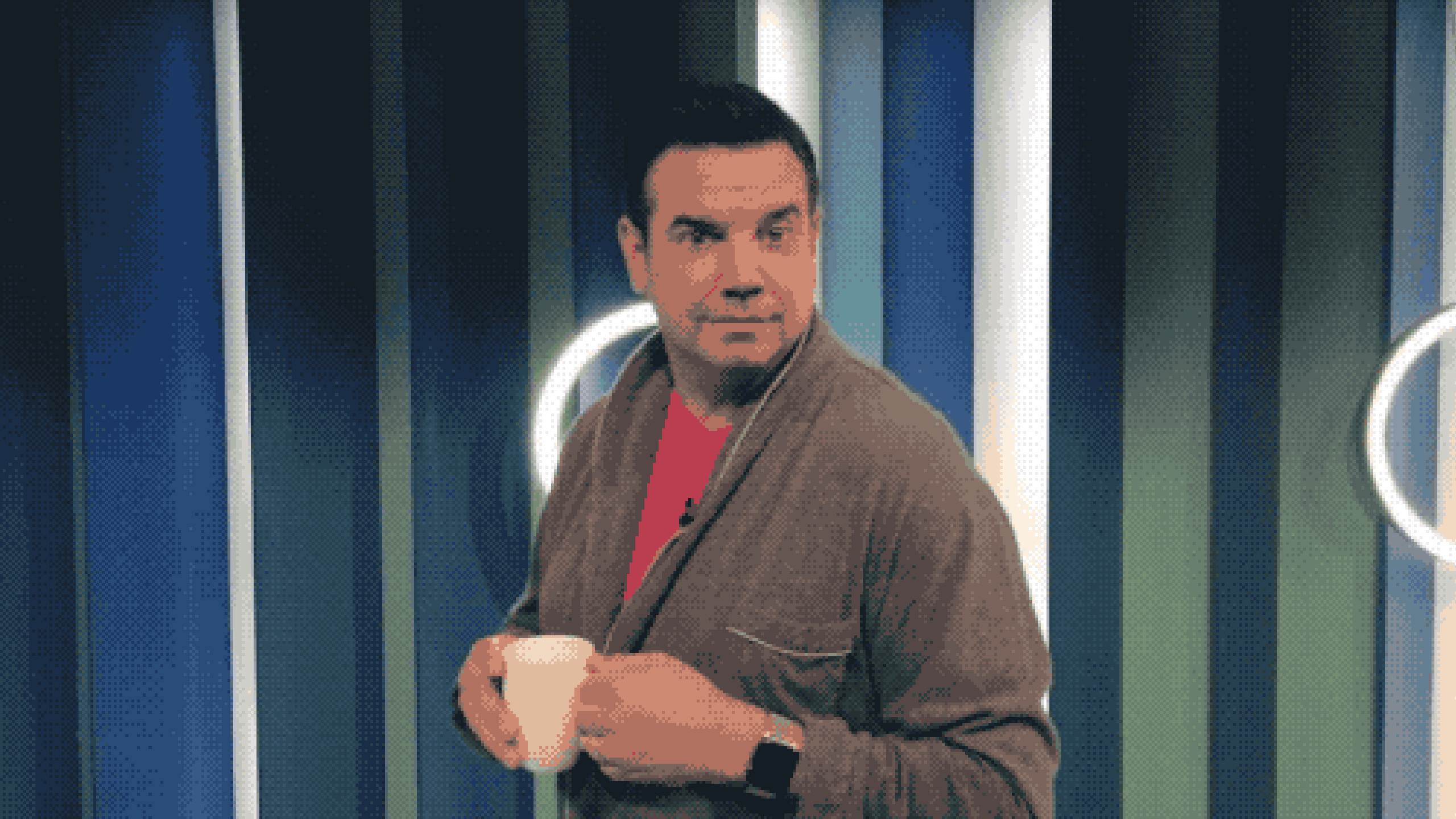
These dates track the progress of study record a
reported results are reviewed by the National Lib
standards before being posted on the public web

Study Registration Dates	
First Submitted	2018-04-24
First Submitted that Met QC Criteria	2018-05-05
First Posted	2018-05-17

Results

Between June 25, 2018, and Feb 15, 2019, 628 people were assessed for eligibility; 165 declined to participate, 65 were ineligible, and 398 were randomly assigned to the integrated multidomain intervention (n=199) or to usual care (n=199; figure 1; appendix p 8). The study ran until March 14, 2020; no remaining participants at each assessment timepoint had missing data and 335 (84%) of 398 completed the 12-month assessment, with median follow-up of 12·0 months (IQR 12·0–12·0). Two deaths occurred during follow-up, which were not related to the study intervention. Both deaths were due to pneumonia, one of which occurred after 9 months in the multidomain intervention group and one of which occurred after 6 months in the usual care group. No serious adverse events were reported.

PROSPECTIVE REGISTRATION

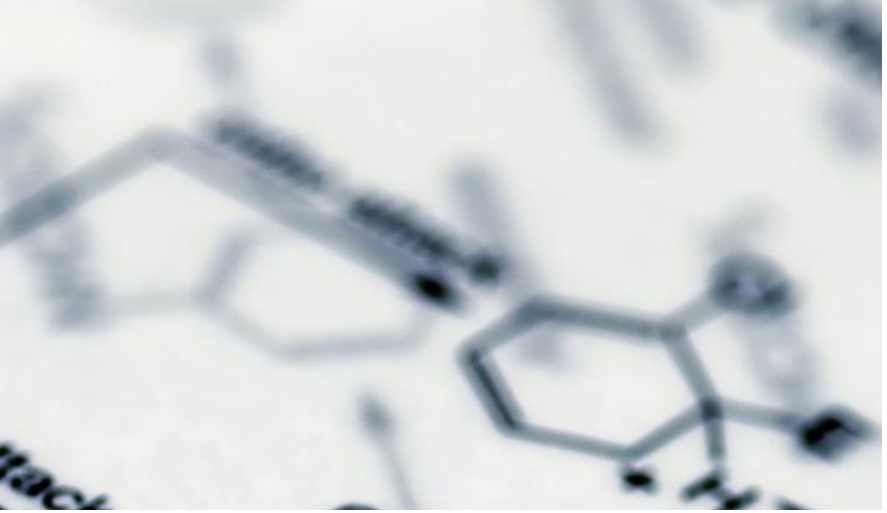


U.S. National Library of Medicine

ClinicalTrials.gov

Why is Registration Important?

- **Transparency**: Publicly accessible records prevent selective reporting and publication bias.
- **Accountability**: Researchers and sponsors are held accountable for conducting trials as planned.
- **Integrity**: Ensures the integrity and reproducibility of clinical research findings.
- **Public Trust**: Enhances public trust in clinical research by providing accessible information about ongoing and completed trials.



Full Publication of Results Initially Presented in Abstracts

A Meta-analysis

Roberta W. Scherer, PhD; Kay Dickersin, PhD; Patricia Langenberg, PhD

Objectives.—To estimate the rate of full publication of the results of randomized clinical trials initially presented as abstracts at national ophthalmology meetings in 1988 and 1989; and to combine data from this study with data from similar studies to determine the rate at which abstracts are subsequently published in full and the association between selected study characteristics and full publication.

Data Sources.—Ophthalmology abstracts were identified by review of 1988 and 1989 meeting abstracts for the Association for Research in Vision and Ophthalmology and the American Academy of Ophthalmology. Similar studies were identified either from reports contained in our files or through a MEDLINE search, which combined the textword "abstract" with "or" statements to the Medical Subject Headings ABSTRACTING & INDEXING, CLINICAL TRIALS, PEER REVIEW, PERIODICALS, MEDICAL SOCIETIES, PUBLISHING, MEDLINE, INFORMATION SERVICES, and REGISTRIES.

Study Selection.—Ophthalmology abstracts were selected from the meeting proceedings if they reported results from a randomized controlled trial. For the summary study, similar studies were eligible for inclusion if they described follow-up and subsequent full publication for a cohort of abstracts describing the results of any type of research study. All studies had to have followed up abstracts for at least 24 months to be included.

Data Extraction.—Authors of ophthalmology abstracts were contacted by letter to ascertain whether there was subsequent full publication. Other information, including characteristics of the study design possibly related to publication, was taken from the abstract. For the summary study, rates of full publication were taken directly from reported results, as were associations between study factors (ie, "significant" results and sample size) and full publication.

Data Synthesis.—Sixty-six percent (61/93) of ophthalmology abstracts were published in full. Combined results from 11 studies showed that 51% (1198/2391) of all abstracts were subsequently published in full. Full publication was weakly associated with "significant" results and sample size above the median.

Conclusions.—Approximately one half of all studies initially presented in abstract form are subsequently published as full-length reports. Most are published in full within 2 years of appearance as abstracts. Full publication may be associated with "significant" results and sample size.

(*JAMA*. 1994;272:158-162)

From the Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, Baltimore, Md.

Presented in part at the Second International Congress on Peer Review in Biomedical Publication, Chicago, Ill, September 10, 1993.

Reprint requests to Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, 660 W Redwood St, 226 Howard Hall, Baltimore, MD 21201 (Dr Scherer).

RESULTS OF MANY types of clinical research are presented at professional meetings and summarized in abstract format. Often these abstracts are not available to the general scientific community. Many are "published" in meeting proceedings accessible only to those who attended the meeting or special journal issues that are not indexed by MEDLINE.

Abstracts may be considered "publication" by some investigators who do not consider it necessary to write up findings for full publication. Considerable evidence from many clinical fields shows that a substantial proportion of studies described in abstracts does not later appear in the scientific literature as full-length reports.[1-10] Little else is known about the factors leading to full publication, however, in part because abstracts contain so little descriptive information.

Failure to publish fully the results of studies, and randomized clinical trials (RCTs) in particular, presents a problem for those conducting meta-analyses or systematic reviews, especially if failure to publish is associated with the results of the study (publication bias). Any attempt to identify all studies in a field will be thwarted by the existence of unpublished studies, and the conclusions drawn from the review may therefore be imprecise or biased.

MATERIALS AND METHODS

Determination of Publication Rate of Abstracts in Ophthalmology

All abstracts summarizing reports made in 1988 and 1989 at either the Association for Research in Vision and Oph-

Publication Bias

- Publication bias
  - small, negative studies least likely to be published
  - negative studies often not submitted to journals
  - only ~40% of meeting abstracts published

Scherer RW, et al. JAMA 1994;272:1410

Publication Bias: The Case for an International Registry of Clinical Trials

By Robert John Simes

A problem in evaluating different therapies from a review of clinical trials is that the published clinical trial literature may be biased in favor of positive or promising results. In this report, a model is proposed for reviewing clinical trial results which is free from publication bias based on the selection of trials registered in advance in a registry. The value of a registry is illustrated by comparing a review of *published* clinical trials located by a literature search with a review of *registered* trials contained in a cancer trials registry. Two therapeutic questions are examined: (1) the survival impact of initial alkylating agent (AA) *v* combination chemotherapy (CC) in advanced ovarian cancer, and (2) the survival impact of AA/prednisone *v* CC in multiple myeloma. In advanced ovarian cancer, a pooled analysis of published clinical trials demonstrates a significant survival advantage for combination chemotherapy (median survival ratio of CC to AA, 1.16; *P* = .02). However, no significant difference in survival is demonstrated based on a pooled analysis of registered trials (median survival ratio, 1.05; *P* = .25). For multiple myeloma, a pooled analysis of published trials also demonstrates a significant survival advantage for CC (median survival ratio, 1.26; *P* = .04), especially for poor risk patients (ratio, 1.66; *P* = .002). A pooled analysis of registered trials also shows a survival benefit for patients receiving combination chemotherapy (all patients, *P* = .06; poor risk, *P* = .03), but the estimated magnitude of the benefit is reduced (all patients: ratio, 1.11; poor risk: ratio, 1.22). These examples illustrate an approach to reviewing the clinical trial literature, which is free from publication bias, and demonstrate the value and importance of an international registry of all clinical trials.

J Clin Oncol 4:1529–1541. © 1986 by American Society of Clinical Oncology.

PUBLISHED CLINICAL TRIALS are an important source of information for clinicians in assessing the clinical efficacy of treatments. However, a major problem that confronts the reviewer is that the published literature may be biased in favor of studies with "significant" or "promising" results. Clinical trials that fail to show any treatment difference are less likely to be published,[1,2] and thus, conclusions of therapeutic effectiveness based on a review of only published trials may be seriously misleading.

An alternative approach to evaluating therapies which is free from publication bias is to consult an international registry of clinical trials and review only those trials contained in the registry. Since trials would be registered *ab initio* with objectives and endpoints clearly stated, their selection in the review would not be influenced by trial results. The International Cancer Research Data Bank (ICRDB) registry of cancer clinical trials,[3] containing the majority of National Institutes of Health (NIH)-funded United States trials and some trials outside the United States, is used to illustrate this approach for two therapeutic issues in cancer.

First, the survival impact of initial alkylating agent (AA) *v* combination chemotherapy (CC) in advanced ovarian cancer is examined. This question, which has been addressed in several review articles, remains the subject of some controversy.[4–7] While several investigators advocate initial CC, with a somewhat higher response rate, others have advocated single AA therapy initially, with CC kept in reserve for treatment failures. This latter strategy spares patients the toxicity of CC whenever the AA alone proves effective. The question of whether initial CC significantly improves survival over initial AA is central to this treatment choice. The second question examined is whether a combination of cytotoxic drugs can

From the Department of Biostatistics, Harvard School of Public Health, Boston; and the Ludwig Institute for Cancer Research (Sydney Branch), Blackburn Building, University of Sydney, Australia.

Submitted Nov 25, 1985; accepted June 9, 1986.

Supported by an NH & MRC (Australia) Applied Health Sciences Research Fellowship. Also supported in part by Grant No. CA-23415 from the National Cancer Institute, Bethesda, Md.

Address reprint requests to Robert John Simes, MBBS, SM, Ludwig Institute for Cancer Research (Sydney Branch), Blackburn Bldg, University of Sydney, Sydney, NSW, Australia.

0732-183X/86/0410-0010$3.00/0

Publication Bias

- Publication bias can mislead clinical practice
  - combination chemo for ovarian cancer
    - p = 0.02 in published trials
    - p = 0.25 in all registered trials

Simes RJ. J Clin Oncol. 1986;4:1529-1541

Review Process

- **Initial Review**: The registry conducts an initial review to ensure that all required fields are completed.
- **Quality Control**: Detailed review to verify the accuracy and consistency of the submitted information.
- **Approval**: Once the trial meets all criteria, it is approved and assigned a registration number.
- **Public Posting**: The trial information is posted publicly, and the trial can commence.

Compliance and Ethical Considerations

- **Regulatory Requirements**: Compliance with international guidelines and local regulations.
- **Ethical Approval**: Ensure that the trial has received ethical approval from a recognized ethics committee.
- **Informed Consent**: Obtain informed consent from all trial participants.
- **Data Protection**: Ensure the confidentiality and protection of participant data.

公告事項

相關網站連結
相關訓練連結
ClinicalTrials

ClinicalTrials.gov登錄

臺北榮民總醫院**Clinicaltrial.gov**網站登錄資訊

- ClinicalTrials.gov是由美國國家衛生院（National Institutes of Health，NIH）所轄美國國家醫學圖書館（National Library of Medicine，NLM）與美國食品藥物管理局（Food and Drug Administration，FDA）於1997年共同開發，自2000年2月開放供大眾使用，是國際上使用最普遍、影響範圍最廣的臨床試驗註冊平台。
- 依據國際醫學雜誌編輯委員會（The International Committee of Medical Journal Editors, ICMJE）之投稿規定(2005年起)，經人體試驗委員會通過之臨床試驗研究計畫，投稿者須於招募第一位受試者參與臨床試驗研究計畫前，臨床試驗研究計畫資料登錄於臨床試驗公開網站。完成登錄作業後，國際醫學雜誌編輯委員會（The International Committee of Medical Journal Editors, ICMJE），始可同意接受研究結果之發表。※未完成臨床試驗登錄之臨床試驗研究計畫，ICMJE有權不接受其文章發表。

Reporting Outcomes & Manuscript Preparation

- Protocol
- Statistical Analytic Plan
- Primary & Secondary Outcomes
- Presenting Results in the Manuscript


謝謝