Effect of a community intervention programme promoting social interactions on functional disability prevention for older adults: propensity score matching and instrumental variable analyses, JAGES Taketoyo study

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ABSTRACT

Background The efficacy of promoting social interactions to improve the health of older adults is not fully established due to residual confounding and selection bias.

Methods The government of Taketoyo town, Aichi Prefecture, Japan, developed a resident-centred community intervention programme called 'community salons', providing opportunities for social interactions among local older residents. To evaluate the impact of the programme, we conducted questionnaire surveys for all older residents of Taketoyo. We carried out a baseline survey in July 2006 (prior to the introduction of the programme) and assessed the onset of functional disability during March 2012. We analysed the data of 2421 older people. In addition to the standard Cox proportional hazard regression, we conducted Cox regression with propensity score matching (PSM) and an instrumental variable (IV) analysis, using the number of community salons within a radius of 350 m from the participant's home as an instrument.

Results In the 5 years after the first salon was launched, the salon participants showed a 6.3% lower incidence of functional disability compared with non-participants. Even adjusting for sex, age, equivalent income, educational attainment, higher level activities of daily living and depression, the Cox adjusted HR for becoming disabled was 0.49 (95% CI 0.33 to 0.72). Similar results were observed using PSM (HR 0.52, 95% CI 0.33 to 0.83) and IV-Cox analysis (HR 0.50, 95% CI 0.34 to 0.74).

Conclusions A community health promotion programme focused on increasing social interactions among older adults may be effective in preventing the onset of disability.

INTRODUCTION

In almost every country, the proportion of older people is growing faster than any other age group. The population of people 60 years or older in the world has doubled since 1980 and is forecast to reach two billion by 2050.[1] Japan, in particular is confronted with population ageing at the fastest pace. The proportion of the Japanese population over the age of 60 years was 32% in 2012 and is projected to rise to 42% by 2050.[2]

To minimise the impact of population ageing on healthcare costs, the Japanese government has prioritised measures that focus on long-term care prevention.[3] One such approach attempts to boost the rates of social participation among older adults.[4] Observational studies suggest that social participation is associated with lower risks of physical and mental problems resulting in functional disability, as well as cardiovascular disease,[5] a decline in motor ability[6] and cognitive function,[7] falls and fractures[8] and frailty.[9] By promoting enjoyable interactions with others and providing individuals with a sense of meaning in life, social participation has been linked to the lowering of psychological distress.[10] Social participation also facilitates access to social support,[11] as well as increased neuronal plasticity for the maintenance of cognitive function.[12 13] However, these studies are prone to confounding biases due to their observational nature, more specifically, selection bias, that is, people who participate in social activities tend to be healthier than those who do not participate.

Evidence is scarce on the effectiveness of community intervention programmes aimed at facilitating social participation and preventing functional disability among older adults. We previously reported observational evidence of an association between participation in a community intervention programme developed in Taketoyo town and improved self-rated health among older adults.[14] In the intervention, community-dwelling seniors were provided opportunities to promote social interactions with other community members in so-called 'community salons' (explained in detail later). However, we do not know whether the community salon intervention is effective for preventing incident functional disability, or the onset of long-term care needs.

In this study, therefore, we evaluated the impact of community salon interventions on the onset of functional disability or long-term care needs. To address the issue of selection bias, we used two identification strategies, namely propensity score matching (PSM) analysis and instrumental variable (IV) analysis.[15] Both techniques attempt to balance treatment and non-treatment groups in terms of the background characteristics that may affect the chance of selecting into treatment.[16]

METHODS

Study population

As a part of the Japan Gerontological Evaluation Study (JAGES), in July 2006 we conducted a mail-in questionnaire survey of all 5759 older

residents of Taketoyo who were physically and cognitively independent and aged 65 years or older. In the Japanese national long-term care insurance system, a municipality certification committee determines the eligibility for receiving services based on an evaluation of each applicant's degree of physical and mental disability, as determined by physical examination.[17] We defined 'Independence' as those who were deemed not to require the use of services covered by the insurance system.[18 19]

In total, 2667 people responded to our invitation, and 2421 were eligible for analysis after excluding volunteers (ie, people who self-selected to assist in organising the salon activities) from the baseline survey. The research team began collaborating with the Taketoyo local government to organise the community salon programme starting in May 2007. We followed the respondents of the baseline survey until 31 March 2012 and collected information on their frequency of participating in salons as well as onset of functional disability. The observation period was 1796 days from 1 May 2007 to 31 March 2012. Our study protocol and informed consent procedure were approved by the Ethics Committee at Seijoh University (No. 2007C0001).

The intervention

Taketoyo is a town with a population of approximately 48 000 residents, located in Aichi prefecture, Japan. The community salon project started in May 2007 when the municipal authorities decided to open a series of community-based centres where the town's senior residents could congregate and participate in social activities, ranging from arts and crafts, games (bingo) and interactive activities with preschool children. The local government recruited volunteers to staff the salons. Initially, three such salons were established, and by 2011 a total of eight salons were in operation. Any resident aged 65 years or older was eligible to participate for a nominal fee of 100 yen (about US$1) per visit.

Outcome variable

Our primary outcome was the onset of functional disability, that is, physical and/or cognitive disability identified from the town's public long-term care insurance database. Since 2001, the Japanese government has operated a national insurance scheme in which eligibility for long-term care (eg, home helpers) is based on a standardised multistep assessment of functional and cognitive impairments based on a physician examination. Individuals are classified into one of six care levels according to the severity of their physical and mental disability, such as functional decline or dementia. The care levels are mainly based on the estimated hours of home care required each week in order to meet their instrumental and basic activities of daily living (eg, bathing, dressing, cleaning the house, preparing meals).[17]

These criteria for determining the onset of disability have been used in previous epidemiological studies and also form the basis of health need assessment by Japanese local governments.[18 19]

Explanatory variable

Our primary treatment variable was whether or not the person participated in a community salon. In total, 437 people visited the salon at least once. Their frequency of participation varied from 1 to 235, with a median of 3 (IQR was 18–1). Among 437 participants, 29.7% (130 people) participated in the salon only once, while 14.0% (61 people) participated twice and 56.3% (246 people) participated three times or more. We defined more than three-time visitors (246 people) as 'participants' because we hypothesised that participation on fewer occasions could not be plausibly expected to prevent functional disability. We also created a continuous variable for the frequency of participation. Since the distribution was right-skewed, we log-transformed the values.

Table 1 Characteristics of subjects at baseline and incidence of functional disability after 5 years

		Non-participants (0–2 times) (n=2175)		Participants (3 times and more) (n=246)		
		N	Per cent	N	Per cent	p Value
Sex	Male	1199	55.1	47	19.1	<0.001
	Female	976	44.9	199	80.9	
	Total	2175	100	246	100	
Age	65–74 years	1502	69.1	155	63.0	0.060
	75 years and over	673	30.9	91	37.0	
	Total	2175	100	246	100	
Educational attainment	10 years and over	987	45.9	95	39.3	0.056
	9 years and under	1165	54.1	147	60.7	
	Total	2152	100	242	100	
Equivalent income	2 million yen (about US$20 000) and more	892	53.4	72	40.9	0.002
	1.99 million yen (about US$19 900) and less	778	46.6	104	59.1	
	Total	1670	100	176	100	
Higher level of ADL	13 points (full marks)	711	36.1	120	53.1	<0.001
	12 points and under	1261	63.9	106	46.9	
	Total	1972	100	226	100	
Depression (GDS-15)	None (0–4 points)	1367	72.7	158	72.5	0.069
	Mild (5–9 points)	387	20.6	37	17.0	
	Severe (10–15 points)	126	6.7	23	10.6	
	Total	1880	100	218	100	
Incidence of functional disability	Non-certification	1870	86.0	227	92.3	0.005
	Certification	305	14.0	19	7.7	
	Total	2175	100	246	100	

GDS-15, Geriatric Depression Scale-15.

Covariates

We selected as potential confounding variables sex, age, educational attainment and equivalent income, higher level activities of daily living (ie, instrumental activities of daily living (ADL), intellectual activities and social roles measured by the Tokyo Metropolitan Institute of Gerontology Index of Competence; TMIG-IC)[20] and depressive symptoms (Geriatric Depression Scale-15; GDS-15)[21] at the baseline survey.[14 22] Age was grouped into: 65–74 years and 75 years or over. Educational attainment was categorised as under 9 vs over 10 years. Household income was equalised by the square root of the number of household members and grouped as over 2 million yen versus under 1.99 million yen. Higher level ADL (instrumental activities of daily living (IADL), intellectual activities, social roles) was split at the median value (12 points). Depressive symptoms were categorised into no risk (under 4 points), mild risk (5–9 points) or high risk (over 10 points).[21]

Statistical analysis

Analyses were performed using STATA V.13.0 (STATA Corp LP, College Station, Texas, USA) and SAS statistical package V.9.4 (SAS Institute Inc., Cary, North Carolina, USA).

After calculating descriptive statistics, we conducted three regression analyses. First, we employed a standard Cox proportional hazard model to estimate the HR and 95% CIs for disability onset according to the number of times the respondent participated in the salons (log-transformed). Multivariate models were adjusted for potential confounders. Next, we conducted Cox regression with a PSM technique which matched individuals on the basis of their probability (ie, propensity) of receiving the treatment (ie, community salon participation) conditional on all the observed covariates.[15]

To calculate the propensity scores, we selected 26 potential variables including the six confounders in a standard Cox proportional hazard model that could theoretically predict the probability of participating in the salons on the basis of previous findings (see online supplementary table S1),[22–29] and predicted participation in community salons three times or more by logistic regression (C-statistic=0.82).

We used one-to-one caliper (0.2) matching with no replacement, to match the treatment and control groups (ie, participants vs non-participants) using Stata command 'psmatch2'.

Lastly, we performed IV analysis.[15] IV analysis can provide unbiased estimates of the effects of treatments in the presence of unobserved confounding. A valid IV needs to be associated with treatment; it must not directly affect the outcome except through its effect on the treatment, and cannot be associated with confounding factors.[30] We used the number of community salons within a radius of 350 m from each respondent's home as the instrument. We created this variable using geographic information systems with geocoded data of each participant's residential addresses and the places where community salons were opened. The conversion from residential addresses to longitude and latitude data was accomplished using a geocoding programme provided by the Center for Spatial Information Science of the University of Tokyo.[31] To test the strength of our instrument, we checked the correlation between the local density of salons and the probability of participation (see online supplementary table S2). We confirmed that the number of community salons within 350 m from a resident's home was related to their frequency of participation (see online supplementary table S3). We performed IV-Cox regression and confirmed that the IV was not weak (F (8, 2412)=20.07). In a two-step

Table 2 Result of the standard and after PSM Cox proportional hazard model

		Categorised model		Log-transformed model		PSM
		Crude model	Multivariate model	Crude model	Multivariate model	
Participation	0–2 times (reference) (n=2175)					
	3 times and more (n=246)	0.50 (0.32 to 0.80)***	0.41 (0.26 to 0.66)***	–	–	–
	Log-transformed (log (X+1))	–	–	0.57 (0.39 to 0.84)**	0.49 (0.33 to 0.72)***	0.52 (0.33 to 0.83)**
Sex	Female (reference: male)	–	1.05 (0.84 to 1.32)	–	1.05 (0.84 to 1.32)	–
Age	75 years and over (reference: 65–74 years)	–	4.87 (3.86 to 6.14)***	–	4.85 (3.85 to 6.12)***	–
Educational attainment	9 years and under (reference: 10 years and over)	–	0.95 (0.76 to 1.19)	–	0.95 (0.76 to 1.19)	–
Equivalent income	¥1.99 million and less (reference: ¥2 million and more)	–	1.14 (0.91 to 1.43)	–	1.14 (0.91 to 1.43)	–
Higher level of ADL	12 points and under (reference: 13 points)	–	1.32 (1.02 to 1.73)*	–	1.32 (1.01 to 1.72)*	–
Depression	None (reference)					
	Mild	–	1.35 (1.04 to 1.75)*	–	1.35 (1.04 to 1.74)*	–
	Severe		2.09 (1.48 to 2.95)***		2.09 (1.48 to 2.95)***	

*p<0.05, **p<0.01, ***p<0.001.
PSM, propensity score matching.

regression procedure, we then regressed the HR of disability onset on the instrumented probability of salon participation. To address potential bias due to missing data, we used multiple imputation assuming MCAR (ie, Missing Completely At Random).

RESULTS

Compared with non-participants, salon participants were more likely to be female (male 19.1% vs female 80.9%, p<0.001), have lower household income (p=0.002) and to be healthier with regard to baseline higher level activities of daily living (p<0.001; table 1). The cumulative incidence of functional disability during the follow-up was lower among participants than non-participants: 7.7% among participants versus 14.0% among non-participants (p=0.005).

Standard Cox regression using categorised participation or not showed a significant result: compared with those participating 2 times and less (non-participants), HR of disability onset among those who participated 3 times and more was 0.50 (95% CI 0.32 to 0.80; table 2). The Cox regression using log-transformed the frequency of participation was significantly associated with lower incidence of functional disability (HR=0.57, 95% CI 0.39 to 0.84).

The multivariate model also indicated the same associations between the incidence of functional disability and participation (HR=0.50, 95% CI 0.32 to 0.80) and the log-transformed variable (HR=0.49, 95% CI 0.33 to 0.72). The sensitivity analysis using categorised participants into two groups based on median (3–13 times 122 people, over 14 times 124 people) also showed similar results (3–13 times, HR=0.43, 95% CI 0.23 to 0.81; 14 times and more, HR=0.39, 95% CI 0.20 to 0.77; see online supplementary table S4).

The application of PSM also showed a significant result. The HR of continuous log-transformed participation frequency was 0.52 (95% CI 0.33 to 0.83; table 2).

When employing IV-Cox, the number of times of participating in the salon was strongly predicted by our instrument, that is, the number of community salons within a radius of 350 m from each participant's address: coefficient 0.04, 95% CI 0.01 to 0.06. The IV estimates on the incidence of functional disability (HR=0.50, 95% CI 0.34 to 0.74) were similar to those of the standard Cox proportional hazard model (table 3).

DISCUSSION

Our study found that participation in the community salon contributed to the prevention of incident functional disability, even after the application of PSM and IV analysis. Previous observational studies showed that participation is effective for prevention of functional disability.[22] Our finding is consistent with these findings.

There are several plausible pathways linking participation in the community salon and prevention of incident functional disability. First, exercise in the salon may contribute to the maintenance of physical and cognitive function. Some salon activities involved light physical activity such as callisthenics,[32] handicraft,[33] chess[34] and calligraphy,[35] which may have contributed to the maintenance of physical and cognitive functions. Second, it is possible that the activities of the community salon helped to establish new social connections, thereby increasing the chances of obtaining more social support, which is a predictor of health for older people.[36]

The strength of this study is the use of multiple identification strategies for reducing selection bias under a quasi-experimental study design. The instrument used, that is, the density of community salons within a radius of 350 m from residential addresses, was significant (F (8, 2412)=20.07). The results were highly consistent across models employed, supporting their robustness. The use of objective measures is another strength: the frequency of salon participation and the names of the salons were officially recorded by community salon organisers. The outcome variable was acquired from the public insurance database, based on the physician's examination.[18 19]

Previous observational studies suggested that social participation is associated with the prevention of functional disability.[5–7] However, there are few intervention studies. Ichida *et al*[14] previously assessed the Taketoyo intervention study 1 year into the programme, and reported showed that salon participation improved self-rated health using IV analysis, but they did not examine whether participation contributed to the prevention of functional disability. On the other hand, 'Experience Corps' and

Table 3 Result of IV-Cox analysis

		IV-Cox	
		Second stage Dependent variable: incidence of functional disability HR	**First stage Dependent variable: number of participations Coefficient**
Endogenous variable	Participation (log-transformation)	0.50 (0.34 to 0.74)**	–
Exogenous variable	Number of community salons within a radius of 350 m from the subject's home	–	0.04 (0.01 to 0.06)**
Sex	Female (reference: male)	9.00 (3.62 to 22.41)***	0.15 (0.12 to 0.18)***
Age	75 years and over (reference: 65–74 years)	7.29 (5.48 to 9.70)***	0.03 (−0.01 to 0.06)
Educational attainment	9 years and under (reference: 10 years and over)	1.18 (0.93 to 1.51)	0.02 (−0.01 to 0.05)
Equivalent income	¥1.99 million and less (reference: ¥2 million and more)	2.21 (1.55 to 3.16)***	0.05 (0.02 to 0.08)**
Higher level of ADL	12 points and under (reference: 13 points)	0.50 (0.31 to 0.81)**	−0.07 (−0.10 to −0.03)***
Depression	None (reference)		
	Mild	0.92 (0.68 to 1.24)	−0.03 (−0.06 to 0.01)
	Severe	4.63 (2.87 to 7.48)***	0.04 (0.01 to 0.06)**
Constant	Constant	–	−0.11 (−0.17 to −0.06)*

In the first-stage regression of 2SLS, F-statistics was 20.07 (p<0.001), and partial R^2 was 0.06.
*p<0.05, **p<0.01, ***p<0.001.
IV, instrumental variable.

'REPRINTS' are two community-based intervention studies in which participants were assigned to social programmes. Experience Corps recruited retired seniors in Baltimore, USA, to serve as a volunteer teacher's aides in local schools. The programme was designed to support the academic success of children and to promote the health of older volunteers by enhancing their physical, social and cognitive functioning.[37] The intervention was reported to improve the physical mobility of the participants.[38] REPRINTS is a programme modelled on Experience Corps, which was launched in Japan, which recruited senior volunteers to read to school-aged children in educational settings.[39] According to Murayama *et al*,[40] the programme was associated with decreased depressive mood. These programmes did not report on whether participation resulted in a significant impact on the prevention of functional disability.

Our study has several limitations. First, our study participants may not be generalisable to the older residents of Taketoyo due to the <50% response to the baseline survey. Generalisability is further limited by the fact that our study was conducted in a single town in Japan.

Nevertheless, our findings suggest that the opening of community-based centres (salons) is a viable intervention for encouraging social participation among Japanese seniors, and that they may be effective for the prevention of disability onset. Future studies should evaluate the cost-effectiveness of this approach as part of determining whether the intervention can be rolled out to communities in the rest of the country.

What is already known on this subject

- Observation studies have shown that participating in community activities by the elderly is effective to prevent the onset of functional disability.
- There is limited evidence that the intervention programme to promote interaction among older residents is effective for the prevention of functional disability.

What this study adds

- Promoting social participation in the elderly is an effective means of preventing the onset of functional disability.
- Community salons promote the opportunity for older residents to interact socially and thereby avoid functional disability.

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Contributors HH was responsible for the study conception, design, analysis and interpretation of the data, as well as the drafting of the article. NK and JA intensively revised the manuscript. IK lent support on the conception and intensively revised the manuscript. KK and TT acquired the data and intensively revised the manuscript.

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市町村単位の転倒者割合と歩行者割合に関する地域相関分析　－JAGES2010-2013 連続横断分析より－

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[目的] 2015 年 4 月からの第 6 期介護保険事業計画では，地域づくりによる介護予防に重点がおかれ，以前にも増して地域診断の重要性が高まっている。本研究では，市町村単位の地域診断の参考指標を探索するため，高齢者の 1 日平均 30 分以上などの歩行者割合（以下，歩行者割合）と転倒者割合の聞に相関があるか，経年変化でも歩行者割合が増加した市町村ほど転倒者割合は減少したか，高齢者の歩行者割合と関連する地域要因は何かについて，地域相関研究を行った。

[方法] 本研究は 2010 年に全国 31 市町村，2013 年に全国 30 市町村で実施された日本老年学的評価研究 (]AGES）から，両時期に参加した 23 市町村を対象とした。前期高齢者・後期高齢者は層別化した。転倒者割合と歩行者割合についてスピアマンの順位相関分析にて相関係数を算出し，続いて歩行者割合が増加した市町村ほど転倒者割合は減少したかを明らかにするため，2010 年から 2013 年への 3 年間の両変数の変化量間の相関係数を算出した。最後に，対象者の属性，環境等の変数の集計値と歩行者割合の相関係数を算出した。

［結果］ 歩行者割合は 2010→2013 年で，前期高齢者 70.9%→79.1%，後期高齢者 59.8%→71.0% と増加していた。両年で前期高齢者・後期高齢者とも歩行者割合と転倒者割合の聞に負の相関が認められた（ρ＝-0.18～-0.67）。3 年間の両変数の変化量間の相関では，歩行者割合が増加した市町村ほど転倒者割合が減少していた（前期高齢者 ρ＝-0.53，後期高齢者 ρ＝-0.37)（ ρ ＜0.05, ρ＜O.l)。歩行者割合と繰り返し有意な相関を認めた要因は，前期高齢者でスポーツ組織参加，趣味の会参加，自宅から 1km 以内に運動・散歩に適した歩道あり，で正の相関，等価所得 200 万円未満で負の相関を認めた。後期高齢者では，自宅から 1km 以内に運動・散歩に適した歩道あり，で正の相闘を認めた。

［結論］ 歩行者割合が高い市町村では転倒者割合が低く，歩行者割合が増加すると転倒者割合は減少するという経時的変化も確認された。同時に，歩行者割合と関連するいくつかの地域要因も認めた。今後，市町村を単位として高齢者の転倒状況や歩行状況を把握し，さらにそれらの経年変化を評価することは，地域診断や市町村の転倒予防事業の評価を行う際に有益と思われた。

キーワード：地域診断，転倒，1 日平均歩行時間，経年変化，社会参加，建造環境 (built environment)

ORIGINAL ARTICLES

Positive affect and incident dementia among the old

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ABSTRACT

Background: We investigated the association between positive affect and incident dementia among the old. Studies have reported the role positive affect has on maintaining health. Still, no longitudinal studies have assessed the association between positive affect and incident dementia.

Methods: We used the Aichi Gerontological Evaluation Study (AGES) data. Participants were older adults (65 +) who did not receive benefits from Japan's public Long-Term Care Insurance System at baseline (N = 14,286) in 6 municipalities. They were followed from 2003 to 2007 for dementia onset. Dementia onset was determined according to the criteria used in the Long-Term Care Insurance System. Positive affect was assessed by sub-scales of the Geriatric Depression Scale (GDS-15). Cox hazard proportional models stratified by sex were employed to calculate hazard ratios for incident dementia.

Results: Of 14,286 participants (6,813 men and 7,473 women), 333 men (4.9%) and 468 women (6.3%) developed dementia during the 4 year follow-up. In age adjusted Cox models, positive affect was significantly associated with lower risk of dementia both among men and women. Even after adjusting for health status, health behaviors, social engagement, and low education, positive affect persisted as a significant protector against dementia.

Conclusions: We observed a protective role of positive affect against cognitive decline. Factors associated with higher positive affect scores were healthier life style, social engagement, and physical health. This implies the importance of maintaining such activities to promote cognitive health among the old. In doing so, the role of positive affect merits attention.

Key Words: Dementia, Positive affect, Cohort study

1. INTRODUCTION

Our society is aging and dementia is a major cause of disability among older adults. In more developed nations, over 1 in 5 people are 60 years or older, and the proportion of older adults is predicted to increase in developing nations in the future as well.[1] Similarly, the estimated number of those suffering from dementia will rise worldwide. In Japan, the number of older adults suffering from dementia in 2012 was estimated to be 2.8 million (9.5% of the 65+ population). In 2025, that number is projected to be about 4.7 million.[2] According to the World Alzheimer Report published in 2009, an estimated 35.6 million people were living with dementia in 2010. The number is expected to increase to 65.7 million by 2030, and to 115.4 million by 2050. Moreover, approximately 63.4% of all people with dementia are expected to live in low- to middle income nations such as Brazil, India, and

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Nigeria in 2030, and that rate will rise to 70.5% by 2050.[3] Dementia is therefore a worldwide concern.

A well-known risk factor for dementia is advanced age, with prevalence doubling roughly every five years for those over the age of 65.[3] Low socio-economic status such as low education is also a risk factor for dementia.[3–5] Moreover, illnesses and poor health conditions such as hypertension or type 2 diabetes are risk factors for dementia,[5–7] as are lifestyle factors such as smoking, heavy drinking, or being sedentary.[8,9] These modifiable factors are important since they are amenable to intervention. Researchers demonstrated the positive effect promotion of social or physical activities has against cognitive decline among the old.[10–12] However, studies have reported that the effect of conventional behavior modification programs is disappointing, especially in terms of their long-term effect.[13] Recently, the role of positive affect has been considered as part of a more effective behavior modification program. In fact, a recent study suggested that laughter had a positive effect on dementia prevention.[14] Hirosaki *et al.* reported that an enjoyable exercise program with laughter sessions was effective for motivating older participants.[15] In another randomized controlled trial in medical care settings, researchers demonstrated that patient education intervention enhanced with positive-affect induction and self-affirmation was more effective than patient education alone in improving medication adherence and blood pressure reduction among 256 hypertensive African Americans.[16]

Positive affect is also associated with better health. For example, Hirosaki *et al.* demonstrated the effect of positive affect against functional decline.[17] Using data from the North Carolina EPESE study, Ostir *et al.* demonstrated that stroke incidence is lower for individuals with a high positive affect score.[18] However, as far as we know, no studies have investigated the association between positive affect and incident dementia. The purpose of this study is to investigate such an association using 4-year follow-up data of community-living older adults in Japan.

2. METHODS

2.1 Data and subjects

The present study is a part of the Aichi Gerontological Evaluation Study (AGES) Project. This is a community-based prospective cohort study in Japan, in which investigators evaluated factors associated with incident functional disability or dementia among non-institutionalized older people aged 65 years or above. A detailed description of the study population and the baseline survey has been published elsewhere.[19] Briefly, the initial cohort included a representative sample of 6 municipalities in Chita Peninsula of Aichi Prefecture. In October 2003, self-administered questionnaires were mailed to community-living older adults aged 65 years or older with no dementia, and thus did not receive benefits from public long-term care insurance (LTCI) services. LTCI is Japan's long-term care insurance system, introduced in April 2000, to entitle every Japanese person aged 65 and older with functional limitations or dementia to care in activities of daily living.[20] Questions on the survey were about health status, lifestyles, and social networks. The researchers used random sampling of 2 larger municipalities and a complete census of 4 smaller cities (N = 29,374). Of these, 14,286 individuals (6,813 men and 7,473 women) provided valid responses (response rate of 48.6%) and were introduced to the AGES Cohort. They were followed for four years from November 2003 to October 2007.

2.2 Incident dementia

We defined people with dementia as those who became eligible for Japan's public LTCI System, Level II or higher, on the index for the evaluation of care needs for the demented. The scale was developed by the Ministry of Health and Welfare, based on observations of symptoms and behaviors that cause daily life impediment and degradation of intellectual functions that causes communication difficulty. This index was validated using MMSE (Mini-Mental State Examination) and HDS-R (Revised Hasegawa Dementia Scale). The correlation coefficients with each scale were -0.744 and -0.735, respectively, indicating strong correlations with a clinically used instrument.[21] Certification of long-term care needs was based on an evaluation of the need for care, a home-visit interview, and a written opinion from the primary care physician. We obtained information regarding certification of long-term care needs, death, and dropping out of subjects (*e.g.* moving out of the study area) from the long-term care insurance database maintained by municipalities. The study protocol and informed consent procedure were approved by the Ethics Committee in Research of Human Subjects at Nihon Fukushi University (# 10-05).

2.3 Explanatory variable

Positive affect was measured using the 15-item Geriatric Depression Scale (GDS-15). In most studies, positive affect was measured using the CES-D (Center for Epidemiological Studies Depression Scale), which includes four positive affect items. GDS is a widely used measure for screening depression among older populations in the community and includes questions regarding both positive and negative affect.[22] As our study participants were older people in community settings, we used GDS-15. Recent studies have used GDS in this manner to assess the predictive power of positive affect on older person's health, such as functional

decline or cognitive impairment.[17,23] The five GDS items for measuring positive affect are "feeling satisfied with life," "feeling happy most of the time," "feeling full of energy," "feeling wonderful to be alive," and "being in good spirits most of the time." The answer was dichotomized as yes/no. The code "1" was assigned to a "yes" answer, and the sum score of these five items was used in the analysis.

2.4 Covariates

Information on smoking, physical activity and alcohol consumption was obtained from a self-report baseline survey. Smoking was dichotomized as yes (current smoker) or no (former or never smoker). Physical activity was assessed by asking "How long do you walk a day on average?" Alcohol consumption was divided into two categories as drinker or non-drinker. Since older adults often experience chronic illnesses that can affect their lifestyle, we also asked for their health status. Diagnosed illnesses and conditions were ascertained by asking if they were currently receiving treatment for any of the following: cancer, heart disease, stroke, hypertension, diabetes, obesity, hyperlipidemia, osteoporosis, arthritis, trauma, respiratory illness, gastrointestinal illness, liver disease, mental illness, visual/hearing impairment, dysphagia, incontinence, and others. Also, we incorporated limitations in basic activities of daily living into the model. Although benefits under LTCI were provided based on an application, a small percentage of people with functional limitations were not receiving LTCI services although they were eligible for the application. We asked them if they needed assistance in performing any of the following activities: bathing, walking, and using the toilet.

As social isolation is also a well-known risk factor for dementia, we asked about marital status and social engagement. Marital status was dichotomized into married/single (never married/widowed/divorced). Social engagement was elicited by asking "Do you belong to the following organizations or groups?" The answer categories were political organizations or groups, industrial or trade associations, volunteer groups, citizen or consumer groups, religious organizations, sports groups, neighborhood associations/senior citizen clubs/fire-fighting teams, and hobby groups. The answer was dichotomized as yes/no. The code "1" was assigned to a "yes" answer and the un-weighted sum of the count was used in the analysis.

Socioeconomic status was evaluated based on the total years of formal education, and was divided into primary (< 9 years) and secondary or above (≥ 10 years). We evaluated negative affect using ten negative affect items in GDS-15.[17]

2.5 Statistical analyses

The incident rates of dementia were calculated by dividing the number of new cases by the number of follow-up years (person-years). Differences in covariates, along with positive and negative affect scores between people with incident dementia and no dementia were assessed using general linear regression models. Since age is an important confounder when assessing the relationship between positive affect and incident dementia, all mean values were adjusted for years of age by means of multiple general linear regression models.

Cox hazard proportional model stratified by sex was employed to calculate the hazard ratios for dementia onset. Those who died or moved away from the study site during the follow-up period were considered censored. To test if the effects of each factor were independent of the influence of others, we used hierarchical regression modeling procedures. First, we constructed a crude model which demonstrated the crude effect of positive affect on incident dementia. Then, to test which factors accounted for incident dementia besides positive affect, we added age, biological/ physiological, social, and socio-economic factors sequentially to each model from Model 2 to Model 5, and inspected changes in the hazard ratios to estimate associations with incident dementia. Lastly, to test if the effect of positive affect is independent of negative affect, we added negative affect scores in the Model 6.

Table 1. Incident dementia during the 4-year follow-up by positive affect score (n = 14,286)

Additive positive affect score	Study population (n)	Dementia cases (%)	Person-years*	Incidence/1000 person-years
Men (6,813)				
Missing	707	67(9.5)	2,543	26.3
0	147	8(5.4)	535	15.0
1	295	20(6.8)	1,046	19.1
2	403	22(5.5)	1,461	15.1
3	861	60(7.0)	3,124	19.2
4	1,769	77(4.4)	6,603	11.7
5	2,631	79(3.0)	10,055	7.8
Total	6,813	333(4.9)	25,367	13.1
Women (7,473)				
Missing	1,091	98(9.0)	4,054	24.2
0	168	23(13.7)	594	38.7
1	239	26(10.9)	875	29.7
2	417	28(6.7)	1,564	17.9
3	885	71(8.0)	3,300	21.5
4	2,066	135(6.5)	7,839	17.2
5	2,607	87(3.3)	10,124	8.6
Total	7,473	468(6.3)	28,350	16.5

*Person years in the table were calculated by adding the number of follow-up years of study population in the row.

We used SPSS 21.0J (SPSS, Chicago, IL, USA) for statis-

tical analysis. A *p*-value of less than .05 was considered statistically significant.

3. Results

Table 1 shows the cumulative incidence and incidence of dementia per 1,000 person-years. Of 14,286 subjects, 333 men (4.9%) and 468 women (6.3%) developed dementia during follow-up. Table 2 shows personal characteristics of those demented and not demented during the follow-up. In Cox models (see Table 3), even after adjustment for age (model 2), a higher positive affect score (range: 0-5) was significantly associated with lower risk of dementia with a hazard ratio of 0.80 ($P < .001$) for a one point increment. Among women, such a hazard was 0.75 ($P < .001$). Positive affect persisted as a significant protector from dementia throughout the models. Such association diminished after adding negative affect scores (model 6) among men, but not among women. Among women positive affect remained a marginally significant protector against dementia.

Table 2. Differences in baseline characteristics between dementia cases and non-dementia cases during the 4-year follow-up

		Men (n = 6,813)		Women (n = 7,473)	
	Range	Not demented	Demented	Not demented	Demented
Demographics					
Age	65-102	72.0(.072)	77.6(.316)	72.9(.069)	80.2(.267)
80 years or older (%)		13.9	17.1	14.0	25.2
Health behavior					
Current smoker (%)		23.8	25.8	2.3	3.7
Drinker (%)		38.4	30.5	3.2	5.8
Sedentary (< 30 min walk a day) (%)		35.6	44.4	37.8	47.9
Health status					
Illnesses or conditions	0-19	1.6(.018)	1.7(.079)	1.7(.017)	1.9(.068)
Functional limitation (%)		2.4	7.8	2.6	10.1
Social factors					
Low education (< 9y) (%)		67.6	79.3	74.3	76.0
Social engagement	0-8	1.5(.019)	1.2(.090)	1.4(.019)	1.0(.076)
Single (%)		18.8	21.9	48.3	56.6
Total GDS score	0-15	3.5(.044)	5.0(.209)	37(.045)	5.4(.188)
Positive affect	0-5	3.9(.017)	3.6(.078)	4.0(.016)	3.4(.067)
Negative affect	0-10	2.5(.032)	3.5(.149)	2.7(.032)	3.9(.133)

Note. Figures in the table are adjusted for years of age by means of multiple general linear regression models; Figures in parentheses are standard errors.

Table 3. Hazard ratios for incident dementia by Cox proportional hazard models by positive affect

Variables	Category/ range	M1	M2	M3	M4	M5	M6
		HR (95% CI) *P* value	HR (95% CI) *P* value	HR (95% CI) *P* value	HR (95% CI) *P* value	HR (95% CI) *P* value	HR (95% CI) *P* value
Men							
Positive affect (continuous)	0-5	0.82(0.75-0.89) $P < .001$	0.80(0.74-0.87) $P < .001$	0.85(0.78-0.92) $P < .001$	0.87(0.80-0.95) $P < .01$	0.87(0.80-0.95) $P < .01$	0.95(0.85-1.06) $P = .952$
Women							
Positive affect (continuous)	0-5	0.76(0.71-0.81) $P < .001$	0.75(0.70-0.81) $P < .001$	0.77(0.72-0.83) $P < .001$	0.79(0.73-0.85) $P < .001$	0.79(0.73-0.85) $P < .001$	0.91(0.82-1.00) $P = .052$

Note. Model 1: Crude;
Model 2: Adjusted for age;
Model 3: Model 2 + diagnosed illnesses, functional limitation (walking, bathing, or using the toilet), and health behaviors (smoking, drinking, walking);
Model 4: Model 3 + marital status, living arrangement, and social engagement;
Model 5: Model 4 + years of education;
Model 6: Model 5 + negative affect score;
HR = hazard ratio; CI = confidence interval.

4. DISCUSSION

We assessed the association between positive affect and dementia. To the best of our knowledge, this is the first large-scale cohort study conducted in Japan to investigate the association between positive affect and dementia onset among community-dwelling old people. Cumulative incidence of dementia in our study was 4.9% for men and 6.3% for women, and 33.0 per 1,000 person years for those 75 years or older. This is slightly higher but comparable to results in another study which reported the five-year incidence of 3.9% among non-demented (Clinical Dementia Rating: CDR = 0) older people.[24] Also, our results are in accordance with international data. The cumulative incidence rate of dementia was 36.60 per 1000 person years in a population of community-living old people aged 75-80 in Belgium,[25] and 34.6 to 105.9 per 1000 person years in a Swedish three-year follow-up study with non–demented (MMSE > 23) people aged 75 years or older at baseline.[12]

In our study, older adults with a higher positive affect score were significantly less likely to develop dementia. This is in agreement with the study result in which researchers demonstrated the independent association of positive affect in lowering the risk of functional decline.[17] Several explanations have been proposed for the mechanisms underlying the link between positive affect and cognitive health. For example, favorable health behaviors such as not smoking are more prevalent among happier people.[26] Positive affect was also associated with better mental and physical health.[27] Since doing physical activities and not smoking also protect against incident dementia,[28,29] this may partly explain the protective role of positive affect on maintaining cognitive health.

We found that men with a higher positive affect score were more likely to be intellectually and socially active, and to be married. Studies report that social engagement is associated with maintenance of cognitive function.[30] Social activities such as gardening, playing music, traveling, and meeting with friends reduce the risk of dementia.[10,31,32]

Although studies in Western nations have consistently found that the prevalence of dementia is high among people of lower income or education,[3] in our study, educational attainment was not a strong predictor for dementia. Low education was associated with a slightly higher risk of dementia among women but not among men (data not shown). Education may influence health in a complex way. Educational attainment protects against dementia through cognitive functional reserve or maintenance.[5,28] A variety of processes may play a role in such associations. One such process might be the direct adverse health effects of poor living conditions. Another is the indirect effect of negative affect such as depression. Physiological processes related to stress may favor neurodegenerative processes in the hippocampus, which plays an important role in memory processes in the brain.[30] Social isolation such as being single, living alone, and having a smaller social network is also prevalent among individuals with a low socio-economic status.[30] Unhealthy lifestyles such as smoking, heavy alcohol consumption and sedentary lifestyle are also more prevalent among people with low educational attainment or income.[33] These factors explain in part the higher prevalence of dementia among people having low educational attainment. However, among our population, such an association was weak. Since our population consisted of older adults, survival effect may in part explain that result.

4.1 Strengths and limitations

The present study adds several new findings to earlier studies. First, the effect of positive affect on dementia is independent of other confounders. Second, positive affect is more strongly associated with dementia than health behaviors or social engagement. The major strength of our study is that we used insurance data maintained by municipalities with very few missing cases. Dementia is often under-diagnosed among community populations,[34] therefore, use of insurance data enables us to better estimate factors associated with dementia onset. Given the fact that the long-term effect of behavior modification programs is disappointing,[13] this study adds evidence that interventions targeting positive affect among participants might be promising.

However, we must be cautious when interpreting the results. First, the association between positive affect and dementia could be confounded by other unknown factors, although in our data, positive affect was independently associated with incident dementia among women even after controlling for negative affect, as seen in the model 6. In addition, we performed sub-analyses excluding those with depression at baseline. Results did not change. Second, we cannot deny that people who already had mild cognitive impairment were included in this study since it was based on self-report. To consider possible reverse causality, we employed a series of analyses excluding subjects who developed dementia within one year from the baseline. However, the result did not change. Third, the diagnosis of dementia was based solely on observed symptoms. This might have led to misclassification of dementia cases.

Another limitation is that the data came from a self-administered survey. This might have led to selection bias. Studies have indicated a higher non-response rate among individuals with poorer mental health and/or lower income or education.[35] We previously assessed the difference between

respondents and non-respondents and found that those who refused to participate were more likely to be older and to have lower income.[36] Thus, the low response rate might contribute to an underestimation of the incidence of dementia, since dementia is more prevalent among people with low income or education.[3]

5. Conclusions

Despite the above limitations, our results suggest the protective role of positive affect against dementia. Overall, positive affect had a strong effect on cognitive health of older adults. In fact, happier people are healthier and live longer.[27] Psychological well-being and/or life-satisfaction are all associated with low risks of morbidity and mortality, as well as functional decline.[36] Possible pathways connecting positive affect and health are health behaviors,[15] stronger social networks and positive human interactions.[27] Further studies are needed to see if promoting positive affect is beneficial in terms of preventing cognitive decline among the old, and to assess the pathways by which a positive affect influences health among the old.

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Conflicts of Interest Disclosure

The authors declare that they have no competing interests.

Keypoints

- There have been reports regarding the role of positive affect on maintaining health. Still, few longitudinal studies are available which established an association between positive affect and incident dementia.
- Even in consideration of health status, health behaviors, social engagement, and low education, positive affect persisted as a significant protector against dementia.
- Although reverse causation cannot be ruled out, our results suggest the protective role of positive affect against cognitive decline among older adults.

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保健・医療・介護における効果・質・格差の評価*

—到達点と課題—

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要　約

限られた社会保障財源を効率的に配分するためには，費用対効果分析の視点が不可欠である。そのためには費用と共に効果の測定が必要である。しかし，今まで日本では医療やケアの効果や質の評価研究が遅れていた。

そこで，筆者らが取り組んで来た保健（介護予防），リハビリテーション医療，介護（特別養護老人ホームのケアの質），終末期ケアにおける研究の事例を紹介し，医療・介護の効果・質の「見える化」の到達点と可能性，そして今後の課題を論じた。いずれの研究においても，効果の大きいものとそうでないものがあった。それらを区別せず一律に費用抑制すれば，効果があるものまで抑制してしまう。社会保障費の拡大のための負担を国民が受け入れてくれるためにも，無駄を排除して，増やした医療費や介護費が，ケアの質や公平性の改善につながるような「見える化」をはじめとする仕組みづくりが必要である。そのためには，各領域における大規模データベースの構築，それらを研究の蓄積，それらを包含するマネジメント・システムの開発が必要である。

キーワード：ケアの質，医療サービス研究，見える化，データベース
JEL Classification：I00, I10, I12, I32

Ⅰ．背景と目的

財政改革の必要性が高まるにつれ，社会保障費用の抑制論議が再燃してきた。財政危機への対策として「痛みを伴う社会保障費用抑制」を主張する論者であっても社会保障の必要性を全面否定する者は少ないだろう。であれば，社会保障の機能を極力保ちつつ，痛みの（少）ない抑制策を慎重に探る必要がある。

限られた財源でより便益・効果・効用（以下，これらをまとめて効果と表記する）の大きな政策・プログラム選択するために，諸外国や我が国でも公共事業などでは広く行われているものが費用効果分析である。効果と同時に費用を分析し，費用を上回る効果があるのか，ＡとＢなど二つ以上の選択肢を比較して，どちらが同じ

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費用で効果が大きいのか，あるいは同じ効果ならどちらの費用が少なくて済むのかなど，費用と効果の比を比較分析するものである。効果が全くない政策やサービスであれば，無駄な費用だけがかかっている。そのことを明らかにし，国民に十分周知すれば，抑制・中止しても痛みはないばかりか，無駄な費用を減らせることになる。つまり，効果がないものを明らかにできれば，痛みのない無駄の削減は可能である。一方，痛みを伴う費用抑制が不可避な事態となった場合にも，伴う痛み・弊害をより小さくするための一つの方法は，費用対効果に優れた部分は残し費用対効果に劣る方から費用を削減することである。つまり，今後，財政制約が強まる中で，費用効果分析の重要性と必要性は高まっていくと考えられる。

保健・医療・福祉（介護）などの社会保障領域でも，費用効果分析の事例が蓄積されてきた。公的医療費でカバーする対象技術を決定する際の一つの判断材料とすることが，多くの国で行われている。一方，日本では，薬剤を対象とする経済評価に比べ，サービスに関わる費用対効果分析は遅れている。その理由として，費用効果分析の前提となる（臨床）効果の評価研究の研究基盤が弱く，その蓄積が乏しいことが指摘できる。

筆者は，その必要性が高まるとみて，以前から保健・医療・介護（以下，医療と略す）サービスの効果や質の評価研究に取り組んできた。その一部については，粗い費用の試算も行ってきた。本論では，それらを紹介しながら，以下のことについて検討する。第１に，なぜ医療サービスにおける費用対効果の評価研究は難しいのかを考察する。第２に，そのような制約の中で取り組んで来たいくつかの事例を取り上げ，医療領域のプログラムやサービスの効果や質の評価はどの程度可能なのかを紹介する。取り上げる事例は，保健（介護予防），リハビリテーション医療，通所並びに施設介護サービス，終末期ケアである。第３に，必要性の高まる費用対効果分析およびその前提となる医療サービス研究を日本で振興するための課題を考察したい。

Ⅱ．なぜ費用対効果の研究は難しいのか

限られた資源の最適配分や導入あるいは廃止の優先順位を考える上で，費用対効果分析はその基礎となる情報を与えてくれる。しかし，日本では薬剤など一部を除き，医療をはじめとする社会保障関連領域の評価研究はあまりなされてこなかった。その背景には，以下のような難しさがあったと考えられる。

Ⅱ－１．経済学と医療サービス研究の共同研究の乏しさ

費用対効果分析を行うためには，資源の最適配分という経済学的な関心を持ち，直接費用と間接費用，便益や効用，限界効果などの概念，さらには費用分析，費用便益分析，費用効果分析，費用効用分析の手法など経済学の学識を持つ者の関与が不可欠である。

一方，ある医療サービスを適用すべき医療ニーズ（疾患や病態，重症度，伴うことが多い合併症）や医療サービス提供のチームやプロセス，比較対照となりうる代替介入策，その過程で発生する費用やレセプトデータの特性や限界，医療サービスの効果・効用・副作用，それらと関連する交絡要因など医療サービスに関わる専門知識もかなり必要とする。（以下，これらの医療サービスに関わる研究を，生物医学を基礎科学とする狭義の医学研究と区別するために，医療サービス研究と表記する。）つまり，費用対効果分析には，経済学と医療サービス研

究の両方の学識を必要とする。このような広範な学識に裏付けられたデータを収集し分析するには，両者が関わる研究プロジェクトチームが必要であるが，日本では，そのようなものは希である。

その結果，日本の経済学者が扱ってきた医療データの多くはレセプトデータであった。レセプトデータには，投入された医療資源（行為）と費用については詳細なデータが含まれる。しかし，その医療行為の適用の妥当性を判断する患者の臨床像がわかる情報はDPC（Diagnosis Procedure Combination）情報にほぼ限定され，治療効果を評価するための臨床情報は入院中死亡程度で，例えば血圧が下がったか，リハビリテーションを受けて歩けるようになったかなどがわかる情報は含まれていない。これでは，医療行為の効果が検証できないので，その費用を計算しても費用対効果はわからない。一方，医療サービス研究に取り組む医療研究者の主な関心は，その効果や質であり，費用に関する情報を集めていることはまれである。その結果，費用対効果の分析に必要な，費用と効果の両方の情報を収集は，厚生労働省に提出が求められている薬剤などを除き極めて少なかった。

Ⅱ－2．複雑な介入による複雑なアウトカム

医療分野でも薬剤については費用対効果分析が蓄積されてきたが，他の医療サービスでは希であったのにも理由がある。例えば，降圧剤なら血圧を測定すれば，薬剤の短期効果を評価できる。しかも，薬剤のような単一要素の効果検証であれば，それ以外の結果に影響する要因については，偽薬を用いた対照群を設定した無作為化対照比較試験（randomized controlled trial: RCT）によって調整することも相対的にはやりやすい。RCTを実施しやすいのは，①比較的単純な介入で，②他の要因の影響が少ない場合で，③アウトカムが明確に定義できて測定可能で，④短期効果を実証する場合，という特徴・性格がある。一方，多くの要因や人手，チームで提供されるサービスの評価となると，介入自体が複雑で，介入の質を標準化することも容易でない[1)]。例えば，後述するリハビリテーション医療の例をあげれば，医師，看護師，理学療法士，作業療法士，医療ソーシャルワーカーなど多くの職種が関与しており，それら全てが提供される医療サービスの質に影響している。ある職種の腕が良くても別の職種の腕が悪いチームもあり，治療成績には，家族介護者の有無も影響することがわかっている。また治療効果の判定でも，退院後のQOL（quality of life）の向上が最終目的となるが，それは単純な指標で測定することが難しい場合が少なくない。

Ⅱ－3．基盤となるデータベースが（利用でき）ない

多くの要因が関わっているとなると，多くの要因に関するデータ収集が必要となる。多面的な分析に用いるデータベースには，多くの項目を必要とする。また，一人として同じ患者はいないので，多様な患者における効果を検討しようとすると，多様な患者データを含む極めて大規模なデータを必要とする。さらに効果を見るためには，介入前と介入後の経時的な変化がわかる縦断データが不可欠となる。

大規模で多面的で経時的な縦断データを含むデータベースを構築するために，利用しうるものとして，行政データがある。例えば，要介護認定データだけで500万人以上ある。しかし，個人情報保護法において，学術研究目的の利用は，適用除外となることが明記されていても，行政の担当者から目的外使用と個人情報保護を理由に使用を断られることが多い。

既存データの二次利用が不可能となれば，評価対象や評価項目をごく一部に限定して，自らデータベースを構築する以外にない。例えば，後で紹介するように転倒予防事業参加者だけ，脳卒中リハビリテーション患者だけ，余命半年と見込まれる終末期ケア対象者だけに限定することになる。対象を限定すればするほど，対象者の均質性は高まるが，今度は一施設や一市村では数例から数十例など，対象者数も限定され，

場合によっては統計学的評価に耐えられなくなる。それを克服するには，多施設や多市町村のデータをプールする必要がある。が，そうなると，その評価研究の意義を認めくれる多数の施設や市町村の協力を得るというハードルが高くなる。仮に協力を得られても，対象施設や市町村が増えるにつれ，あるサービスの質を検証したくてもサービスの質や得られるデータの質にもバラツキが増えることになり，その標準化に必要な努力は大きくなる。また独自調査やデータベースを構築する場合には，調査票への回答やデータベースへの入力を依頼する項目が増えるほど無回答や欠損値が増えるので，把握できる変数は限られることになる。

このように医療の効果や質の評価に使えるデータベースの構築だけでも，制約は多い。それを克服するには，かなりの人的資源と研究費と協力者との幸運な出会いが必要となる。現状の競争的研究資金の助成期間は３～５年程度で，人件費を捻出できない規模のものが多いので，前提となるデータベースの構築自体が容易でない。

Ⅱ－４．行政と研究者の共同研究の乏しさ

行政が持つデータには大きな潜在力があるが，学術的批判に耐えられる政策評価目的に使われていることはまれである。それにもいくつかの背景要因が指摘できる。行政と研究者が重視するものの違いである。研究者は，例えば年齢の影響などを差し引く統計学的な手法による調整を重視する。年齢以外にも，性別や診断名，重症度など，効果に影響する多くの要因についてのデータを求める。効果を見るためには，介入群と対照群が必要で，介入前と後の両方の情報が必要と考える。それらを高度な統計手法を用いて，諸要因の影響を取り除いた後でも，医療技術や要因による「真の影響」があるのかを明らかにすることが使命だと思っている。

一方，行政の立場から見れば，個人を特定できる情報を提供することは，個人情報の観点からハードルは高く，介入する前の情報を集めること，まして介入していない対照群の情報を集める「評価のためだけの評価」は「行政目的上はあり得ない」となる。さらに，厳密な研究論文になるほど，読んでも意味不明であり，「政策にはとても使えない」となる。一方で，行政に使える評価や分析を手伝おうという研究者が表れても，それらは学術論文に求められる要件を満たしていないために，研究業績としては評価されない。そのため，取り組んでも若手のポスドク研究員は職にありつけず，多くの研究者にとって負担に感じられるものに留まってしまう。

こうして互いが重視するものが異なるためにすれ違い，行政と研究者との共同研究はめったに進まないことになる。

以上，多くの要因が絡み合って，他の先進国に比べ，とりわけ日本では，費用対効果分析に必要な大規模データベースや関係者の共同が進んでいない現実があった。

Ⅲ．医療サービス研究の事例

このような制約のある中で，筆者らが取り組んで来た研究を以下では紹介する。その対象は，１．保健（介護予防），２．リハビリテーション医療，３．介護サービス，４．終末期ケアにおける評価研究事例である。

医療では，①費用や効率（Efficiency）以外にも②質や効果（Effectiveness），③アクセスや公平・公正（Equity）なども大事である。これらの「３E」，さらには（患者・国民の）参加やエンパワメント（Empowerment）を加え

て「4E」と呼ばれる評価基準があり，それらのバランスが取れていることが，良い医療システムの要件とされる[2)]。

しかし日本では，医療サービスの質やアクセスの善し悪しの評価が，他の先進諸国に比べ遅れていた。見えていたのは，費用だけである。しかし，費用だけでは費用対効果の評価はできない。まずは，前提となる効果のある医療やその質を評価する方法論や仕組みを構築していくことが必要である。それは上述したように容易ではないが，不可能という訳でもない。

Ⅲ－1．保健（介護予防）

2006年度の介護保険制度改革の一つの柱は，介護予防重視システムの導入であった。世界一の高齢化先進国である日本が導入した介護予防政策の成否には，今後，高齢者が増えていくアジアなど，他の国々も関心を寄せている。介護予防は，果たして成果をあげつつあるのであろうか。

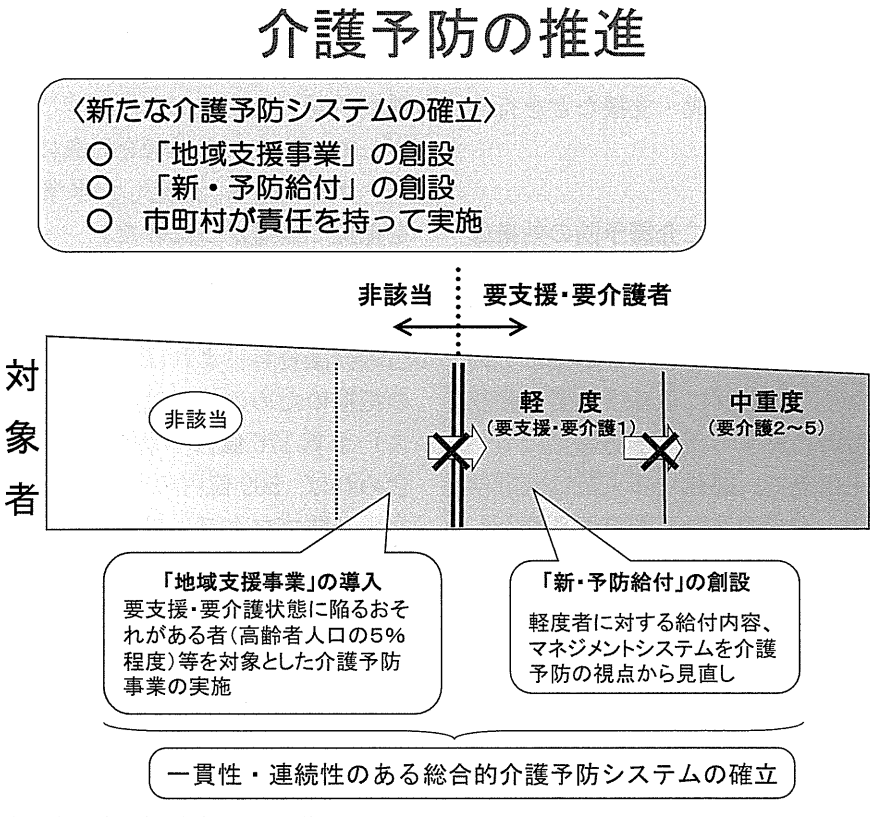
期待したほどの成果があがらなかった状況とその原因を掘り下げ，「もう一つの戦略」の必要性とその基本方向を述べる。その後，新しい地域づくり型予防の効果検証のための地域介入研究の結果とその費用分析の概要を紹介する。

Ⅲ－1－1．介護予防事業の枠組み

介護予防は，二つの部分で構成されている。一つは，既に要介護認定を受けている者を対象とする「予防給付」であり，もう一つは，まだ要介護認定を受けていない者を対象とし，「地域支援事業」の中で行われる「介護予防事業」である。（図1）

後者の「介護予防事業」は，さらに「特定高齢者施策」と「一般高齢者施策」の二つに分けられていた。特定高齢者とは，「要支援・要介

図1　介護予防重視システムの概要



（出所）　厚生労働省資料を一部修正

護状態に陥る恐れのある者」であり，一般高齢者はそれ以外を指す。（今では，名称変更がなされているが，ここでは特定高齢者という導入時の表現を用いることとする。）

予防医学では，ハイリスク戦略とポピュレーション戦略の二つの戦略があり，それらを組み合わせることが重要とされる[3]。ハイリスク戦略とは，危険性の高いハイリスク者をスクリーニングにより特定し，その人に対して介入する戦略である。一方，ポピュレーション戦略とは，スクリーニングを行わず，人口集団全体を対象とする戦略である。

厚生労働省老健局「地域包括支援センター業務マニュアル」（2005年12月19日）によれば，特定高齢者施策はハイリスク戦略，介護予防一般高齢者施策はポピュレーション戦略に立っている。特定高齢者施策では，健診受診者を対象に，基本チェックリストでスクリーニングを行って，特定高齢者を特定し，その人達を対象に，介護予防事業への参加を勧める。一方，一般高齢者施策では，パンフレットの作成・配布，講演会などで介護予防についての知識を普及啓発，介護予防にかかわるボランティアなどの人材育成，地域活動組織の育成・支援などを行うものである。

Ⅲ－１－２．新・予防給付に介護予防の効果はあったのか？

介護予防については，導入時の国会審議でも，その効果について疑問が出され，３年後にその効果検証がされた[4]。それによれば，要介護認定を受けている者に対する新・予防給付については「施策導入前後で，悪化する人数は統計学的有意に減少し，介護予防効果が実証された」という。ただし，この分析の対照群は，施策導入前の同等群（ヒストリカルコントロール）であり，他にも分析手法に多くの制約があり報告書の中でも「さらに検討を続ける必要がある」とされている。

Ⅲ－１－３．特定高齢者施策の問題点

次に特定高齢者施策では，「特定高齢者については，施策導入前後で，要介護度が悪化する者の発生率は減少するが，統計学的に有意な介護予防効果を算出することができなかった」[4]とされた。

以下で示すように，特定高齢者施策の有効性が示されなかった理由として，予防策が有効であるために必要な３条件を満たしていなかったことが指摘できる。第１に，介護予防事業の対象者とすべきハイリスク者をスクリーニングできなかった問題，第２に，その人たちが介護予防プログラムに参加してくれなかった問題，第３に，参加してもらう介護予防プログラムの効果の問題である。

（１）スクリーニングにおける問題点

要介護状態になりやすいリスク因子を持つ虚弱な高齢者は，当初高齢者人口の５％程度と見込まれていた。しかし，実際には，わずか0.14％にとどまった[5]。その理由の一つは，スクリーニングを健診参加者を対象に行ったことにある。

調べてみると健診非受診者に比べて受診者の健康状態はむしろ良かった[6;7]。つまり意図せずして，健康な高齢者を対象にして，スクリーニングした結果，想定した水準の「特定高齢者」を把握できなかったのだ。

もうひとつの問題は，高額な費用である。平成22年６月15日地域包括支援センター全国担当者会議資料によれば，健診による特定高齢者の把握のための費用は，介護予防事業（国費ベース）予算176億円の約50％，保険者負担分を含めれば，509億円のうち340億円（66.7％）と，介護予防プログラム提供よりも多い額が対象者の把握のために使われていた。

（２）事業への参加辞退を巡る問題

第２の条件，「スクリーニングされた特定高齢者の介護予防プログラムへの参加」にも問題があった。特定高齢者に，介護予防プログラムへの参加を勧めても辞退する者が少なくなかっ