# A feasibility study of early multimodal intervention for elderly patients with advanced pancreatic and non-small-cell lung cancer

the NEXTAC-ONE study

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## Introduction and Objective

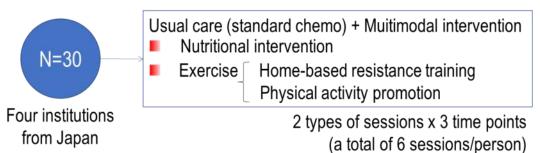
Combination of exercise and nutritional intervention might improve functional-prognosis of cachectic cancer patients. However, high attrition and poor compliance to the intervention limits its efficacy. We aimed to test the feasibility of the early induction of new multimodal interventions specific for elderly patients with advanced cancer (the NEXTAC-ONE study, Trial No. UMIN000023207).

## Methods

#### Study Design

Patients:

Advanced NSCLC or Pancreatic cancer, being to start chemotherapy ECOG-PS 0-1, ≥70v.o., no disability (Barthel index ≥95 points)



Endpoint

Primary: Feasibility (attendance, threshold 0.45, expectation 0.70) Secondary: Safety, Compliance, Adherence

in 8-week study period

Sessions	Contents of NEXTAC program
Nutrition 20-30 min	Nutritional intervention  Nutritional advice  Management of nutrition impact symptoms
Exercise 20-30 min In each	<ul> <li>Home-based resistance training</li> <li>Prescription of daily program</li> <li>Education of sick-day program</li> </ul>
	<ul><li>Physical activity promotion</li><li>Prescription of target step</li><li>Counseling for behavioral change</li></ul>

BCAAenriched ONS



Inner Power® (Otsuka Pharmaceutics, Japan)



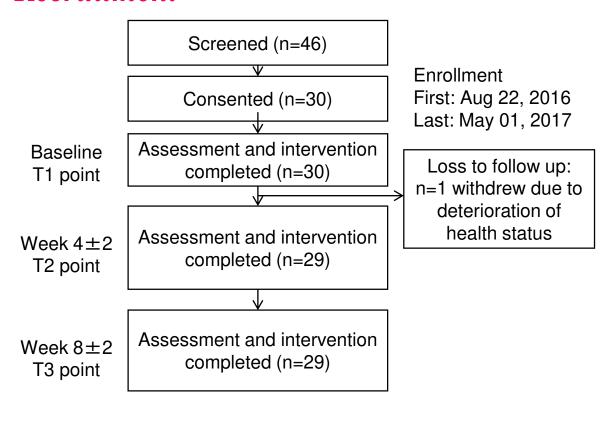
Monitoring & Self-feedback



Pedometers
/accelerometer
(Lifecorder®,
Suzuken, Japan)

### Results

#### Recruitment



## Feasibility |

N = 30	No (%) of attendee	No. of sessions
Nutritional sessions	90 (100)	90
Resistance training sessions	07 (07)	90
Physical activity sessions	87 (97)	
Feasibility	N	% (95%CI)
No. of patients who attended ≥2/3 of all sessions	28	96.7 (83.3-99.4)

## **Compliance**

N = 29 completers	Median (IQR)
Intervention period	57 (51-65) days
Supplement consumption day	99 (88-100) %
Exercise Performance day	91 (69-95) %
Accelerometer wear day (≥5 h/day)	98 (85-100) %

#### Changes in Physical Parameters

Assessments	Baseline value	8-week changes
Nutrition		
Calorie intake (kcal/day)	1638±65	NC
Body-mass index(kg/m <sup>2</sup> )	22±1	NC
Skeletal muscle index (cm²/m²)	41±1	NC
Full MNA score (point)	24±1	NC
Physical function		
6-minute walking distance (m)	422±13	NC
5-meter gait speed (m/sec)	1.2±0.0	NC
5-time-sit-to-stand test (sec)	10.8±0.4	-0.5±1.0*
Hand-grip strength (kg)	26±1	NC
Physical activity		
Daily steps (steps/day)	4253±463	NC
Time spent in PA (min/day)	47±5	NC
Time spent in MVPA (min/day)	5±1	2.3±1.1*

\*Wilcoxon signed-rank test p<0.05

# Conclusions

The early induction of multimodal NEXTAC program showed excellent compliance and safety in elderly patients with newly diagnosed pancreatic and non-small-cell lung cancer receiving concurrent chemotherapy. We are now conducting a randomized phase two study to measure the impact of these interventions on functional prognosis. (NEXTAC-TWO study, Trial No. UMIN000028801)

#### Patient Characteristics

Variables	N = 30
Median age (range)	<b>75</b> (70-84)
Women:Men	10:20
ECOG-PS	n (%)
0	11 (37)
1	19 (63)
Lung cancer	24 (80)
Pancreatic cancer	6 (20)
Stage IV	27 (90)
Chemotherapy	
Cytotoxic	20 (67)
Targeted	10 (33)
Lifestyle, n (%)	
Smoker	21 (70)
Unemployed	18 (60)
No exercise habit	16 (53)
Living alone	4 (13)
History of falls	3 (10)
Nutritional status	
Cancer cachexia	12 (40)
Skeletal muscle depletion	21 (70)