Repérage patients vulnérables et fragiles

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Nous avons un problème à résoudre…

…avec les patients âgés atteints de cancer

- Mauvais pronostic
- Risque majoré de toxicités
- Toxicités inattendues
  - Liées aux comorbidités existantes
- Conséquences inattendues de ces toxicités

Nous avons des solutions…

Evaluation gériatrique

- Identification du groupe des patients vulnérables à l’aide d’une batterie de questionnaires et à l’expérience des gériatres

Nous avons des solutions…

QUESTIONNAIRE
Rarely

1425 pts	Anormal	n	%
ADL	<6	217	15.2
IADL	<8	682	47.9
GDS15	≥6	457	32.1
MMS	<24	290	20.3
MNA	≤23,5	623	43.7
Timed Get up & Go	>20 s	328	23
CIRS-G	Grade 3-4	595	41.8

Nous avons des solutions…

364 patients	**Early death < 6 m.** *Odd ratio (95% CI)*	**Functional decline** *Odd ratio (95% CI)*	**Hospitalization for toxicity** *Odd ratio (95% CI)*
Events	***59**/339*	***50**/299*	***47**/354*
Extension (M+ vs M-)	**4.1** ***(1.65-10.1)***		
Sex	**2.62** ***(1.31-5.28)***		
Platelet count ***<150 G/l***			**3.8** ***(1,3-10,8)***
Clinician opinion		**ns**	**0.51** ***(0,26-0,99)***
PS	**ns**	**ns**	
MNA ≤ 23.5	**2.91** ***(1.31-56.48)***	**ns**	**4.19** ***(1,7-10,3)***
Get up and go ***> 20 s***	**2.51** ***(1,31-4,82)***	**ns**	
IADL ***≤ 7***	**ns**	**3** ***(1,13-8,09)***	
GDS15 ***≥6***		**2.4** ***(1,23-4,66)***	
MMS	**ns**	**ns**	
ADL	**ns**		
CIRS-G			
	Soubeyran JCO 2012	**Hoppe JCO2013**	**Warkus submitted**

Nous avons des solutions…

…mais elles sont disponibles pour une minorité

1435 consecutive cancer patients

Duration of CGA = 67.7 mn +/- 24.6

- **Evaluation gériatrique**
  - Identification du groupe des patients vulnérables à l’aide d’une batterie de questionnaires
- **Consommatrice de temps**
  - A peu près une heure
- **Disponible pour une minorité de patients**

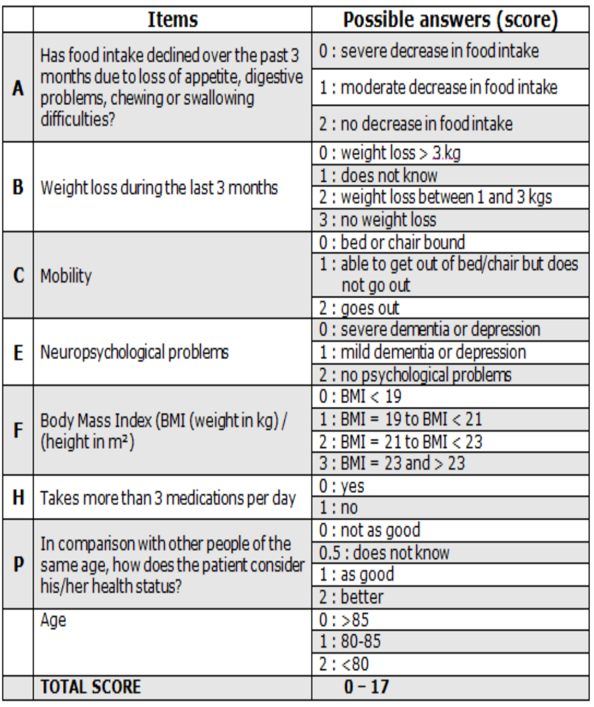
Le screening peut aider les médecins…
…à identifier les patients vulnérables

SANTA CAME EARLY THIS YEAR!
TSA
TSA

ELDERLY FLIER CLAIMS STRIP-SEARCH BY TSA

- **Nombreux outils**
  - Propriétés variables
- **Faisable par tous en moins de 5’**
  - Médecin, IDE ou ARC
- **Faisable dans la majorité des centres qui traitent des cancers**
  - Sans besoin d’expertise gériatrique

Le screening peut aider les médecins… …à identifier les patients vulnérables



	Items	Possible answers (score)
A	Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?	0 : severe decrease in food intake
		1 : moderate decrease in food intake
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F	Body Mass Index (BMI (weight in kg) / (height in m²)	0 : BMI < 19
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H	Takes more than 3 medications per day	0 : yes
		1 : no
P	In comparison with other people of the same age, how does the patient consider his/her health status?	0 : not as good
		0.5 : does not know
		1 : as good
		2 : better
	Age	0 : >85
		1 : 80-85
		2 : <80
	TOTAL SCORE	**0 – 17**

- **Nombreux outils**
  - Propriétés variables
- **Faisable par tous en moins de 5'**
  - Médecin, IDE ou ARC
- **Faisable dans la majorité des centres qui traitent des cancers**
  - Sans besoin d'expertise gériatrique

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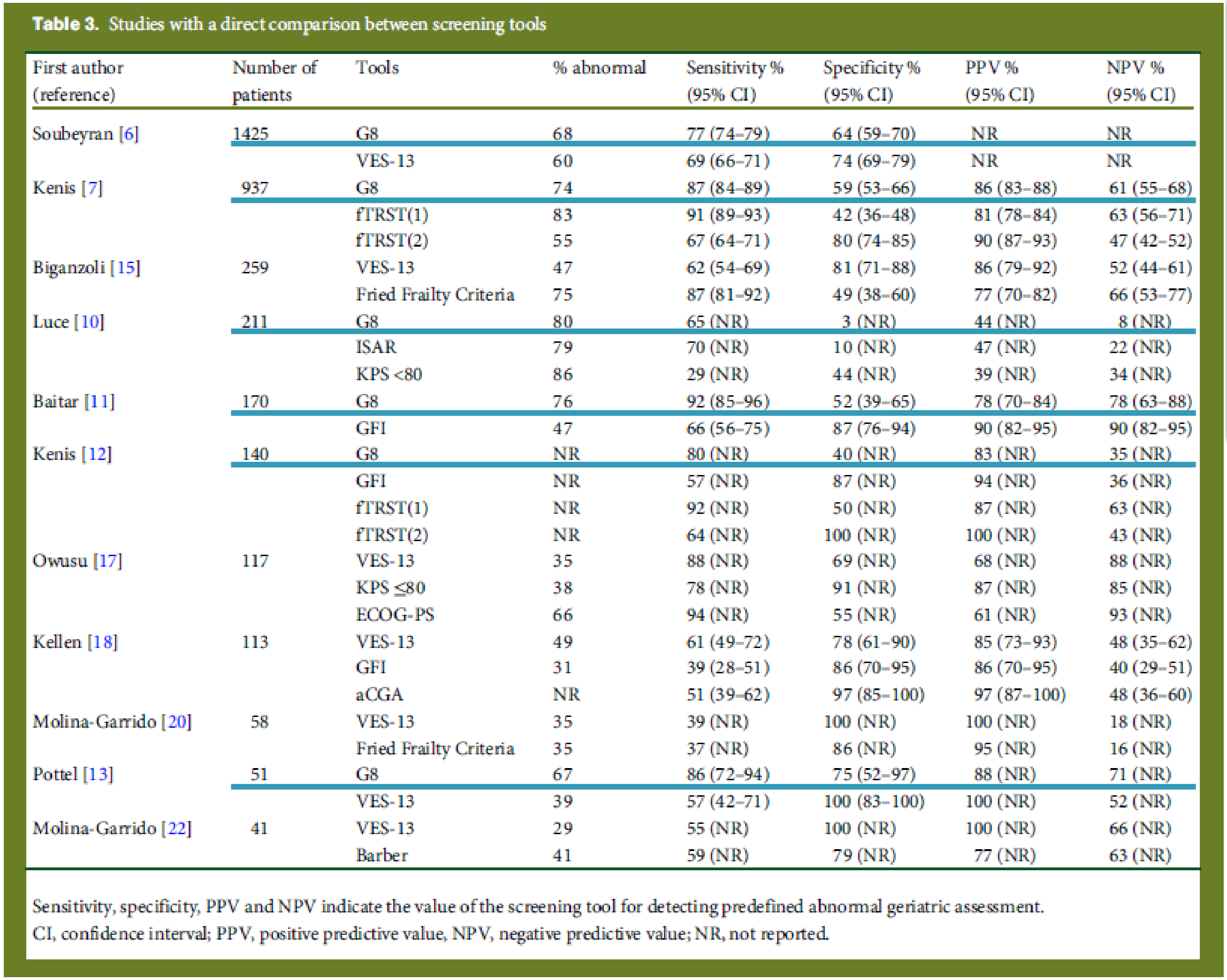
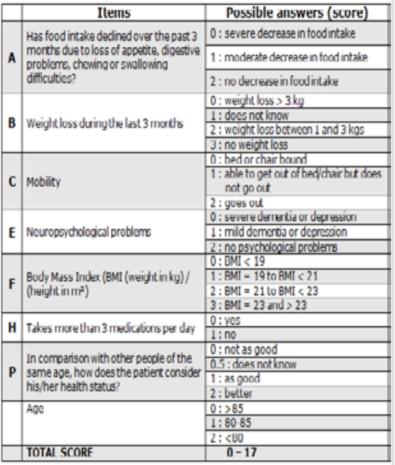


Table 3. Studies with a direct comparison between screening tools

First author (reference)	Number of patients	Tools	% abnormal	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
Soubeyran [6]	1425	G8	68	77 (74–79)	64 (59–70)	NR	NR
		VES-13	60	69 (66–71)	74 (69–79)	NR	NR
Kenis [7]	937	G8	74	87 (84–89)	59 (53–66)	86 (83–88)	61 (55–68)
		fTRST(1)	83	91 (89–93)	42 (36–48)	81 (78–84)	63 (56–71)
		fTRST(2)	55	67 (64–71)	80 (74–85)	90 (87–93)	47 (42–52)
Biganzoli [15]	259	VES-13	47	62 (54–69)	81 (71–88)	86 (79–92)	52 (44–61)
		Fried Frailty Criteria	75	87 (81–92)	49 (38–60)	77 (70–82)	66 (53–77)
Luce [10]	211	G8	80	65 (NR)	3 (NR)	44 (NR)	8 (NR)
		ISAR	79	70 (NR)	10 (NR)	47 (NR)	22 (NR)
		KPS <80	86	29 (NR)	44 (NR)	39 (NR)	34 (NR)
Baitar [11]	170	G8	76	92 (85–96)	52 (39–65)	78 (70–84)	78 (63–88)
		GFI	47	66 (56–75)	87 (76–94)	90 (82–95)	90 (82–95)
Kenis [12]	140	G8	NR	80 (NR)	40 (NR)	83 (NR)	35 (NR)
		GFI	NR	57 (NR)	87 (NR)	94 (NR)	36 (NR)
		fTRST(1)	NR	92 (NR)	50 (NR)	87 (NR)	63 (NR)
		fTRST(2)	NR	64 (NR)	100 (NR)	100 (NR)	43 (NR)
Owusu [17]	117	VES-13	35	88 (NR)	69 (NR)	68 (NR)	88 (NR)
		KPS ≤80	38	78 (NR)	91 (NR)	87 (NR)	85 (NR)
		ECOG-PS	66	94 (NR)	55 (NR)	61 (NR)	93 (NR)
Kellen [18]	113	VES-13	49	61 (49–72)	78 (61–90)	85 (73–93)	48 (35–62)
		GFI	31	39 (28–51)	86 (70–95)	86 (70–95)	40 (29–51)
		aCGA	NR	51 (39–62)	97 (85–100)	97 (87–100)	48 (36–60)
Molina-Garrido [20]	58	VES-13	35	39 (NR)	100 (NR)	100 (NR)	18 (NR)
		Fried Frailty Criteria	35	37 (NR)	86 (NR)	95 (NR)	16 (NR)
Pottel [13]	51	G8	67	86 (72–94)	75 (52–97)	88 (NR)	71 (NR)
		VES-13	39	57 (42–71)	100 (83–100)	100 (NR)	52 (NR)
Molina-Garrido [22]	41	VES-13	29	55 (NR)	100 (NR)	100 (NR)	66 (NR)
		Barber	41	59 (NR)	79 (NR)	77 (NR)	63 (NR)

Sensitivity, specificity, PPV and NPV indicate the value of the screening tool for detecting predefined abnormal geriatric assessment.
CI, confidence interval; PPV, positive predictive value, NPV, negative predictive value; NR, not reported.

Decoster L, Ann Oncol 2015



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Le screening peut aider les médecins…

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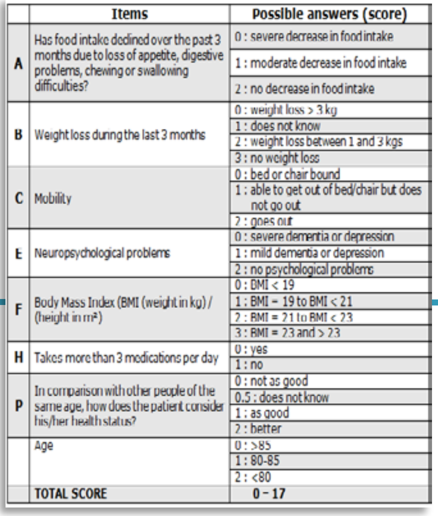

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>14

32%

Bon état ou peu vulnérable

41% MGA normale
32% un Q anormal
28% > un Q anormal

≤14

68%

Probablement vulnérable

90% avec MGA anormale
Médiane: 3 questionnaires anormaux
10% avec MGA normale

Le screening peut aider les médecins…
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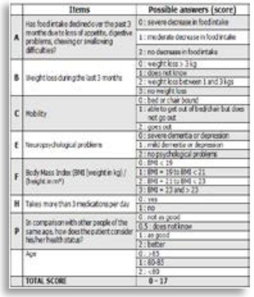

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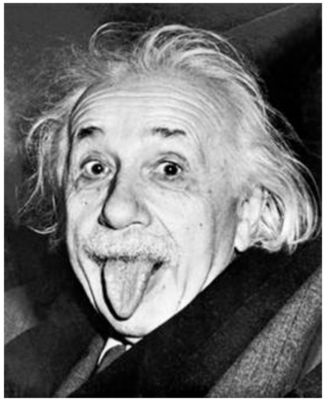
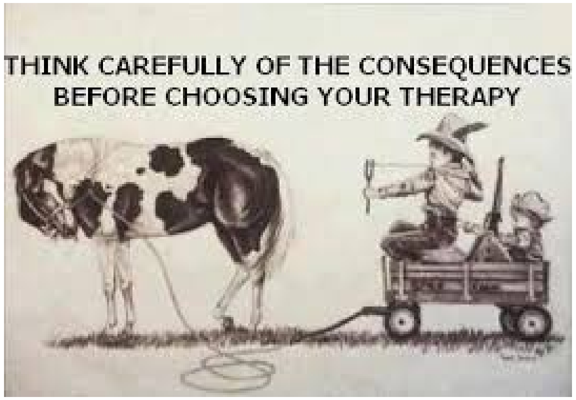
32%

≤14

68%




THINK CAREFULLY OF THE CONSEQUENCES
BEFORE CHOOSING YOUR THERAPY

Pas de besoin de CGA

Traitement standard

Nécessité d'attention spécifique

CGA à envisager

Traitement adapté à l'état du patient

Etapes suivantes ?

- **Diffusion du G8 en routine quotidienne**
  - *Comment rendre le questionnaire disponible?*
    - Dans le dossier informatisé
    - Formulaires disponibles
    - Application web
  - *Qui doit le proposer au patient ?*
    - Médecin
    - IDE
    - ‘ *Temps d’accompagnement soignant* ’
    - ARC
- **Amélioration du questionnaire**

Performance d’un test G8 modifié avec remplacement de l’item E par l’IADL4

Population	Abnormal		Se	*(95%CI)*	Sp	*(95%CI)*	AUC	*(95%CI)*
	N (%)	Total						
Development	**756 (80%)**	**948**	**77%**	*(74-80)*	**67%**	*(60-74)*	**81%**	*(78-84)*
Internal validation	**394 (81%)**	**486**	**78%**	*(73-82)*	**71%**	*(60-80)*	**83%**	*(79-87)*
External validation	**322 (95%)**	**338**	**88%**	*(84-91)*	**69%**	*(41-89)*	**90%**	*(84-95)*

Petit A, J Ger Oncol

Intervention gériatrique ?

- **Intuitivement oui mais…**
- **Essai d'intervention nutritionnelle INOGAD**
- **Pas de différence malgré une intervention efficace**
- **Coût de mise en place**
  - EGA et intervention
  - Les autorités de santé ont besoin de données

Taskforce SIOG - Méthodologie

Elaboration des questions auxquelles répondre

	Intervention	Question
1	**Geriatric interventions**	Does diet intervention improve **nutrition parameters**?
2		Does exercise intervention improve **physical functioning**?
3		Does diet and exercise intervention improve **quality of life**?
4		Does exercise intervention improve **other dimensions of patients' outcome**?
5		Does geriatric advices improve **appropriate application of treatment plan**?
6		Does geriatric domain-specific intervention (physical, nutritional …) improve **survival**?
7		Does geriatric domain-specific intervention improve **fatigue**?
8	**Patient education**	Does it improve **quality of life**?
9		Does it improve **other dimensions of patients' outcome**?
10	**Case management**	Does it improve **survival**?
11		Does it improve **quality of life**?
12		Does it improve **other dimensions of patients' outcome**?

Taskforce SIOG - Méthodologie

Evaluation des essais

Evaluation de chaque essai

- Niveaux d'évidence ASCO pour l'objectif principal

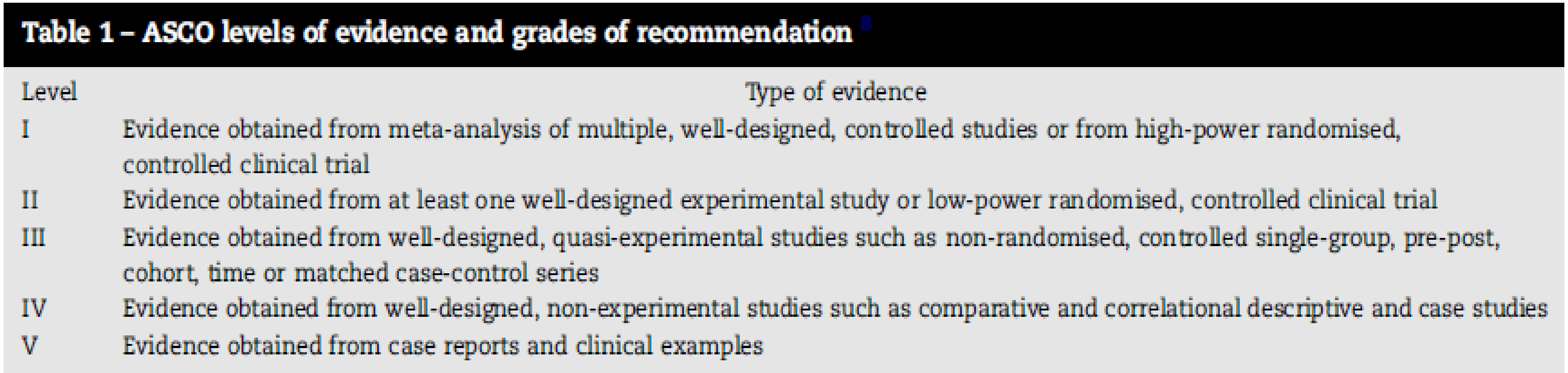


Table 1 – ASCO levels of evidence and grades of recommendation [8]

Level	Type of evidence
I	Evidence obtained from meta-analysis of multiple, well-designed, controlled studies or from high-power randomised, controlled clinical trial
II	Evidence obtained from at least one well-designed experimental study or low-power randomised, controlled clinical trial
III	Evidence obtained from well-designed, quasi-experimental studies such as non-randomised, controlled single-group, pre-post, cohort, time or matched case-control series
IV	Evidence obtained from well-designed, non-experimental studies such as comparative and correlational descriptive and case studies
V	Evidence obtained from case reports and clinical examples

Taskforce SIOG - Méthodologie

Evaluation des essais

- **Regroupement des essais par question**
- **Synthèse en grade de recommandation** ***(ASCO)***

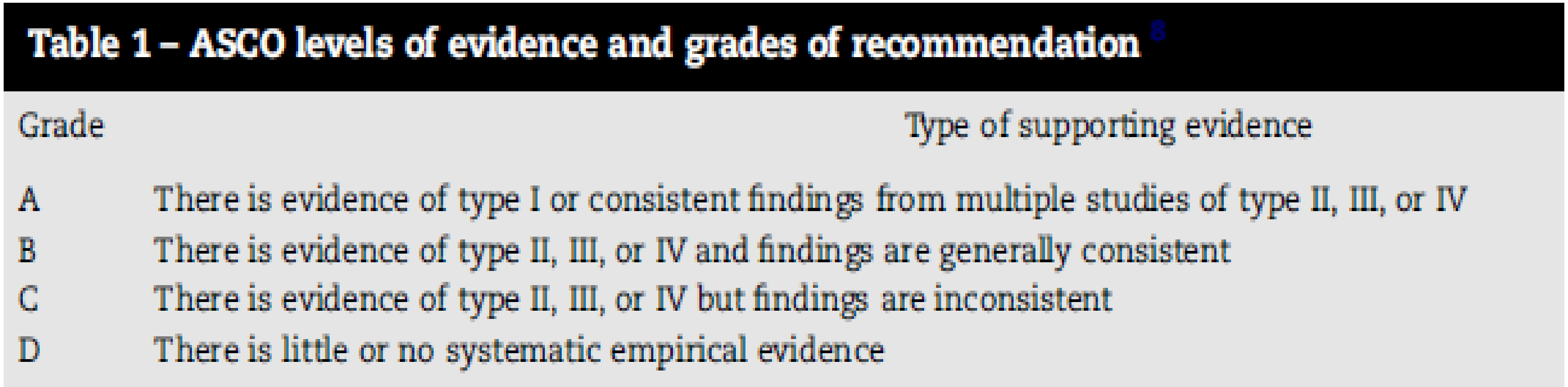
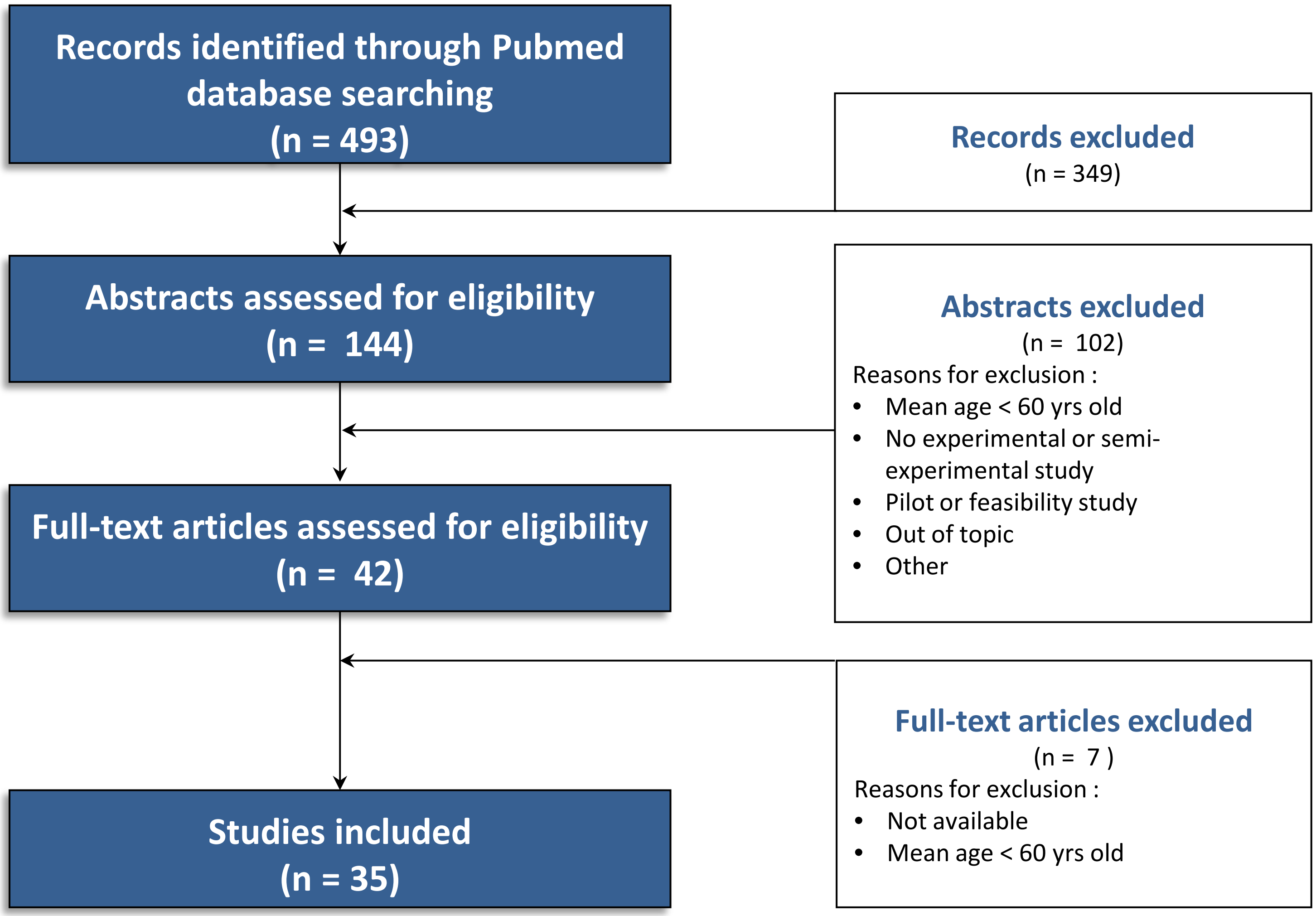


Table 1 – ASCO levels of evidence and grades of recommendation [8]

Grade	Type of supporting evidence
A	There is evidence of type I or consistent findings from multiple studies of type II, III, or IV
B	There is evidence of type II, III, or IV and findings are generally consistent
C	There is evidence of type II, III, or IV but findings are inconsistent
D	There is little or no systematic empirical evidence

Recherche bibliographique



Records identified through Pubmed database searching
(n = 493)

Records excluded
(n = 349)

Abstracts assessed for eligibility
(n = 144)

Abstracts excluded
(n = 102)
Reasons for exclusion :
- Mean age < 60 yrs old
- No experimental or semi-experimental study
- Pilot or feasibility study
- Out of topic
- Other

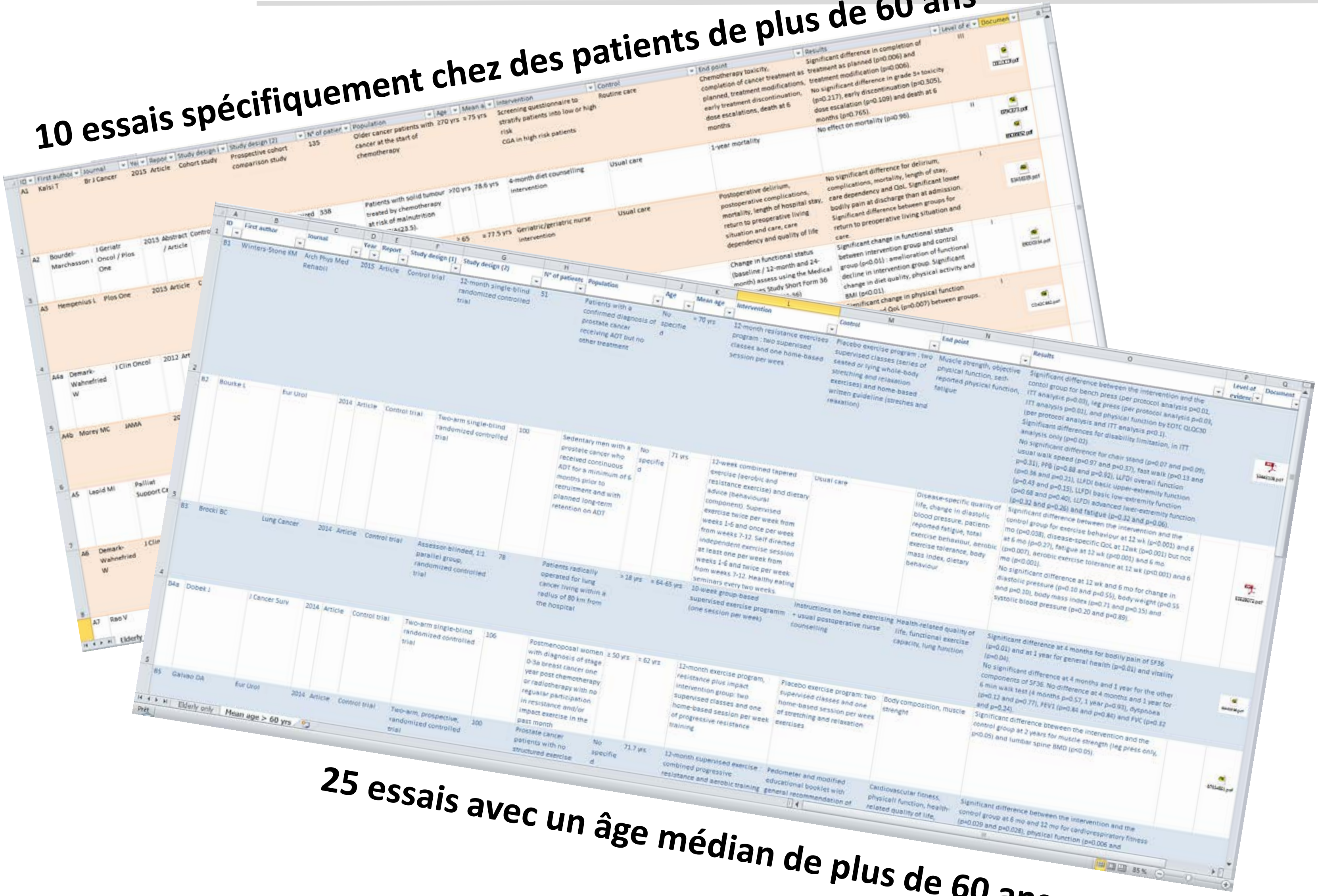
Full-text articles assessed for eligibility
(n = 42)

Full-text articles excluded
(n = 7)
Reasons for exclusion :
- Not available
- Mean age < 60 yrs old

Studies included
(n = 35)

Synthèse des résultats

10 essais spécifiquement chez des patients de plus de 60 ans



ID	First author	Journal	Yea	Repor	Study design (	Study design (2)	N° of patier	Population	Age	Mean a	Intervention	Control	End point	Results	Level of e	Documen
A1	Kalsi T	Br J Cancer	2015	Article	Cohort study	Prospective cohort comparison study	135	Older cancer patients with cancer at the start of chemotherapy	≥70 yrs	≈ 75 yrs	Screening questionnaire to stratify patients into low or high risk CGA in high risk patients	Routine care	Chemotherapy toxicity, completion of cancer treatment as planned, treatment modifications, early treatment discontinuation, dose escalations, death at 6 months	Significant difference in completion of treatment as planned (p=0.006) and treatment modification (p=0.006). No significant difference in grade 3+ toxicity (p=0.217), early discontinuation (p=0.305), dose escalation (p=0.109) and death at 6 months (p=0.765).	III	[illegible]
A2	Bourdel-Marchasson I	J Geriatr Oncol / Plos One	2013	Abstract / Article	Contro	ized	338	Patients with solid tumour treated by chemotherapy at risk of malnutrition	>70 yrs	78.6 yrs	4-month diet counselling intervention	Usual care	1-year mortality	No effect on mortality (p=0.96).	II	[illegible] [illegible]
A3	Hempenius L	Plos One	2013	Article	C				≥ 65	≈ 77.5 yrs	Geriatric/geriatric nurse intervention	Usual care	Postoperative delirium, postoperative complications, mortality, length of hospital stay, return to preoperative living situation and care, care dependency and quality of life	No significant difference for delirium, complications, mortality, length of stay, care dependency and QoL. Significant lower bodily pain at discharge than at admission. Significant difference between groups for return to preoperative living situation and care.	I	[illegible]
A4a	Demark-Wahnefried W	J Clin Oncol	2012	Art									Change in functional status (baseline / 12-month and 24-month) assess using the Medical	Significant change in functional status between intervention group and control group (p<0.01) : amelioration of functional group. Significant decline in intervention group. Significant change in diet quality, physical activity and BMI (p<0.01).	I	[illegible]
A4b	Morey MC	JAMA	20											Significant change in physical function	I	[illegible]
A5	Lapid MI	Palliat Support Ca														
A6	Demark-Wahnefried W	J Clin														
A7	Rao V															

Elderly

ID	First author	Journal	Year	Report	Study design (1)	Study design (2)	N° of patients	Population	Age	Mean age	Intervention	Control	End point	Results	Level of evidenc	Document
B1	Winters-Stone KM	Arch Phys Med Rehabil	2015	Article	Control trial	12-month single-blind randomized controlled trial	51	Patients with a confirmed diagnosis of prostate cancer receiving ADT but no other treatment	No specified	≈ 70 yrs	12-month resistance exercises program : two supervised classes and one home-based session per week	Placebo exercise program : two supervised classes (series of seated or lying whole-body stretching and relaxation exercises) and home-based written guideline (streches and relaxation)	Muscle strength, objective physical function, self-reported physical function, fatigue	Significant difference between the intervention and the contol group for bench press (per protocol analysis p=0.01, ITT analysis p=0.03), leg press (per protocol analysis p=0.01, ITT analysis p=0.01), and physical function by EOTC QLQC30 (per protocol analysis and ITT analysis p<0.1). Significant differences for disability limitation, in ITT analysis only (p=0.02). No significant difference for chair stand (p=0.07 and p=0.09), usual walk speed (p=0.97 and p=0.37), fast walk (p=0.13 and p=0.31), PPB (p=0.88 and p=0.92), LLFDI overall function (p=0.36 and p=0.21), LLFDI basic upper-extremity function (p=0.43 and p=0.15), LLFDI basic low-extremity function (p=0.68 and p=0.40), LLFDI advanced lwer-extremity function (p=0.32 and p=0.26) and fatigue (p=0.32 and p=0.06).		[illegible]
B2	Bourke L	Eur Urol	2014	Article	Control trial	Two-arm single-blind randomized controlled trial	100	Sedentary men with a prostate cancer who received continuous ADT for a minimum of 6 months prior to recruitment and with planned long-term retention on ADT	No specified	71 yrs	12-week combined tapered exercise (aerobic and resistance exercise) and dietary advice (behavioural component). Supervised exercise twice per week from weeks 1-6 and once per week from weeks 7-12. Self directed independent exercise session at least one per week from weeks 1-6 and twice per week from weeks 7-12. Healthy eating seminars every two weeks.	Usual care	Disease-specific quality of life, change in diastolic blood pressure, patient-reported fatigue, total exercise behaviour, aerobic exercise tolerance, body mass index, dietary behaviour	Significant difference between the intervention and the control group for exercise behaviour at 12 wk (p<0.001) and 6 mo (p=0.038), disease-specific QoL at 12wk (p=0.001) but not at 6 mo (p=0.27), fatigue at 12 wk (p<0.001) and 6 mo (p=0.007), aerobic exercise tolerance at 12 wk (p<0.001) and 6 mo (p<0.001). No significant difference at 12 wk and 6 mo for change in diastolic pressure (p=0.10 and p=0.55), bodyweight (p=0.55 and p=0.10), body mass index (p=0.71 and p=0.15) and systolic blood pressure (p=0.20 and p=0.89).		[illegible]
B3	Brocki BC	Lung Cancer	2014	Article	Control trial	Assessor-blinded, 1:1 parallel group, randomized controlled trial	78	Patients radically operated for lung cancer living within a radius of 80 km from the hospital	> 18 yrs	≈ 64-65 yrs	10-week group-based supervised exercise programm (one session per week)	Instructions on home exercising + usual postoperative nurse counselling	Health-related quality of life, functional exercise capacity, lung function	Significant difference at 4 months for bodily pain of SF36 (p=0.01) and at 1 year for general health (p=0.01) and vitality (p=0.04). No significant difference at 4 months and 1 year for the other components of SF36. No difference at 4 months and 1 year for 6 min walk test (4 months p=0.57, 1 year p=0.93), dyspnoea (p=0.12 and p=0.77), FEV1 (p=0.84 and p=0.84) and FVC (p=0.32 and p=0.24).		[illegible]
B4a	Dobek J	J Cancer Surv	2014	Article	Control trial	Two-arm single-blind randomized controlled trial	106	Postmenopausal women with diagnosis of stage 0-3a breast cancer one year post chemotherapy or radiotherapy with no regualar participation in resistance and/or impact exercise in the past month	≥ 50 yrs	≈ 62 yrs	12-month exercise program, resistance plus impact intervention group: two supervised classes and one home-based session per week of progressive resistance training	Placebo exercise program: two supervised classes and one home-based session per week of stretching and relaxation exercises	Body composition, muscle strenght	Significant difference bteween the intervention and the control group at 2 years for muscle strength (leg press only, p<0.05) and lumbar spine BMD (p<0.05).		[illegible]
B5	Galvao DA	Eur Urol	2014	Article	Control trial	Two-arm, prospective, randomized controlled trial	100	Prostate cancer patients with no structured exercise	No specified	71.7 yrs	12-month supervised exercise combined progressive resistance and aerobic training	Pedometer and modified educational booklet with general recommendation of	Cardiovascular fitness, physicall function, health-related quality of life,	Significant difference between the intervention and the control group at 6 mo and 12 mo for cardiorespiratory fitness (p=0.029 and p=0.028), physical function (p=0.006 and		

Elderly only | Mean age > 60 yrs

Prêt 85 %

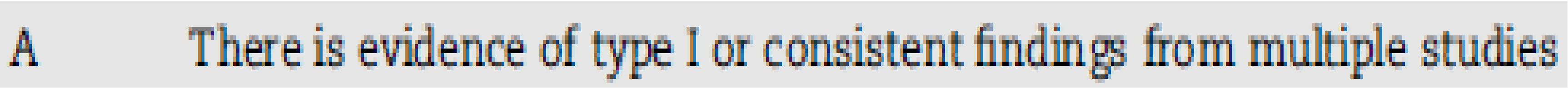
25 essais avec un âge médian de plus de 60 ans

Selon les domaines d’intervention

Interventions physiques et état physique

Intervention physique

- 15 essais (dont 2 spécifiques sujets âgés)
- Trois de niveau I
- 11 significatifs

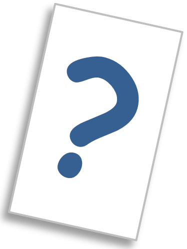


A	There is evidence of type I or consistent findings from multiple studies

Survie

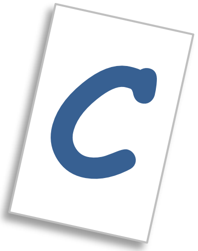
Intervention gériatrique

- 2 essais (dont 1 spécifique sujets âgés)
- 2 niveaux II
- 2 négatifs

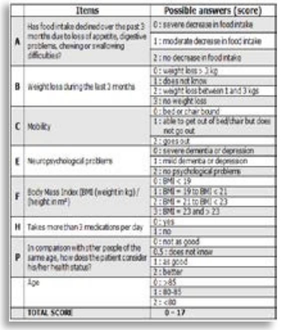


Case Management

- 4 essais spécifiques sujets âgés
- 3 niveaux II, 1 niveau III
- 1 positif, 3 négatifs



Essai de Phase III PREPARE



	Items	Possible answers (score)
A	Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?	0 : severe decrease in food intake
		1 : moderate decrease in food intake
		2 : no decrease in food intake
B	Weight loss during the last 3 months	0 : weight loss > 3 kg
		1 : does not know
		2 : weight loss between 1 and 3 kgs
		3 : no weight loss
C	Mobility	0 : bed or chair bound
		1 : able to get out of bed/chair but does not go out
		2 : goes out
E	Neuropsychological problems	0 : severe dementia or depression
		1 : mild dementia or depression
		2 : no psychological problems
F	Body Mass Index (BMI (weight in kg) / (height in m²)	0 : BMI < 19
		1 : BMI = 19 to BMI < 21
		2 : BMI = 21 to BMI < 23
		3 : BMI = 23 and > 23
H	Takes more than 3 medications per day	0 : yes
		1 : no
P	In comparison with other people of the same age, how does the patient consider his/her health status?	0 : not as good
		0.5 : does not know
		1 : as good
		2 : better
	Age	0 : >85
		1 : 80-85
		2 : <80
	TOTAL SCORE	0 - 17

> 14

Standard management

1500 patients to be screened

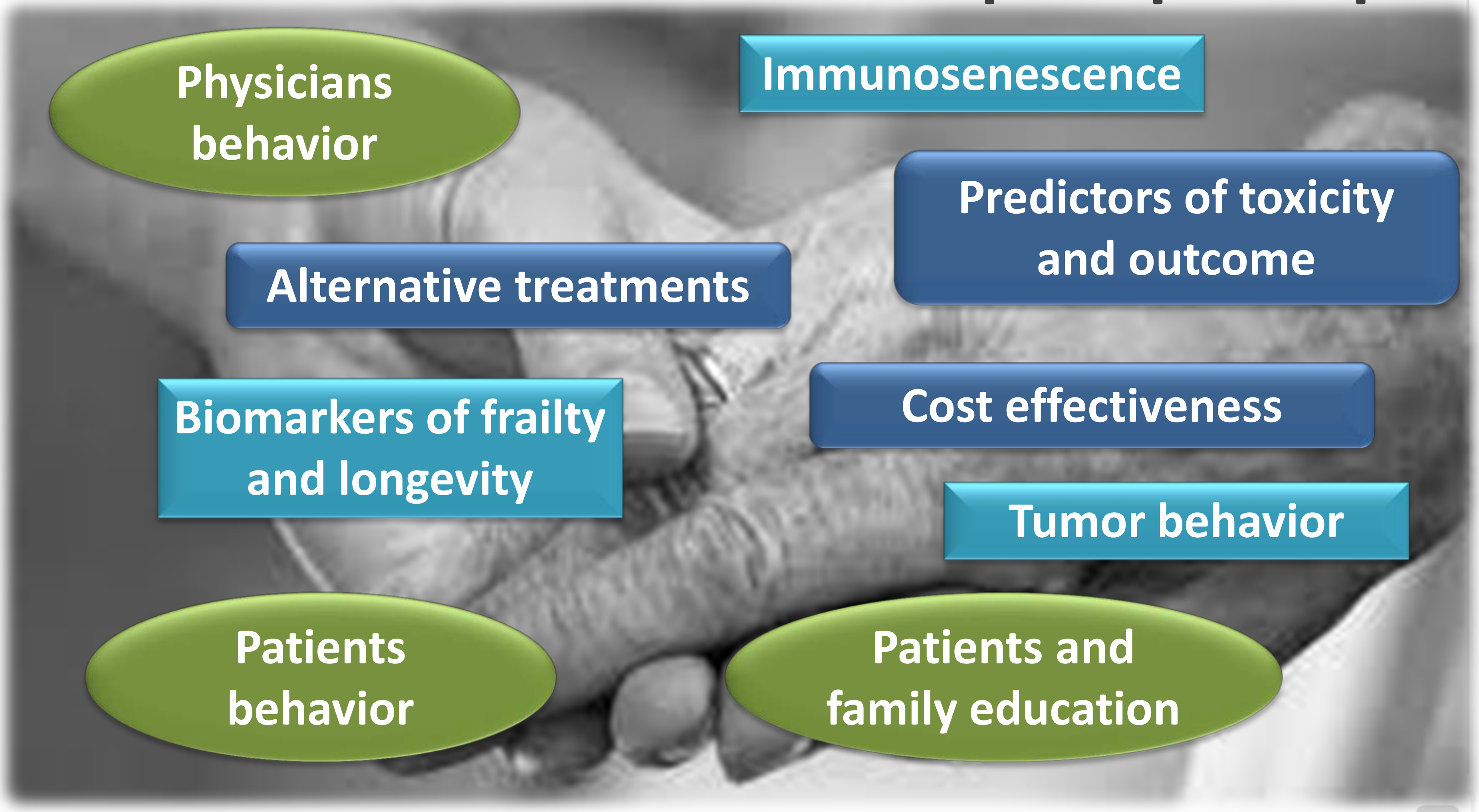
≤14

Randomiaation

Standard management
Oncologist
Predefined protocol
Consensus validation

Case Management
Geriatrician + Nurse
Predefined protocol
Consensus validation

Tout le monde est bienvenu pour participer



Physicians behavior

Immunosenescence

Predictors of toxicity and outcome

Alternative treatments

Biomarkers of frailty and longevity

Cost effectiveness

Tumor behavior

Patients behavior

Patients and family education

Pour eux…