1 ONS Guidelines ™ to Support Patient Adherence to Oral Anticancer Medications

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Table 1. Study characteristics of additional studies for PICO 1

Study	Country	Study	N subjects	% female	Age mean	Type of cancer	Tools/methods used	Timing of risk	Findings from the risk assessment	Funding
		Design	(intervention/co		(SD) /	regimen	to assess risk	assessment		Source
			mparator)		Median					
					(IQR)					
Berry	US	RCT	70 (49/21)	40	Median: 61	Diverse cancers	Measured odds of	Demographic	Symptom distress: OR: SDS-15+1	N/A
2015					Range: 34-	on chemotherapy	low/medium	characteristics	vs SDS-15a 1.1 (1.0–1.2)	
					80	and hormonal	adherence on	at baseline.		
						therapy	Symptom distress:	Unknown when	Depression:	
							SDS-15, Depression:	depression and	Demographic characteristics:	
							PHQ-9; demographic	symptom	Lack of a spouse/	
							characteristics	distress	partner, symptom distress,	
								assessments	younger age, not working at the	
								were taken.	start of therapy, female sex, and	
									oral chemotherapy vs oral	
									hormonal medications	

Decke	US	Cohort	30 (23/7)	94	Mean (SD):	Diverse cancers	Depression: CESD-		NS association with low/medium adherence: cancer stage, working status, education, minority identification, age, married/partner status, time on regimen Functional ability (SF-12): NS btw	N/A
r/200					59.93	on diverse	20;, Functional	end of study (at	adherence and nonadherence	
9					(12.03)	treatments	ability: SF-12	the exit	group	
					Range:			interview)		
					21-71+				Depression (CESD-20): lower	
									scores at baseline (10.91 vs 13.13)	
									and end of study (8.67 vs 11.0) in	
									adherence group (NS)	
DosSa	France	Cohort	129	40%	Median: 70	Renal cell, lung,	Depression: CES-D,	Baseline (before	Significant negative association	N/A
ntos/						prostate,	Anxiety: STAI-Trait	initiation of	between depression and non-	
2019						colorectal, breast	(score range, Global	treatment)	adherence	

						cancers treated	cognitive status:			
						with targeted	MoCA, Digit			
						therapy,	memory: WAIS-III,			
						chemotherapy,	Information			
						and	processing speed:			
						chemoradiothera	TMT, Autonomy:			
						ру	IADL			
Jacob	US	Cohort	90	55.6	Mean (SD):	Diverse cancers	Symptom distress:	Baseline and	- Demographic: Women had	Massac
s/					58.06	on oral	Symptom Distress	post-	greater adherence than men	husetts
2017					(13.08)	chemotherapy	Scale, Anxiety and	assessment (12	(93.48% vs 83.90%) (S)	General
					Range: 28-		depressive	weeks)	- Significant associations with	Hospital
					88		symptoms: Hospital		better adherence: improvements	Cancer
							Anxiety and		in symptom distress (-0.79),	Center
							Depression Scale,		depressive symptoms (-1.57),	
							Cancer-specific		quality of life (0.38),	
							psychological		- Improvements in patient-	
							distress: Cancer		reported symptom distress (23.94	

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							Worries Inventory		at baseline and -0.22 change from	
							(CWI)		baseline), depressive symptoms	
									(4.23 at baseline and 0.37 change	
									from baseline), satisfaction with	
									clinician communication and	
									treatment (92.68 at baseline and -	
									2.84 change from baseline), and	
									perceived burden to others (5.04	
									at baseline and -0.04 change from	
									baseline) were associated with	
									better adherence. No association	
									between anxiety and adherence	
Krikor	US	RCT	200 (101/99)	77	Interventio	Diverse cancers	Beliefs about	Assessment	Non-adherence was associated	N/A
ian/					n - Mean	on oral	medicines: BMQ	taken at	with forgetfulness, wanting to	
2019					(SD): 61.8	antine oplastic		baseline.	avoid side-effects, being	
					(11.5)	medication		Demographic	depressed or overwhelmed,	
					Control -			forms were	falling asleep before taking	

					Mean (SD):			updated at later	medication. Numbers not	
					61.9 (12)			time points.	provided. Supplement only	
									provides the questions in BMQ.	
									Statistically significant	
									correlations associated with non-	
									adherence were forgetfulness (p =	
									0.009), wanting to avoid side	
									effects (p = 0.02), feeling	
									depressed or overwhelmed (p =	
									0.032), or falling asleep before	
									taking medication (p = 0.048) in	
									both groups	
Krolo	German	Cohort	73	74	N/A	Breast cancer,	N/A	Separated into	Found no associations between	Supple
p/201	У					colorectal cancer,		initially non-	age, gender, any	mentar
3						and esophageal		adherent and	sociodemographic or disease-	y grant
						cancer treated		adherent after	related characteristics to	was

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						with capecitabine		first follow-up	adherence. No numbers	provide
						in combination or			reported.	d by
						monotherapy				Roche,
										Basel
Timm	Netherl	Cohort	62	47	Mean: 63.5	Non small cell	Demographic	Collected at	Relationships with incorrect	Roche,
ers/	ands					lung cancer on	characteristics,	baseline	intake were: older age (OR 1.10,	The
2015						erlotinib	smoking, co-		95 % CI 1.00–1.21), MARS < 25	Netherl
							medications, Quality		(OR 4.83, 95 % CI 1.06–21.99),	ands
							of life: SF-12,		oculair symptoms (OR 3.13, 95 %	
							Attitude(s) towards		CI 1.11–8.82) and stomatitis (OR	
							medication: BMQ,		6.59, 95 % CI 1.77–24.60)	
							Illness perception:			
							Brief IPQ, and		BMQ and Brief IPQ can be found	
							symptoms (likert		in Table 8	
							scale)			
Wicke	US	Cohort	198 (162/36)	100	Mean (SD):	Breast cancer	Sociodemographic	Information on	Depressive symptoms, fatigue,	Nationa
rsham					59.1 (7.5)	treated with	variables: University	predictor	gastrointestinal symptoms,	E

/2013					Range: 39-	Anastrozole,	of Pittsburgh, School	variables was	cognitive symptoms, weight	Institut
					75	Letrozole,	of Nursing Center for	measured pre-	concerns, gynecological	e for
						Examestane,	Research in Chronic	treatment	symptoms, musculoskeletal pain,	Nursing
						Tamoxifen	Disorders		and total BCPT score were	
							Sociodemographic		identified as linear predictors of	
							Questionnaire,		nonadherence. Numbers are not	
							Depressive		reported	
							symptoms: Beck			
							Depression			
							Inventory-II, Anxiety:			
							Profile of Mood			
							States (POMS)			
							Tension-Anxiety			
							subscale, Side effects			
							of hormonal therapy:			
							ВСРТ			
Yusuf	US	Cohort	73 (54/19)	100	Mean (SD):	Breast cancer on	Depression: The	All measured at	Psychological and menopause	N/A

ov/	55 (10.1)	tamoxifen and	Patient Health	baseline	symptoms (depression,
2020		aromatase	Questionnaire (PHQ-		generalized anxiety, insomnia,
		inhibitors	8), Tendency to		somatosensory amplification, hot
			perceive normal		flash frequency, and hot flash-
			visceral or somatic		related interference) were
			sensations as being		assessed pre-AET initiation as
			dangerous,		predictors of subsequent non-
			abnormal, intense,		adherence
			or potentially		Adherent vs non-adherent:
			harmful The		Anxiety: 3.1(4.2) vs 4.1(4.6)
			Somatosensory		Depression: 3.4 (3.3) vs 6.0 (3.9)
			Amplification Scale		Insomnia (subthreshold): 7.5 (5.3)
			(SSAS), Anxiety: The		vs 7.7(4.6)
			Generalized Anxiety		Hot flash related interference: 6.2
			Disorder (GAD-7),		(15.2) vs 7.4(14.1)
			Sleep: The Insomnia		Somatosensory Amplification:
			Severity Index (ISI),		22.3(6.5) vs 26.5(8.5)

serves all	Hot flash related	Hot flash frequency: 1.1(2.0) vs
Org. ONS res	interference: The	2.0(3.0)
sions @ ons.	Hot Flash-Related	
i pubpermis:	Daily Interference	
please emai	Scale (HFRDIS)	

- **Table 2. Evidence Profile for PICO 1** 15
- 16 Question: Standardized assessment for risk/barriers compared to standard of care for Patients starting a new oral anti-cancer medication
- 17 regimen
- **Setting**: Outpatient 18

In rights.	.5 Ta	able 2. Evidence Profile for PICO 1												
ons rese	.6 Q ı	u estion : S	tandardized asse	essment for ris	k/barriers con	npared to sta	andard of care for	Patients sta	irting a r	new oral anti-ca	ncer medicat	ion		
o.sions@ons.0	.7 re	regimen												
1 ul pubpermiss	.8 Se	tting : Out	patient											
s, please ema			Certainty as	ssessment			Nº of patie	ents		Effect				
No of studies on the post on the studies or repeat or re	Study design		Inconsistency	Indirectness	Imprecision	Other considerat ions	standardized assessment for risk/barriers	standard of care	Relati ve (95% CI)	Absolute (95% CI)	Certainty	Importance		

Adherence rate (follow up: 4 months; assessed with: self-report)

rando	not	not serious	serious ^b	very	none	25 participants who received risk assessment plus	ФООО	CRITICAL
mised	serious			serious ^{c,d}		tailored intervention had an adherence rate of	VERY LOW	
trials	a					95.1% vs 20 participants in the control arm with an		
						adherence rate of 82.4%.		

Self-efficacy to manage medications - not reported

2												
-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

Health-related Quality of Life and Patient-reported Outcomes (HRQOL/PROs) - not reported

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reserves all ri	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
So Patient	satisfact	ion - not	reported									
lissions @o	-	-	-	-	-	-	-	-	-	-	-	CRITICAL

- 19 **CI:** Confidence interval
- 20 Explanations
- a. Minimal information provided about randomization and allocation concealment.
- b. Intervention included tailored coaching intervention in addition to risk assessment.
- 23 c. Sample doesn't meet optimal information size. Concerns with fragility.
- d. The possibility of no difference cannot be excluded due to limited information.
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Table 3. Evidence Profile for PICO 2 28

29 Question: Educational programs compared to standard of care for patients starting a new oral anticancer medication regimen

30 **Setting**: Outpatient

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nail pubperm			(Certainty assessr	ment			Nº of pa	tients		Effect		
n to post online, reprint, adapt, or reuse, please em pt str	of dies	Study design	Risk of bias	Inconsistency	Indirectness		Other consid eration	educational programs	standard of care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Adh	neren	ce rate (fo	ollow up:	3-12 weeks; ass	sessed with: s	elf-report	and pill	count)					

2 ^{1,2}	randomi	serious	not serious	not serious	very	none	215	156	-	MD 0.4 % higher	ФООО	CRITICAL
Nursing S	sed	a			serious					(1.87 lower to 2.68 higher)	VERY LOW	
4 by the Oncolog	trials				b,c							
Adhere Adhere	nce rate (f	ollow up:	2-24 weeks; ass	sessed with: se	elf-report	and med	dication event	monitoring	g system pillk	ooxes)		

4 3,4,5,6	observat	very	not serious	not serious	serious	none	83	100	-	MD 10.61 % higher	ФООО	CRITICAL
a-user licens	ional	serious			b					(7.21 higher to 14.01	VERY LOW	
2024. əm <u>ə</u> ir	studies	d								higher)		

Proportion with high adherence (follow up: 14-24 weeks; assessed with: MMAS-4 and MMAS-8)

2 ^{7,8}	randomi	serious	not serious	not serious	not	none	222/391	175/354	RR 1.16	79 more per 1,000	$\Theta \Theta \Theta \bigcirc$	CRITICAL
	sed	е			serious		(56.8%)	(49.4%)	(1.01 to	(from 5 more to 163 more)	MODERATE	
20 20 20 20 20 20 20 20 20 20 20 20 20 2	trials								1.33)			
Patient	satisfactio	n (assess	ed with: Helpful	ness of meeti	ng with s	pecialty p	oharmacist an	d medication	on navigator	- % "very")		
1 9	observat	very	not serious	not serious	very	none	30/39	32/37	RR 0.89	95 fewer per 1,000	⊕000	CRITICAL
es es es es es es es es es es es es es e	ional	serious			serious		(76.9%)	(86.5%)	(0.72 to	(from 242 fewer to 86	VERY LOW	
	studies	f,g			c,h				1.10)	more)		
Patient	satisfactio	n (assess	ed with: Helpful	ness of medic	ation info	sheet - 9	% "very")	ı				
1º	observat	very	not serious	not serious	very	none	25/39	28/37	RR 0.85	114 fewer per 1,000	ФООО	CRITICAL
- A	ional	serious			serious		(64.1%)	(75.7%)	(0.63 to	(from 280 fewer to 106	VERY LOW	
	studies	f,g			c,h				1.14)	more)		
Patient	satisfactio	n (assess	ed with: Helpful	ness of check	in with n	nedicatio	n navigator -	% very")				
1 ⁹	observat	very	not serious	not serious	serious	none	27/39	34/37	RR 0.75	230 fewer per 1,000	⊕○○○	CRITICAL
	ional	serious			b		(69.2%)	(91.9%)	(0.60 to	(from 368 fewer to 46	VERY LOW	
	studies	f,g							0.95)	fewer)		
Patient	knowledge	e of regim	nen (follow up: 2	2 cycles; asses	sed with:	Dosage a	and frequency	y)				
1 ¹⁰	observat	very	not serious	not serious	serious	none	29/29	23/29	RR 1.26	206 more per 1,000	⊕○○○	CRITICAL
<u></u>	L	l l			l l							

b. Small sample, concerns with fragility.

35

- 36 c. The 95% CI cannot exclude the potential for no difference.
- 37 d. Critical concern with confounding and missing data. Serious concern with bias in the selection of participants.
- e. Some concerns with randomization, effect of assignment to intervention, missing outcome data and measurement of the outcome.
- 39 f. Critical concern with confounding, moderate concern in selection of participants and measurement of outcome.
- 40 g. Not measuring satisfaction before and after intervention, instead looks at satisfaction a little after start of intervention and end of
- 41 intervention.
- 42 h. Few events reported do not meet the optimal information size and suggest fragility of the estimate.
- 43 i. Critical concern with confounding.

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- Question: Standardized, periodic/ongoing assessment of adherence compared to usual care for patients on an oral anti-cancer medication

. 200	Ques regin	s tion : Sta			g assessment o	of adhere	ence compared to	o usual care	for patien	ts on an oral anti-cancer med	cation	
In Deministration to post online, reprint, adapt, or reuse, please email purp. No of studies studies studies studies and studies stu	Study design	Risk of bias	Certainty asso		Imprecision	Other conside rations	ng assessment		Relative (95% CI)	Effect Absolute (95% CI)	Certainty	Importance
Sovidh 2024 by the Oncology Nursing Soc	random ised trials	not serious	: 12 weeks; ass not serious	not serious	very serious	none	75	83	-	MD 2.34 % higher (5.58 lower to 10.26 higher)	⊕⊕○○ LOW	CRITICAL
o en se	e rate (fo	•	: 6 months; ass	not serious	serious ^a	none	34	51	-	MD 7 % higher	⊕○○○	CRITICAL

1 ¹	random	not	not serious	not serious	very serious	none	75	83	-	MD 2.34 % higher	$\Theta\ThetaOO$	CRITICAL
	ised	serious			a,b					(5.58 lower to 10.26 higher)	LOW	
	trials											

1 ²	observa	very	not serious	not serious	serious ^a	none	34	51	-	MD 7 % higher	ФООО	CRITICAL	
	tional	serious								(0.66 higher to 13.34	VERY LOW d		
	studies	С								higher)			

e (Tollow	up: 21-2	28 days; assess	ed with: rela	tive dose inter	isity)						
random	serious	not serious	not serious	very serious	none	31	37	-	MD 0.32 % higher	⊕○○○	CRITICAL
ised	е			a,b					(0.08 lower to 0.72 higher)	VERY LOW	
trials											
f life (foll	ow up: 1	2 weeks; asses	ssed with: FA	CT-G; higher=k	etter; N	IID 5-7; Scale fro	m: 0 to 108))			
random	not	not serious	not serious	serious ^a	none	77	85	-	MD 2.28 points higher	$\oplus \oplus \oplus \bigcirc$	CRITICAL
ised	serious								(1.93 higher to 2.63 higher)	MODERATE	
trials	f										
f life (foll	ow up: 3	months; asses	ssed with: EO	RTC; higher=b	etter; M	ID 4-11)		L			
observa	serious	not serious	not serious	serious ^a	none	56	56	-	MD 15.7 points higher	ФФОО	CRITICAL
tional	g								(8.84 higher to 22.56	LOW	
studies									higher)		
atisfactio	n (follow	up: 3 months	; assessed wit	th: self-report	(single q	uestion on satisf	faction))	<u> </u>			
observa	very	not serious	not serious	very serious i	none	20/20 (100.0%)	15/20	RR 1.32	240 more per 1,000	⊕○○○	CRITICAL
tional	serious						(75.0%)	(1.02 to	(from 15 more to 540 more)	VERY LOW	
studies	h							1.72)			
	random ised trials life (foll random ised trials life (foll observa tional studies citisfactio observa tional	random serious ised e trials Flife (follow up: 1 random not ised serious trials f Flife (follow up: 3 observa serious tional g studies citisfaction (follow observa very tional serious	random serious not serious ised e trials Flife (follow up: 12 weeks; asses random not not serious ised serious trials f Flife (follow up: 3 months; asses observa serious not serious tional g studies observa very not serious tional serious tional serious	random serious not serious not serious ised e trials	random serious not serious not serious very serious ised e trials Flife (follow up: 12 weeks; assessed with: FACT-G; higher=k random not not serious not serious serious ised serious f life (follow up: 3 months; assessed with: EORTC; higher=b observa serious not serious not serious serious itional g studies rational g not serious not serious not serious serious itisfaction (follow up: 3 months; assessed with: self-report observa very not serious not serious very serious itional serious serious very serious itional serious very serious itional serious serious not serious very serious itional serious very serious itional serious very serious itional serious very serious itional serious very serious very serious itional serious very serious itional serious very serious	ised c trials c c c c c c c c c c c c c c c c c c c	random serious not serious not serious very serious none sised e trials life (follow up: 12 weeks; assessed with: FACT-G; higher=better; MID 5-7; Scale from not serious not serious serious none serious serious erious f serious not serious serious serious none file (follow up: 3 months; assessed with: EORTC; higher=better; MID 4-11) observa serious not serious not serious serious none file serious serious none serious serious none file serious serious none file serious none file serious none file serious none serious serious none file serious none serious not serious not serious very serious none file serious none file serious none serious not serious very serious none file serious none file serious none serious very serious none file serious none file serious none file serious very serious none file serious none file serious none file serious very serious none file serious none file serious very serious none file serious none file serious very serious none file serious very serious none file serious none file serious very serious none file serious very serious none file serious none file serious very serious none file serious ve	random serious not serious not serious very serious none 31 37 ised c life (follow up: 12 weeks; assessed with: FACT-G; higher=better; MID 5-7; Scale from: 0 to 108 random not not serious not serious serious none 77 85 ised serious f life (follow up: 3 months; assessed with: EORTC; higher=better; MID 4-11) observa serious not serious not serious serious none 56 56 tional s studies litisfaction (follow up: 3 months; assessed with: self-report (single question on satisfaction)) observa very not serious not serious very serious none 20/20 (100.0%) 15/20 tional serious serious not serious very serious none 20/20 (100.0%) 15/20 (75.0%)	random serious not serious not serious very serious none 31 37 - ised c trials life (follow up: 12 weeks; assessed with: FACT-G; higher=better; MID 5-7; Scale from: 0 to 108) random not not serious not serious serious serious none 77 85 - ised serious f life (follow up: 3 months; assessed with: EORTC; higher=better; MID 4-11) observa serious not serious not serious serious serious none 56 56 - tional s studies ltisfaction (follow up: 3 months; assessed with: self-report (single question on satisfaction)) observa very not serious not serious very serious none 20/20 (100.0%) 15/20 RR 1.32 tional serious serious serious very serious none 20/20 (100.0%) (1.02 to	random serious not serious not serious very serious none 31 37 - MD 0.32 % higher (0.08 lower to 0.72 higher) random random not not serious not serious serious not serious not serious not serious serious serious serious random not serious not se	random serious not

Cancer-related morbidity (follow up: 24 weeks; assessed with: global toxicity score; higher=worse; Scale from: 0 to 36)

1 6	random	serious	not serious	not serious	very serious	none	92	91	-	MD 1 points higher	ФООО	CRITICAL
	ised	j			a,b					(1.72 lower to 3.72 higher)	VERY LOW	
	trials											
Cancer-re	elated mo	rbidity (follow up: 21-7	28 days; asses	ssed with: Sym	nptom Ex	perience Invent	ory; higher	=worse; So	ale from: 0 to 190)		
1 ³	random	serious	not serious	not serious	very serious	none	31	37	-	MD 1.75 points lower	ФООО	CRITICAL
	ised	e			a,b					(9.48 lower to 5.98 higher)	VERY LOW	
	trials											
Cancer-re	elated mo	rbidity (follow up: 8 w	eeks; assesse	d with: Sympt	om Expe	rience Inventor	 y; higher=w	orse; Scale	e from: 0 to 190)		
1 ⁷	observa	very	not serious	not serious	serious ^a	none	24	30	-	MD 4.78 points lower	ФООО	CRITICAL
	tional	serious								(7.8 lower to 1.76 lower)	VERY LOW	
	studies	k										
Self-effic			-28 days; asse	ssed with: MA	ASES-R; higher	=better;	Scale from: 1 to	4)				
Self-effica		w up: 21		ssed with: M/	ASES-R; higher	= better; none	Scale from: 1 to	4) 37	-	MD 0.51 points lower	⊕○○○	IMPORTANT
	acy (follov	w up: 21							-	MD 0.51 points lower (1.3 lower to 0.28 higher)	⊕○○○ VERY LOW	IMPORTANT
	random	w up: 21			very serious				-	·		IMPORTANT
1 ³	random ised trials	w up: 21 serious		not serious	very serious	none	31		-	·		IMPORTANT

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erves	tional	serious			a,b					(0.36 lower to 0.34 higher)	VERY LOW			
org. ONS res	studies	k												
g Adherenc	Adherence to supportive care/lab monitoring - not reported													
nission	•		a. e, iase											

- 74 CI: Confidence interval; MD: Mean difference; MID: Minimally important difference; RR: Risk ratio; MASES-R: Medication Adherence Self-
- 75 Efficacy Scale Revision
- 76 Explanations
- a. Small sample, concerns with fragility.
- 78 b. 95% CI cannot exclude the possibility of no effect.
- 79 c. Moderate concern with confounding. and measurement of outcome due to subjective measure. Serious concern with missing data.
- d. An additional study reported a risk ratio of 0.92; 95% CI: 0.54, 1.56 comparing on-going assessment to no assessment measured with self-
- reported adherence at 3 months.
- e. Some concerns due to deviations from the intended interventions.
- f. Self-reported outcome measurement could lead to some concerns with risk of bias but not serious.
- 84 g. Critical concern with confounding and serious concern with subjectivity of outcome.
- h. Critical concern for confounding and moderate concern with measurement of outcome due to self-report.
- i. Few events reported do not meet the optimal information size and suggest fragility of the estimate.
- i. Some concerns due to deviations from the intended interventions and self-reported outcome measurement.

- k. Serious concern with confounding, bias in selection of participants, missing data and measurement of outcome. Moderate concern withdeviations from intervention.
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Table 5. Evidence Profile for PICO 4 112

Setting: Outpatient 114

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org. ONS reser	113 Qu e	estion: Ad	ctive follow-up co	ompared to us	ualcare for pa	tients on ar	n oral antica	ancer medicatio	on regimen who ha	ve additional risk fac	tors			
114 Setting: Outpatient Certainty assessment No of nationts Fffect														
Certainty assessment Nº of patients Effect														
or reuse, please ema	Nº of Study Risk of Inconsistency Indirectness Imprecision consider follow- Other active standard of Relative Absolute Certainty													
studie studie	design	bias	Í			ations	up	care	(95% CI)	(95% CI)				
to bost online Adher	Adherence rate (follow up: 6 cycles; assessed with: MEMS (medication event monitoring system) pillboxes)													
Adherence rate (follow up. 6 cycles; assessed with: MEIVIS (medication event monitoring system) philoxes) 1 observ very not serious not serious very serious none 10 10 - MD 17.8 % higher + OO CRITI														
ociety. For p	ational	serious			b					(6.43 higher to	0			
v Nursing S	studies	а								29.17 higher)	VERY			
the Oncology Nursing Society.											LOW			
>	r-related m	norbidity	- not reported					1	I	1		l J		
only. Copyri	-	-	-	-	-	-	-	-	-	-	-	CRITICAL		
Qualit	y of life - n	ot report	ed			1	1	1	ı	1				
2024. Single-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL		
Öl –			_											

reserves all rig	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
Patient s	self-effica	acy about	treatment - not	t reported								
nissions@o	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT

- 115 **CI:** Confidence interval; **MD:** Mean difference
- 116 Explanations
- a. Critical concern with confounding.
- b. Small sample, concerns with fragility.
- 119 References
- 120 1. Vacher, Laure, Thivat, Emilie, Poirier, Camille, Mouret-Reynier, Marie-Ange, Chollet, Philippe, Devaud, Hervé, Dubray-Longeras, Pascale,
- 121 Kwiatkowski, Fabrice, Durando, Xavier, van Praagh-Doreau, Isabelle, Chevrier, Régine. Improvement in adherence to Capecitabine and Lapatinib
- by way of a therapeutic education program. Supportive Care in Cancer; 07/2020.

123 Table 6. Evidence Profile for PICO 5

Question: Coaching compared to usual care for patients on an oral anti-cancer medication regimen who have additional risk factors

Setting: Outpatient

			Certainty as	sessment			Nº of ∣	patients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerati ons		standard of care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Adhere	nce rate	(follow u	p: 3-4 weeks; as	sessed with:	pill count)							
1 ¹		serious	not serious	not serious	very serious	none	101	99	-	MD 0.8 % higher	ФООО VERVI ОМ	CRITICAL
	ised trials	a			U,C					(2.24 lower to 3.84 higher)	VERY LOW	
Adhere	nce rate	(follow u	p: 2 educational	sessions eve	ry three cycle	es; assessed	 with: MI	EMS pillbo	xes) ^d			
1 ²	observa	very	not serious	not serious	serious ^c	none	10	10	-	MD 17.8 % higher	⊕○○○	CRITICAL
	tional	serious								(6.43 higher to 29.17 higher)	VERY LOW	
	studies	e										
Adhere	nce (follo	ow up: 3 r	nonths; assesse	d with: MPR	greater than	or equal to	90%)			1		
1 ³	random	serious ^f	not serious	serious ^g	very serious	none	59/64	54/59	RR 1.01	9 more per 1,000	ФООО	CRITICAL

	ised				b,h		(92.2%)	(91.5%)	(0.91 to 1.12)	(from 82 fewer to 110 more)	VERY LOW	
	trials											
Adhere	ence (follo	ow up: 6-3	31.9 months; as	ssessed with:	MPR)							
2 4,5	observa	very	serious ^j	serious ^g	serious ^c	none	84	281	-	MD 2.98 % higher	⊕○○○	CRITICAL
	tional	serious ⁱ								(2.95 higher to 3.01 higher)	VERY LOW	
	studies											
Cancer	-related n	norbidity	-Symptom seve	erity (follow u	p: 3 months;	assessed w	ith: 13 ite	em M.D. A	Inderson Sympt	om Inventory; higher=worse; N	11D 1.0 per 10) point scale
Scale f	rom: 0 to	130)										
	1 .	. f		1 .	_		1		1	-		
1 ³	random	serious '	not serious	not serious	very serious	none	64	62	-	MD 0 points	ФООО	CRITICAL
1 ³	ised	serious '	not serious	not serious	very serious	none	64	62	-	MD 0 points (0.55 lower to 0.55 higher)	ΨΟΟΟ VERY LOW	CRITICAL
1 ³		serious '	not serious	not serious	,	none	64	62	-	·		CRITICAL
	ised trials				b,c				er; Scale from: 1	(0.55 lower to 0.55 higher)		CRITICAL
	ised trials t self-effic			s; assessed wi	b,c				er; Scale from: 1	(0.55 lower to 0.55 higher)	VERY LOW	
Patient	ised trials t self-effic	acy (follo	w up: 3 month	s; assessed wi	b,c ith: General s	elf-efficacy	scale; hig	her=bette	er; Scale from: 1	(0.55 lower to 0.55 higher)	VERY LOW	
Patient	ised trials t self-effice random	acy (follo	w up: 3 month	s; assessed wi	th: General so	elf-efficacy	scale; hig	her=bette	er; Scale from: 1	(0.55 lower to 0.55 higher) to 40) MD 1.8 points higher	VERY LOW	
Patient	ised trials self-effice random ised trials	serious ^f	w up: 3 month	s; assessed wi	th: General so very serious b,c,h	e lf-efficacy none	scale; hig	her=bette	-	(0.55 lower to 0.55 higher) to 40) MD 1.8 points higher	VERY LOW	IMPORTAN ⁻

erves all ri	ised		b,c			(6.18 lower to 6.58 higher)	VERY LOW	
is.org. ONS rese	trials							

gPatient satisfaction (follow up: 3 months; assessed with: self-designed scale; higher=better; Scale from: 0 to 5)

ised (0.9 lower to 1.1 higher) VERY LOW	1 ³	random	serious ^f	not serious	not serious	very serious	none	64	62	-	MD 0.1 points higher	ФООО	CRITICAL
		ised				b,c					(0.9 lower to 1.1 higher)	VERY LOW	
trials trials		trials											

- 126 CI: Confidence interval; MD: Mean difference; MEMS: Medication event monitoring system; MPR: Medication possession ratio; RR: Risk ratio;
- 127 MID: Minimally important difference
- 128 Explanations
- a. Serious concern with missing outcome data and selection of the reported result.
- b. The 95% CI cannot exclude the potential for no difference.
- 131 c. Small sample, concerns with fragility.
- d. Reflects the mean of the daily adherence scores which correspond to the proportion of pills actually taken (recorded opening by MEMS) in
- 133 comparison with prescribed amounts (expected openings).
- e. Critical concern with confounding and missing outcome data.
- f. Serious concerns with missing outcome data.
- g. MPR is surrogate for adherence.

- h. Few events reported do not meet the optimal information size and suggest fragility of the estimate.
- i. Critical concern with confounding.
- j. Concerns with heterogeneity due to I2 value of 100%.
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153 Table 7. Evidence Profile for PICO 6

Question: Motivational interviewing compared to usual care for patients on an oral anti-cancer medication regimen who have additional risk

155 factors

154

156 **Setting**: Outpatient

se, please e				Certainty a	assessment			Nº of pati	ents		Effect		
to post online, reprint, adapt, or reus	№ of studies		Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns		standard of care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
ssior	۸dharan	ce rate (f	follow u	n: 12 wooks: as	seesed with	elf-report)							

Adherence rate (follow up: 12 weeks; assessed with: self-report)

1 ¹	random	not	not serious	not serious	very serious	none	57	114	-	MD 3.23 % higher	$\Theta\ThetaOO$	CRITICAL	
	ised	seriou			a,b					(0.45 higher to 6.02	LOW		
	trials	S								higher)			

Cancer-related morbidity - Summed symptom severity (follow up: 8 weeks; assessed with: Symptom Experience Inventory; Higher=worse; Scale from: 0 to 190)

1 ²	observa	very	not serious	not serious	serious ^a	none	24	30	-	MD 4.78 points lower	ФООО	CRITICAL
-censer icens	tional	seriou								(7.8 lower to 1.76	VERY LOW	
2024- Oligin	studies	s ^c								lower)		

Patient-self efficacy about treatment (follow up: 12 weeks; assessed with: MASES; higher=better; Scale from: 1 to 96)

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LOW

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VERY LOW

higher)

higher)

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- d. Some concerns with bias due to subjectivity of outcome measurement and limited information provided about analysis used to estimate theeffect of assignment to intervention.
- e. Scale used to measure outcome not specified.
- 166 f. CI does not have meaningful difference thus not docked down for CI.

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167

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ves all rights.	75 Ta l	ble 8. Ev	idence Profile 1	or PICO 7								
SNO. 17	76 Q u	estion:	Гесhnology con	npared to usu	ıal care for pa	itients on an o	ral anti-cancer n	nedication regir	nen			
gions @ one.	77 Se t	tting: Ou	itpatient									
ail pubpermis			Certainty a	ssessment			Nº of pa	atients		Effect		
Moort, or reuse, please em No of studies	Study design		Inconsistency	Indirectness	Imprecision	Other consideratio	technology	standard of care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Adherei	_	(follow u		; assessed wi	th: self-repor	ns t and smart bo	ottle openings)	99		MD 8.23 % higher	A000	CRITICAL
sing Society. For permi	mised	a	serious	not senous	serious	none	91	33	-	(2.9 higher to 13.55	VERY	CRITICAL
Aby the Oncology Net of th	trials	(follow u	up: 6 months; a	ssessed with	: MPR)					higher)	LOW	
1 ³	observ ational	very serious	not serious	not serious	serious ^c	none	50	51	-	MD 4.7 % higher (1.19 higher to 8.21	⊕○○○ VERY	CRITICAL
Single-user licer	studies		se intensity (fo	llow up: 2 12	wooks: associ	esod with pill	counts			higher)	LOW	
-22-20						·	<u> </u>					
2 4,5 2 4,5	rando	serious	not serious ^f	not serious	very serious	none	149	152	<u>-</u>	MD 0.01 % lower	$\Theta \cup \cup \cup$	CRITICAL
Down											22	

	mised	е			c,g					(0.04 lower to 0.02	VERY	
	trials									higher)	LOW	
Cancer r	elated n	norbidity	- Summed syı	mptom sever	ty (follow up	: 21 days; ass	essed with: Symp	otom Experien	ce Inventory; hi	gher=worse; Scale fro	om: 0 to 190	0)
1 ⁶	rando	not	not serious	not serious	very serious	none	49	26	-	MD 3.5 points	@	CRITICAL
	mised	serious			c,g					lower	LOW	
	trials									(12.48 lower to 5.48		
										higher)		
Quality	of Life (f	ollow up	: 3-12 weeks;	assessed with	: FACT-G and	WHO Quality	y of Life-BREF Sca	ile; higher=bet	tter)		<u> </u>	
2 ^{1,7}	rando	serious	serious ^h	not serious	serious ^c	none	77	85	-	SMD 1.44 SD higher	Ф ООО	CRITICAL
	mised	a								(1.15 higher to 1.74	VERY	
	trials									higher)	LOW	
Quality	of Life (f	ollow up	: 6 months; as	sessed with:	assessed usin	g the EuroQo	I-5D (EQ-5D); MI	D 0.061; highe	er=better)			
1 ³	observ	very	not serious	not serious	serious ^c	none	50	51	-	MD 0.13 points	⊕ ○○○	CRITICAL
	ational	serious								higher	VERY	
	studies	d								(0.07 lower to 0.2	LOW	
										higher)		
Patient s	satisfact	ion (follo	ow up: 6 cycles	(ranging fror	m 21 day to 90	0 day cycles);	assessed with: F	ACIT-TS-PS; hi	gher=better; Sca	ale from: 0 to 73)	<u> </u>	
											34	

1 ⁸ ra	rando	serious	not serious	not serious	very serious	none	56	33	-	MD 0 points	ФООО	CRITICAL
m	mised	i			c,g					(1.31 lower to 1.31	VERY	
t	trials									higher)	LOW	

178 CI: Confidence interval; MD: Mean difference; MPR: Medication possession ratio; SMD: Standardised mean difference

Explanations

179

- a. Limited information on effect of assignment to intervention and some concerns with measurement of the outcome.
- 181 b. Rated down due to I2 value of 74%.
- 182 c. Small sample, concerns with fragility.
- d. Critical concerns with confounding. Serious concerns with missing data.
- e. Some concerns with bias due to deviations from the intended interventions.
- 185 f. I2 value is 61%; however, rating down for imprecision accounts for the variability between study findings.
- 186 g. 95% CI cannot exclude the possibility of no effect.
- h. Rated down due to the I2 value of 95%.
- i. Some concerns with effect of assignment to intervention and measurement of outcome.

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213 Table 9. Evidence Profile for PICO 8

214 **Question**: Interactive technology compared to non-interactive technology for patients on an oral anti-cancer medication regimen

215 **Setting**: Outpatient

trials

mail pubpe			Certainty a	assessment			№ of patients		Eff	fect			
line, reprint, adapt, or reuse, please e	f Study es design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations		non-interactive technology	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance	
Adhe	Adherence (follow up: 8 weeks; assessed with: only adherence rate ≥80%)												
1 ¹	rando	very	not serious	not serious	very serious	none	56/79	33/40 (82.5%)	RR 0.86	116 fewer per	ФОО	CRITICAL	
ng Society. For	mised	seriou			b,c		(70.9%)		(0.70 to 1.05)	1,000	0		

Cancer related morbidity - Exit symptom severity (follow up: 8 weeks; assessed with: Symptom Experience Inventory range 0-150; higher = worse)

	rando	seriou	not serious	not serious	very serious	none	79	40	-	MD 4.12 points	\oplus	CRITICAL
P.USEI III.	mised	s ^d			b,e					higher	0	
2024. Olingis	trials									(0.4 lower to 8.64	VERY	
-77-51 NO D										higher)	LOW	

VERY

LOW

(from 248 fewer

to 41 more)

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CI: Confidence interval; RR: Risk ratio; MD: Mean difference

Explanations

- a. Serious concerns with randomization, measurement of outcome and bias in selection of the reported result.
- b. 95% CI cannot exclude no difference.
- c. Few events reported do not meet the optimal information size and suggest fragility of the estimate.
- d. Serious concerns with randomization.
- e. Small sample, concerns with fragility.

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Table 10. Evidence Profile for PICO 9

Question: Structured oral anti-cancer medication program compared to no structured oral anti-cancer medication program for institutions providing care to patients on an oral anti-cancer medication regimen

Setting: Outpatient

500			Certainty as	sessment			Nº of	patients	E	ffect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerat ions	structured oral anti-cancer medication program	no structured oral anti-cancer medication program	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Adheren	ce rate (fo	llow u	p: 6 cycles; asse	essed with: me	edication eve	nt monitorir	ng system)					
2 ^{1,2}	observat	very	not serious	not serious	serious ^b	none	18	29	-	MD 12.22 %	ФОО	CRITICAL
	ional	serio								higher	0	
7 4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	studies	us ^a								(9.19 higher	VERY	
										to 15.24	LOW	
										higher)		
Adheren	ce rate (fo	llow u	p: 6 months - e	nd of treatme	nt; assessed	with: medica	ation possession rati	io)				

8	. .												
	3,4,5,6	observat	very	not serious	serious ^d	not serious	none	12536	31123	-	MD 6 %	ФОО	CRITICAL

rights.												
erves all r	ional	serio								higher	0	
org. ONS res	studies	us ^c								(4 higher to	VERY	
ilssions @ ons.										8 higher)	LOW	
Adheren	ce (follow	up: en	d of treatment	; assessed wit	h: pill countii	ng)						
1 ⁷	observat	very	not serious	serious ^d	very serious	none	87/100 (87.0%)	38/50 (76.0%)	RR 1.14	106 more	\oplus	CRITICAL
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s, reprint, add	studies	us ^e							1.36)	(from 30	VERY	
to post online										fewer to 274	LOW	
r permission 1										more)		
Cancer-r	elated mo	rbidity	- Physical func	tioning (follow	w up: 1 year;	assessed wit	th: EORTC QoL physic	cal function; higher = k	better; MID	6 points; Scal	e from: 0 to	o 100)
1 8	observat	very	not serious	serious ^g	serious ^b	none	56	56	-	MD 11.1	ФОО	CRITICAL
/ the Oncolog	ional	serio								points	0	
right 2024 by	studies	us ^e								higher	VERY	
se only. Copy										(7.45 higher	LOW	
e-user licens										to 14.75		
-2024. Singl										higher)		

rights.													
erves all rights.	18	observat	very	not serious	not serious	serious ^b	none	56	56	-	MD 15.7	ФОО	CRITICAL
org. ONS res		ional	serio								points	0	
sions@ons.c		studies	us ^e								higher	VERY	
il pubpermis											(12.7 higher	LOW	
please ema											to 18.7		
apt, or reuse,											higher)		
reprine add	tient s	atisfactio	n (follo	w up: once dur	ing or after tr	eatment; asse	essed with:	telephone survey)					
oost on ne	1 ⁹	observat	very	not serious	not serious	serious ^b	none	20/20 (100.0%)	15/20 (75.0%)	RR 1.32	240 more	ФОО	CRITICAL
rmission to p		ional	serio							(1.02 to	per 1,000	0	
ciety. For pe		studies	us ^h							1.72)	(from 15	VERY	
ly Nursing So											more to 540	LOW	
/ the Oncolog											more)		
right 2024 by	tient f	inancial to	oxicity	(follow up: 1 ye	ar; assessed v	vith: EORTC f	inancial diff	iculties; higher = wor	rse; Scale from: 0 to 10	00)	<u> </u>		
nly. Capy	18	observat	very	not serious	not serious	very serious	none	56	56	-	MD 0	ФОО	CRITICAL
user license c		ional	serio			b,f					(1.57 lower	0	
024. Single-i		studies	us ^e								to 1.57	VERY	
d on 12-22-2											higher)	LOW	
loade													

Time to	obtain me	dicatio	n - not reporte	d										
ONS rese	-	-	-	-	-	-	-	-	-	-	-	CRITICAL		
ons.org														
OCIVI mo	OCM model/value-based care - not reported													
-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL		
maii.														

CI: Confidence interval; MD: Mean difference; RR: Risk ratio

Explanations

- a. Critical concerns with confounding and missing data. Moderate concern with measurement of outcome.
- b. Small sample, concerns with fragility.
- c. Critical concerns with confounding. Moderate concerns with selection of participants.
- d. Indirect measure of adherence.
- e. Critical concerns with confounding.
- f. The 95% CI cannot exclude the potential for no difference.
- g. Indirect measure of morbidity.
- h. Critical concerns with confounding. Serious concerns with selection of participants.

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