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# 1.1 Service delivery models

## 1.1.1 GRADE profile for RCTs comparing integrated service models with standard care

			Ouglity access					Summar	y of find	ings			
			Quality assess	sment			No of pati	ents		Effect			
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	INTEGRATED SERVICE MODELS	STANDARD CARE	Relative (95% CI)	Absolute	Quality	Importance	
Substanc	e use: 1. Subs	tance use ratin	g (high=poor) - b	y 6 months (Bett	er indicated b	y lower values)			•			•	
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.14 higher (0.26 lower to 0.54 higher)	⊕⊕OO LOW	CRITICAL	
Substanc	e use: 1. Subs	tance use rating	g (high=poor) - b	y 12 months (Bet	tter indicated	by lower values)							
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.18 higher (0.22 lower to 0.58 higher)	⊕⊕OO LOW	CRITICAL	
Substance use: 1. Substance use rating (high=poor) - by 18 months (Better indicated by lower values)													
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.15 lower (0.55 lower to 0.25 higher)	⊕⊕OO LOW	CRITICAL	
Substanc	e use: 1. Subs	tance use ratin	g (high=poor) - b	y 24 months (Bet	tter indicated	by lower values)				<u> </u>		•	
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.05 higher (0.35 lower to 0.45 higher)	⊕⊕OO LOW	CRITICAL	
Substanc	e use: 2. Days	used substanc	es - by 6 months	(Better indicated	l by lower val	ues)							
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.08 higher (0.33 lower to 0.48 higher)	⊕⊕OO LOW	CRITICAL	
Substanc	e use: 2. Days	used substanc	es - by 12 months	(Better indicate	d by lower va	alues)							
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.11 higher (0.3 lower to 0.51 higher)	⊕⊕OO LOW	CRITICAL	
Substanc	e use: 2. Days	used substanc	es - by 18 months	(Better indicate	d by lower va	alues)							

1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.09 higher (0.31 lower to 0.49 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 2. Days	used substand	ces - by 24 month	s (Better indicate	ed by lower v	alues)						
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	SMD 0.13 higher (0.28 lower to 0.53 higher)	⊕⊕OO LOW	CRITICAL
Service u	se: 1. Days in	stable commu	nity residences (	not in hospital) -	by 6 months	(Better indicated	by lower values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	MD 3.17 higher (0.52 lower to 6.86 higher)	⊕⊕OO LOW	CRITICAL
Service u	se: 1. Days in	stable commu	nity residences (	not in hospital) -	by 12 month	s (Better indicated	l by lower values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	46	49	-	MD 2.84 higher (2.07 lower to 7.75 higher)	⊕⊕OO LOW	CRITICAL
Service u	se: 1. Days in	stable commu	nity residences (	not in hospital) -	by 18 month	s (Better indicated	l by lower values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	46	49	-	MD 6.46 higher (1.36 to 11.56 higher)	⊕⊕⊕O MODERATE	CRITICAL
Service u	se: 1. Days in	stable commu	nity residences (	not in hospital) -	by 24 month	s (Better indicated	l by lower values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	46	49	-	MD 5.7 higher (0.59 to 10.81 higher)	⊕⊕⊕O MODERATE	CRITICAL

<sup>&</sup>lt;sup>1</sup> Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met. <sup>2</sup> CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

### 1.1.2 GRADE profile for RCTs comparing integrated assertive community treatment with integrated case management

			Ouality assess					Summar	y of finding	ζs		
			Quanty assess	sment			No o	of patients		Effect		Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	INTEGRATED ACT	CLINICAL CASE MANAGEMENT	Relative (95% CI)	Absolute	Quality	Importance
Death - l	by 36 months											
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	7/208 (3.4%)	6/213 (2.8%)	RR 1.18 (0.39 to 3.57)	5 more per 1000 (from 17 fewer to 72 more)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 1. Not	in remission -	by 36 months - a	lcohol								
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	43/75 (57.3%)	34/68 (50%)	RR 1.15 (0.84 to 1.56)	75 more per 1000 (from 80 fewer to 280 more)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 1. Not	in remission -	by 36 months - d	rugs								
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	26/45 (57.8%)	26/40 (65%)	RR 0.89 (0.63 to 1.25)	72 fewer per 1000 (from 240 fewer to 162 more)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 2. Subs	stance abuse (S	SATS, low=poor)	[skewed data]	- by 6 month	s (Better indicate	d by lower values	s)	•			
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	198	181	-	SMD 0.03 higher (0.17 lower to 0.23 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substan	ce use: 2. Subs	stance abuse (S	SATS, low=poor)	[skewed data]	- by 12 mont	hs (Better indicat	ed by lower value	es)		,		
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	192	182	-	SMD 0.08 higher (0.23 lower to 0.39 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substan	ce use: 2. Subs	stance abuse (S	SATS, low=poor)	[skewed data]	- by 18 mont	hs (Better indicat	ed by lower value	es)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	193	182	-	SMD 0.02 lower (0.22 lower to 0.19 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substan	ce use: 2. Subs	stance abuse (S	SATS, low=poor)	[skewed data]	- by 24 mont	hs (Better indicat	ed by lower value	es)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious¹	none	184	181	-	SMD 0.11 higher (0.14 lower to 0.37 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substan	ce use: 2. Subs	stance abuse (S	SATS, low=poor)	[skewed data]	- by 30 mont	hs (Better indicat	ed by lower value	es)				

2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	185	173	-	SMD 0.11 higher (0.1 lower to 0.31 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substan	ce use: 2. Sub	stance abuse (	SATS, low=poor	skewed data]	- by 36 mont	hs (Better indicate	ed by lower value	es)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	183	177	-	SMD 0.05 higher (0.15 lower to 0.26 higher)	⊕⊕⊕O MODERATE	CRITICAL
Service	use: 1. Days ir	n stable comm	unity residences	(not in hospital	l) - by 12 mon	ths (Better indica	ted by lower valu	ies)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	197	181	-	MD 10 lower (38.61 lower to 18.6 higher)	⊕⊕OO LOW	CRITICAL
Service	use: 1. Days ir	stable comm	unity residences	(not in hospital	l) - by 24 mon	ths (Better indica	ted by lower valı	ies)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	194	183	-	MD 8.54 higher (4.46 lower to 21.55 higher)	⊕⊕OO LOW	CRITICAL
Service	use: 1. Days ir	ı stable comm	unity residences	(not in hospital	l) - by 36 mon	ths (Better indica	ted by lower valu	ıes)				
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	186	178	-	MD 5.17 higher (9.2 lower to 19.55 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. Avera	ge general sco	re (GAS, low=po	or) - by 6 mont	hs (Better ind	icated by lower v	alues)			•		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	87	75	-	SMD 0.13 higher (0.18 lower to 0.43 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. Avera	ge general sco	re (GAS, low=po	or) - by 12 mon	ths (Better in	dicated by lower	values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	89	82	-	SMD 0.07 higher (0.23 lower to 0.38 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. Avera	ge general sco	re (GAS, low=po	or) - by 18 mon	ths (Better in	dicated by lower	values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	90	86	-	SMD 0.11 higher (0.18 lower to 0.41 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. Avera	ge general sco	re (GAS, low=po	or) - by 24 mon	ths (Better in	dicated by lower	values)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	81	85	-	SMD 0.18 higher (0.13 lower to 0.48 higher)	⊕⊕OO LOW	CRITICAL
Function		<u> </u>	re (GAS, low=po	or) - by 30 mon	ths (Better in	dicated by lower						
1	randomised	no serious	no serious	no serious	very	none	84	80	-	SMD 0.06 lower	$\oplus \oplus OO$	CRITICAL

	trials	limitations	:	indirectness	serious <sup>1,2</sup>					(0.37 lower to 0.24	LOW	1
	triais	illilliations	inconsistency	mairectness	serious <sup>1,2</sup>					higher)	LOW	
·	· 1 A		(CAC 1		the (Detterning	1	1\			riigitei)		
unction			, · · · ·	T		dicated by lower	vaiuesj					T
		no serious	no serious	no serious	very	none	0.5	0.5		SMD 0.04 higher	$\oplus \oplus OO$	CDITTICAL
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		85	85	-	(0.26 lower to 0.34 higher)	LOW	CRITICAL
Satisfact	ion: Average	general score	(QOLI, low=poor	) - by 6 months	(Better indic	ated by lower val	lues)					
	randomised	no serious	no serious	no serious	very	none				SMD 0.07 lower	0000	
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		189	172	-	(0.28 lower to 0.14	⊕⊕OO LOW	CRITICAL
										higher)	LOW	
atisfact	ion: Average	general score	(QOLI, low=poor	) - by 12 month	s (Better ind	cated by lower va	alues)					•
	randomised	no serious	no serious	no serious	very	none				SMD 0.01 higher	⊕⊕00	
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		193	179	-	(0.19 lower to 0.22	LOW	CRITICAL
										higher)	LOW	
atisfact	ion: Average	general score	(QOLI, low=poor	r) - by 18 month	s (Better ind	cated by lower va	alues)					
	randomised	no serious	no serious	no serious	very	none				SMD 0.06 higher	⊕⊕00	
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		194	183	-	(0.17 lower to 0.29	LOW	CRITICAL
										higher)	LOW	
atisfact	ion: Average	general score	(QOLI, low=poor	r) - by 24 month	s (Better ind	cated by lower va	alues)					
	randomised	no serious	no serious	no serious	very	none				SMD 0.01 higher	0000	
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		186	184	-	(0.2 lower to 0.23	⊕⊕OO LOW	CRITICAL
										higher)	LOW	
			(OOLI low=poor	r) - by 30 month	s (Better ind	cated by lower va	alues)					
atisfact	ion: Average	general score	(QOLI, IOW-POOL	, ,								
atisfact	ion: Average randomised	Ĭ	no serious	no serious	very	none	,			SMD 0.02 higher	0000	
atisfact	0	Ĭ	1 2	<del>1                                    </del>	very serious <sup>1,2</sup>	none	188	178	-	SMD 0.02 higher (0.19 lower to 0.22	⊕⊕OO	CRITICAL
ntisfact	randomised	no serious	no serious	no serious	2	none	Í	178	-		⊕⊕OO LOW	CRITICAL
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1,2</sup>	none	188	178	-	(0.19 lower to 0.22		CRITICAL
	randomised trials ion: Average	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1,2</sup>		188	178	-	(0.19 lower to 0.22 higher)	LOW	CRITICAL
	randomised trials ion: Average	no serious limitations general score	no serious inconsistency (QOLI, low=poor	no serious indirectness c) - by 36 month	serious <sup>1,2</sup>	cated by lower va	188	178	-	(0.19 lower to 0.22		CRITICAL

<sup>&</sup>lt;sup>1</sup>Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

<sup>&</sup>lt;sup>2</sup>CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

# 1.1.3 GRADE profile for RCTs comparing staffed accommodation with standard care

			Ouglitz access					Summary of	findings			
			Quality assess	ment			No of paties	nts		Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	STAFF ACCOMMODATION	STANDARD CARE	Relative (95% CI)	Absolute	Quality	Importance
Substanc	e use: 1. Days	used alcohol (l	ow=poor) - 3 mor	ths (Better indic	ated by lowe	r values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	57	47	-	SMD 0.32 lower (0.71 lower to 0.07 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 1. Days	used alcohol (l	ow=poor) - 6 mor	ths (Better indic	cated by lowe	r values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	49	48	-	SMD 0 higher (0.4 lower to 0.4 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 1. Days	used alcohol (l	ow=poor) - 9 mor	ths (Better indic	ated by lowe	r values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	45	37	-	SMD 0.05 lower (0.49 lower to 0.38 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 2. Level	of alcohol use	(low=poor) - 3 me	onths (Better ind	licated by low	ver values)			•		•	
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	57	47	-	SMD 0.21 lower (0.6 lower to 0.18 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 2. Level	of alcohol use	(low=poor) - 6 me	onths (Better ind	licated by low	ver values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	49	48	-	SMD 0.06 lower (0.46 lower to 0.33 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 2. Level	of alcohol use	(low=poor) - 9 me	onths (Better ind	licated by low	ver values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	45	37	-	SMD 0.21 lower (0.65 lower to 0.23 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 3. Days	used drugs (lo	w=poor) - 3 mont	hs (Better indica	ted by lower	values)						
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	57	47	-	SMD 0.22 lower (0.61 lower to 0.17 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 3. Days	used drugs (lo	w=poor) - 6 mont	hs (Better indica	ted by lower	values)						

	•	,				-						
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	49	48	-	SMD 0.11 lower (0.51 lower to 0.28 higher)	⊕⊕OO LOW	CRITICAL
0.1.1	1 D	11 (1	) 0	1 /D // ' 1'		1 \				niigher)		
Substan		, 6	ow=poor) - 9 mon		ated by lower	values)			I	T	1	
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	45	37	-	SMD 0.04 lower (0.48 lower to 0.39 higher)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 4. Seve	rity of drug us	e (low=poor) - 3 n	nonths (Better in	dicated by lo	wer values)						
1	randomised	no serious	no serious	no serious	very	none				SMD 0.14 lower		
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		57	47	-	(0.52 lower to 0.25 higher)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 4. Seve	rity of drug us	e (low=poor) - 6 n	nonths (Better in	dicated by lo	wer values)						
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	49	48	-	SMD 0.18 lower (0.57 lower to 0.22 higher)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 4. Seve	rity of drug us	e (low=poor) - 9 n	onths (Better in	dicated by lo	wer values)						
1	randomised	no serious	no serious	no serious	very	none				SMD 0.16 lower (0.6		
	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>		45	37	-	lower to 0.28 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. % time	on streets (lov	v=poor) - 3 month	s (Better indicat	ed by lower v	alues)			-			
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	57	47	-	SMD 0.04 higher (0.35 lower to 0.42 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. % time	on streets (lov	v=poor) - 6 month	s (Better indicat	ed by lower v	alues)			-		,	
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	49	48	-	SMD 0.06 lower (0.46 lower to 0.34 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 1. % time	on streets (lov	v=poor) - 9 month	s (Better indicat	ed by lower v	alues)						
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	45	37	-	SMD 0.1 higher (0.34 lower to 0.54 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 2. % time	in independe	nt housing (low=1	oor) - 3 months	(Better indicate	ated by lower valu	ies)					
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	57	47	-	SMD 0.16 lower (0.55 lower to 0.23 higher)	⊕⊕OO LOW	CRITICAL
Function	ning: 2. % time	in independer	nt housing (low=1	ooor) - 6 months	(Better indicate	ated by lower valu	ies)					
1	randomised	no serious	no serious	no serious	very	none	49	48	-	SMD 0.22 lower	$\oplus \oplus OO$	CRITICAL

	trials	limitations	inconsistency	indirectness	serious <sup>1,2</sup>					(0.61 lower to 0.18 higher)	LOW			
Functio	unctioning: 2. % time in independent housing (low=poor) - 9 months (Better indicated by lower values)													
1	randomised trials	no serious limitations		no serious indirectness	very serious <sup>1,2</sup>	none	45	37	-	SMD 0.22 higher (0.22 lower to 0.66 higher)	⊕⊕OO LOW	CRITICAL		

<sup>&</sup>lt;sup>1</sup>Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

<sup>&</sup>lt;sup>2</sup>CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

# 1.2 Psychological/psychosocial interventions

## 1.2.1 GRADE profile for RCTs comparing CBT with standard care

			O1:1						Summary	of findings		
			Quality assess	ment			No of	patients		Effect		Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	СВТ	standard care	Relative (95% CI)	Absolute	Quality	importance
Substance	use: 1. Using	substances - by	1 month - alcohol o	or drugs								
L	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	9/31 (29%)	18/30 (60%)	RR 0.48 (0.26 to 0.9)	31 fewer per 100 (from 6 fewer to 44 fewer)	⊕⊕⊕O MODERATE	CRITICAL
Substance	use: 2. Using	substances - by	3 months - alcohol		•			•	•		•	•
L	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	7/25 (28%)	1/21 (4.8%)	RR 5.88 (0.79 to 44.03)	23 more per 100 (from 1 fewer to 205 more)	⊕⊕OO LOW	CRITICAL
Substance	use: 2. Using	substances - by	3 months - drugs								•	•
I	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	12/25 (48%)	5/21 (23.8%)	RR 2.02 (0.85 to 4.8)	24 more per 100 (from 4 fewer to 90 more)	⊕⊕OO LOW	CRITICAL
Substance	use: 2. Using	substances - by	3 months - alcohol	or drugs								
L	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	20/31 (64.5%)	26/30 (86.7%)	RR 0.74 (0.55 to 1)	23 fewer per 100 (from 39 fewer to 0 more)	⊕⊕OO LOW	CRITICAL
Substance	use: 3. Any su	ıbstance (skewe	d data) - average so	ore (ASI) by 3 m	onths (Better i	ndicated by lower	values)				•	
<u> </u>	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,3</sup>	none	31	31	-	MD 0.07 lower (0.16 lower to 0.02 higher)	⊕⊕OO LOW	CRITICAL
Substance	use: 3. Any sı	ıbstance (skewe	d data) - average so	ore (ASI) by 6-9 i	months (Better	r indicated by low	er values)		•		•	•
l	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,3</sup>	none	31	31	-	MD 0.06 lower (0.16 lower to 0.04 higher)	⊕⊕OO LOW	CRITICAL
Substance	use: 3. Any su	ıbstance (skewe	d data) - days repo	rting any substan	ce use (ASI) b	y 3 months (Better	indicated	l by lower v	values)	<del>'</del>		
L	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2,3</sup>	none	31	30	-	MD 2.1 lower (5.9 lower to 1.7 higher)	⊕⊕OO LOW	CRITICAL
Substance	use: 3. Any su	ıbstance (skewe	d data) - days repo	rting any substan	ce use (ASI) b	y 6 months (Better	indicated	l by lower v	alues)		•	•
l	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2,3</sup>	none	31	30	-	MD 2.7 lower (7.25 lower to 1.85 higher)	⊕⊕OO LOW	CRITICAL
Substance	e use: 4. Drugs	use - by 3 montl	ns (skewed data) (l	Better indicated b	y lower value	s)						

2	randomised trials	no serious limitations	no serious inconsistency		very serious <sup>1,3</sup>	none	54	49	-	MD 0.05 higher (1.55 lower to 1.66 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 5. Drugs	use - by 6 month	ns (skewed data) -	days reporting dr	ug use (ASI) b	y 6 months (Better	r indicated	l by lower v	alues)			
1		no serious limitations	no serious inconsistency		very serious <sup>1,2,3</sup>	none	29	28	-	MD 3.7 lower (7.99 lower to 0.59 higher)	⊕⊕OO LOW	CRITICAL
Substanc	bstance use: 6. Alcohol use - by 3 months (skewed data) (Better indicated by lower values)											
2			no serious inconsistency		very serious <sup>1,2,3</sup>	none	54	49	-	MD 1.95 lower (4.48 lower to 0.58 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 7. Alcoho	ol use - by 6 mon	ths (skewed data)	- days reporting a	lcohol use (A	SI) by 6 months (B	etter indic	cated by lov	ver values)			•
1	randomised trials	no serious limitations	no serious inconsistency		very serious <sup>1,2,3</sup>	none	29	28	-	MD 0 higher (3.66 lower to 3.66 higher)	⊕⊕OO LOW	CRITICAL

<sup>&</sup>lt;sup>1</sup>Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met. <sup>2</sup>CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

<sup>&</sup>lt;sup>3</sup>Skewed data.

#### 1.2.2 GRADE profile for RCTs comparing MI with standard care

			Ouglitz access					S	ummary of fi	ndings		
			Quality assess	ment			No of pation	ents		Effect		Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Motivational interviewing	standard care	Relative (95% CI)	Absolute	Quality	importance
Substance	e use: 1. Not al	ostinent or not	improved on all s	ubstances - by 12	months							
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	5/13 (38.5%)	9/12 (75%)	RR 0.51 (0.24 to 1.1)	37 fewer per 100 (from 57 fewer to 8 more)	⊕⊕OO LOW	CRITICAL
Substance use: 2. Not abstaining from alcohol - by 3 months												
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	6/15 (40%)	10/13 (76.9%)	RR 0.52 (0.26 to 1.03)	37 fewer per 100 (from 57 fewer to 2 more)	⊕⊕OO LOW	CRITICAL
Substance	e use: 2. Not al	bstaining from	alcohol - by 6 mor	nths								
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	5/15 (33.3%)	12/13 (92.3%)	RR 0.36 (0.17 to 0.75)	59 fewer per 100 (from 23 fewer to 77 fewer)	⊕⊕⊕O MODERATE	CRITICAL
Substance	e use: 3. Other	measures of al	cohol use (skewed	d data) - drinking	g days - by 6 n	nonths (Better ind	icated by lower va	alues)				
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,3</sup>	none	15	13	-	SMD 1.29 lower (2.12 to 0.46 lower)	⊕⊕OO LOW	CRITICAL

<sup>&</sup>lt;sup>1</sup> Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

<sup>&</sup>lt;sup>2</sup> CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

<sup>&</sup>lt;sup>3</sup> Skewed data.

# 1.2.3 GRADE profile for RCTs comparing CBT plus MI with standard care

			Quality assess	sment				Su	mmary of fir	idings		
			Quanty assess				No of patier	nts		Effect		Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	CBT + motivational interviewing	standard care	Relative (95% CI)	Absolute	Quality	
Death - b	y about 1 year											<u> </u>
_	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	6/246 (2.4%)	8/246 (3.3%)	RR 0.73 (0.22 to 2.41)	9 fewer per 1000 (from 25 fewer to 46 more)	⊕⊕OO LOW	CRITICAL
								3.1%		8 fewer per 1000 (from 24 fewer to 44 more)		
Substanc	e use: 1. Avera	ige number of	different drugs us	ed during the pa	ast month (OT	TI, high = poor) -	by 3 months (Better i	ndicated b	y lower valu	es)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	58	61	-	MD 0.37 higher (0.01 lower to 0.75 higher)		CRITICAL
Substanc	e use: 1. Avera	ige number of	different drugs us	sed during the pa	ast month (OT	TI, high = poor) -	by 6 months (Better i	ndicated b	y lower value	es)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	58	61	-	MD 0.19 higher (0.22 lower to 0.6 higher)		CRITICAL
Substanc	e use: 2. Avera	ge score - alcol	hol (skewed data)	- estimated dail	y consumptio	n - past month - 3	months (Better indicate)	cated by lo	wer values)			
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	21	31	-	MD 1.57 higher (0.9 lower to 4.04 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substanc	e use: 2. Avera	ige score - alcol	hol (skewed data)	- estimated dail	y consumptio	n - past month - 6	months (Better indic	cated by lo	wer values)			<u>I</u>

1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	21	31	-	MD 1.21 higher (1.07 lower to 3.49 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 2. Avera	age score - alc	ohol (skewed data	) - alcohol - estir	nated daily co	onsumption - pas	t month - 12 months (	Better indi	cated by low	er values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	18	28	-	MD 1.39 higher (1.1 lower to 3.88 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 3. Avera	age score - am	phetamine (skewe	ed data) - amphe	tamine- estim	ated daily consu	mption - past month -	3 months (	Better indica	ited by lower values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	11	9	-	MD 0.09 higher (0.4 lower to 0.58 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 3. Avera	age score - am	phetamine (skewe	ed data) - amphe	tamine- estim	ated daily consu	mption - past month -	6 months	Better indica	ited by lower values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	11	9	-	MD 1.28 lower (2.79 lower to 0.23 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 3. Avera	age score - am	phetamine (skewe	ed data) - amphe	tamine- estim	ated daily consu	mption - past month -	12 months	(Better indic	cated by lower values		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	9	8	-	MD 0.13 higher (0.11 lower to 0.37 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 4. Avera	age score - can	nabis (skewed da	ta) - cannabis- es	stimated daily	consumption - p	past month - 3 months	(Better inc	licated by lov	wer values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	39	34	-	MD 0.57 lower (4.27 lower to 3.13 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substar	nce use: 4. Avera	age score - can	nnabis (skewed da	ta) - cannabis- es	stimated daily	consumption - p	past month - 6 months	(Better inc	licated by lov	wer values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	39	34	-	MD 0.7 higher (4 lower to 5.4 higher)	⊕⊕OO LOW	CRITICAL
Substar	nce use: 4. Avera	age score - can	nabis (skewed da	ta) - cannabis- es	stimated daily	consumption - p	oast month - 12 month	s (Better in	dicated by lo	ower values)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	29	29	-	MD 4.41 higher (1.4 lower to 10.22	⊕⊕OO LOW	CRITICAL

										higher)		
ıbstan	ce use: 7. TLFB	: % days absti	nent main substa	nce (skewed data	) - 12 months	Better indicate	ed by lower values)					
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	138	137	-	MD 6.81 higher (2.07 lower to 15.69 higher)	⊕⊕OO LOW	CRITICAI
ubstan	ce use: 7. TLFB	: % days absti	nent main substa	nce (skewed data	) - 18 months	Better indicate	ed by lower values)			1		ļ
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	130	128	-	MD 1.21 lower (10.74 lower to 8.32 higher)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 7. TLFB	: % days absti	nent main substa	nce (skewed data	) - 24 months	Better indicate	ed by lower values)	1		,		_
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	129	117	-	MD 2.52 higher (7.42 lower to 12.46 higher)	⊕⊕OO LOW	CRITICAL
ubstan	ce use: 8. TLFB	: % days absti	nent all substance	e (skewed data) -	12 months (Be	tter indicated	by lower values)					
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	137	136	-	MD 5.73 higher (2.62 lower to 14.08 higher)	⊕⊕OO LOW	CRITICAL
ubstan	ce use: 8. TLFB	: % days absti	nent all substance	e (skewed data) -	18 months (Be	tter indicated	by lower values)					1
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	129	127	-	MD 0.3 lower (9.14 lower to 8.54 higher)	⊕⊕OO LOW	CRITICAL
Substan	ce use: 8. TLFB	: % days absti	nent all substance	(skewed data) -	24 months (Be	tter indicated	by lower values)	<u> </u>	1	1		<u> </u>
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	130	117	-	MD 7.07 higher (2.32 lower to 16.46 higher)	⊕⊕OO LOW	CRITICAL

	1									3 CD 0 E 1 (= 0 =		
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	58	61	-	MD 2.7 lower (7.05 lower to 1.65 higher)	⊕⊕OO LOW	CRITICA
uncti	oning: 1. Averag	e global funct	ioning score (GAI	$l_{l}$ , low = poor) - 6	months (Bette	r indicated by lo	ower values)					
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	58	61	-	MD 0.09 lower (3.7 lower to 3.52 higher)	⊕⊕⊕O MODERATE	CRITIC
uncti	oning: 1. Averag	e global funct	ioning score (GAI	l, low = poor) - 9	months (Bette	r indicated by lo	ower values)					
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	17	15	-	MD 8.44 higher (0.48 to 16.4 higher)	B ⊕⊕⊕O MODERATE	CRITIC
uncti	oning: 1. Averag	e global funct	ioning score (GAI	, low = poor) - 1	2 months (Bett	er indicated by	lower values)					
3	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	196	202	-	MD 1.87 higher (2.36 lower to 6.11 higher)		CRITIC
										,		
uncti	oning: 1. Averag	e global funct	ioning score (GAI	, low = poor) - 1	8-24 months (F	Better indicated l	by lower values)					
Functi	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	8-24 months (E	1	by lower values)	128	-	MD 0.69 higher (3.86 lower to 5.25 higher)		CRITIC.
)	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none			-	MD 0.69 higher (3.86		CRITIC
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious	none	134		-	MD 0.69 higher (3.86	LOW	CRITIC
uncti	randomised trials oning: 2. Averag randomised trials	no serious limitations re social functi no serious limitations	no serious inconsistency  oning score (SFS,  no serious inconsistency	no serious indirectness  low = poor) - by  no serious indirectness	very serious  very serious  very serious <sup>1,2</sup>	none h treatment (Bet	134 ter indicated by low	er values)	- d by lower	MD 0.69 higher (3.86 lower to 5.25 higher)  MD 5.01 higher (0.55 lower to 10.57 higher)	LOW ⊕⊕OO	

<sup>&</sup>lt;sup>1</sup> Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

<sup>&</sup>lt;sup>2</sup> CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

# 1.2.4 GRADE profile for RCTs comparing group psychotherapy with standard care

			01.1					Summary	of findin	gs		
			Quality assess	sment			No of patients			Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Social skills training/psychoeducation	standard care	Relative (95% CI)	Absolute	Quality	Importance
Substanc	e use: 1. Aver	age score - C-D	IS-R Drugs (ske	wed data) - C-D	IS-R DRUGS	by 6 months (Be	tter indicated by lower values	s)	•			
			no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	21	25	-	MD 2.99 lower (5.51 to 0.47 lower)	⊕⊕⊕O MODERATE	CRITICAL
Substanc	e use: 1. Aver	age score - C-D	IS-R Drugs (ske	wed data) - C-D	IS-R DRUGS	by 12 months (Be	etter indicated by lower value	es)				
		no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	21	25	-	MD 2.47 lower (5.76 lower to 0.82 higher)	⊕⊕OO LOW	CRITICAL
Substanc	e use: 1. Aver	age score - C-D	IS-R Drugs (ske	wed data) - C-D	IS-R DRUGS	by 18 months (Be	etter indicated by lower value	es)				
			no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	7	18	-	MD 0.79 lower (3.35 lower to 1.77 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substanc	e use: 2. Aver	age score - C-D	IS-R Alcohol (sk	ewed data) - C-	DIS-R Alcoho	ol by 6 months (B	etter indicated by lower value	es)	ļ.	<u> </u>		•
		no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	21	25	-	MD 1.81 lower (3.41 to 0.21 lower)	⊕⊕⊕O MODERATE	CRITICAL
Substanc	e use: 2. Aver	age score - C-D	IS-R Alcohol (sk	ewed data) - C-	DIS-R Alcoho	ol by 12 months (l	Better indicated by lower valu	ies)	•			
		no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	21	25	-	MD 0.71 lower (2.54 lower to 1.12 higher)	⊕⊕⊕O MODERATE	CRITICAL
Substanc	e use: 2. Aver	age score - C-D	IS-R Alcohol (sk	ewed data) - C-	DIS-R Alcoho	ol by 18 months (l	Better indicated by lower valu	ıes)				
		no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	7	18	-	MD 0.04 higher (2.27 lower to 2.35 higher)	⊕⊕⊕O MODERATE	CRITICAL
Function	ing: 1. Averag	ge role function	ing score (RFS, h	igh = better fur	nctioning) - by	y 6 months (Bette	r indicated by lower values)					
1	randomised	no serious	no serious	no serious	serious1	none	22	25	-	MD 0.61 higher	$\oplus \oplus \oplus O$	CRITICAL

	trials	limitations	inconsistency	indirectness						(1.63 lower to 2.85 higher)	MODERATE	
unction	ing: 1. Averag	e role function	ning score (RFS, h	igh = better fur	nctioning) - b	y 12 months (Bett	er indicated by lower values)					
-	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	22	25	-	MD 1.07 higher (1.15 lower to 3.29 higher)	⊕⊕⊕O MODERATE	CRITICAL
unction	ing: 1. Averag	e role function	ning score (RFS, h	igh = better fur	nctioning) - b	y 18 months (Bett	er indicated by lower values)					
-	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	7	18	-	MD 2.55 lower (6.24 lower to 1.14 higher)	⊕⊕OO LOW	CRITICAL
unction	ing: 2. Averag	e social adjust	tment score (SAS,	high = better fi	unctioning) -	by 6 months (Bet	ter indicated by lower values)					
=	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	22	25	-	MD 0.92 lower (6.58 lower to 4.74 higher)	⊕⊕OO LOW	CRITICAL
unction	ing: 2. Averag	e social adjust	tment score (SAS,	high = better fo	unctioning) -	by 12 months (Be	tter indicated by lower values	)				
=	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	22	25	-	MD 2.58 higher (3.39 lower to 8.55 higher)	⊕⊕OO LOW	CRITICAL
unction	ing: 2. Averag	e social adjust	tment score (SAS,	high = better fi	unctioning) -	by 18 months (Be	tter indicated by lower values	)				
	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	7	18	-	MD 4.66 lower (15.29 lower to 5.97 higher)	⊕⊕OO LOW	CRITICAL
Service u	se: Days in h	ospital (skewe	d data) (Better inc	dicated by lowe	r values)	<u> </u>						
-	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	very serious <sup>1,2</sup>	none	16	13	-	MD 1.8 higher (4.46 lower to 8.06 higher)	⊕⊕OO LOW	CRITICAL

<sup>&</sup>lt;sup>1</sup> Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

<sup>&</sup>lt;sup>2</sup> CI includes both 1) no effect and 2) appreciable benefit or appreciable harm.

### 1.2.5 GRADE profile for RCTs comparing contingency management with standard care

			Quality assessi	nent				Sum	ımary of f	indings		
			Quality assessi				No of patie	ents		Effect		Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Contingency management	standard care	Relative (95% CI)	Absolute	Quality	1
Substance	e use: 1. No. of	days/weeks of d	lrug use (confirma	tion by urine drug	g screen) - Da	ys of cocaine use (	Better indicated by	lower valu	ies)			
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	15	15	-	SMD 1.04 lower (1.8 to 0.28 lower)	⊕⊕⊕O MODERATE	CRITICAL
Substance	e use: 2. No. of	days/weeks of a	lcohol use (confirm	nation by breatha	lyzer) (Better	indicated by lowe	er values)					
2	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	37	34	-	SMD 1.21 lower (1.68 to 0.73 lower)	⊕⊕⊕O MODERATE	CRITICAL
Substance	e use: 3. No. of	days/weeks usii	ng both drugs and	alcohol (confirma	tion by urine	or breathalyzer) -	weeks (Better indi	cated by lo	wer value	es)		
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	22	19	-	SMD 0.82 lower (1.47 to 0.17 lower)	⊕⊕⊕O MODERATE	CRITICAL
Substance	use: 4. Alcoho	ol positive breat	halyzer samples (B	etter indicated by	lower value	s)		1	ļ			
1	randomised trials	no serious limitations	no serious inconsistency	no serious indirectness	serious <sup>1</sup>	none	15	15	-	SMD 0.97 lower (3.03 to 0.91 lower)	⊕⊕⊕O MODERATE	CRITICAL

<sup>&</sup>lt;sup>1</sup> Optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.