Additional File 4: Figure: Supporting resources for each concept

Understanding implementability in clinical trials: a pragmatic review and concept map

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	Design	Resources*	Conduct	Resources*	Reporting	Resources*
Validity	· · · · · · · · · · · · · · · · · · ·	14 12-3	All randomised participants included in ITT analysis	63,67 40	Reporting complete	14,26 28,62 5,56-7
laie l	Team has methodology training & includes a statistician	34			Sufficient information to assess risk of bias	14,26,34,46 48 3,18,21,28,53
>	Protocol uses standardised statistical/analytical procedures	34		' I		29,36
	1.			' I	No selective reporting	14,26 22,30,35,37,54,66
					Declaration of interests	34,46 <mark>48</mark>
ıce	Design informed by stakeholdes & end users	4,9,16,17,20,33,45,46,63,65	Analysis & conclusions meaningful to stakeholders	17	Sufficient information to assess applicability	1,14,25,26,39,45,52,61 28,41
٧ar	·	23,24,59 48 50				2,7-8,27,36,43,55,60
Relevance	Pragmatic design	34		·	Information relevant to different stakeholders	45
	Population			·	Rationale for selection/exclusion of harm outcomes	15
	Realistic (inclusive of diverse populations & risks)	46,49,61,63,67 <mark>40,64</mark>				
	Feasible diagnostic/eligibility criteria.	40				1
	Actively seeking diversity (for applicability, risk stratification)	49				1
	Sites comparable to where implementation occurs	61,65 <mark>40,64</mark>		' I		1
	Interventions & comparators					l l
	Feasible & acceptable in current practice & systems	16,46,51,52 <mark>8,36</mark>		·		1
	Intervention as it would be delivered in practice	49,61,67 <mark>20,64</mark>		·		1
	Comparators based in current practice	9,67 <mark>7-8,64</mark>		' I		1
	Evidence of current clinical practice is available	46,67		·		1
	Outcomes			' I		1
	Important to end users	9,15,16,17,25,34,38,45,61,63		·		1
		7-8,19,40		·		1
	Routine collection	63,65 <mark>40</mark>				!
	Pragmatic collection	63				
iii	Registered	32,34,47	Procedures, training & other materials retained	31,42,60	Published, regardless of outcome	14,32,47 22,48,68
		34,47			Accessible to end users	14,32 <mark>48</mark>
	Specify theory/logic model of how intervention will work	45			Clearly reported	48
	Outcomes				Sufficient information to replicate	25,26,34,45,46 <mark>44</mark>
	Consent obtained for data re-use	58				10,11,27,31,36,42,43
	Fidelity measures included	6,45,51,52 11,31,42			Authors responsive to requests for data	14,34,47
	Process information/evaluation/feasibility included	25,45 11,42,43,60				1
	Economic information/evaluation included	9,25,38,45,46,52 7-8,42,60				1

^{*}Resources refer to the number listed in the Characteristics of Included Resources table (Additional File 3). Resource types: Guidance, Descriptive data (benefit), Descriptive data (problem), Tool. Concepts in italics have ≥10 supporting resources.