Additional File 2: Preliminary reference lists and excluded studies

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

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A. Preliminary concept map

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USABILITY	RELEVANCE		VAI	LIDITY	
Registered Protocol published Outcomes Consent obtained for data re-use Fidelity measures included Process information, evaluation, feasibility included Economic information / evaluation included	Routine collection Pragmatic collection Persuasive (prespecified outcomes would be sufficient to motivate change) Evidence of persuasiveness of outcomes is available Out of scope Addresses a question of importance to stakeholders Addresses a gap in knowledge or practice	Design informed by stakeholders and end users Population Realistic (inclusive of diverse populations & risks) Feasible diagnostic/eligibility criteria Actively seeking diversity (to increase applicability, allow risk stratification) In sites comparable to those where implementation would need to occur Interventions & comparators Feasible in current practice & systems Intervention as it would be delivered in practice Comparators based in current practice Evidence of current clinical practice is available Outcomes	Out of scope Risk of bias, precision, ethics	Trial protocol complete Trial protocol considers implementability	DESIGN
Procedures, training & other materials retained			Out of scope Conduct and analysis as per protocol Data collection complete		CONDUCT
Published, regardless of outcome Accessible to end users Sufficient information to replicate Authors responsive to requests for data		Sufficient information to assess applicability (PICO, context)			REPORTING

B. Preliminary list of key papers used for snowballing

Brennan, S. E., M. Cumpston, M. L. Misso, S. McDonald, M. J. Murphy and S. E. Green (2016). "Design and formative evaluation of the Policy Liaison Initiative: a long-term knowledge translation strategy to encourage and support the use of Cochrane systematic reviews for informing health policy." Evidence & Policy: A Journal of Research, Debate and Practice 12(1): 25-52.

Campbell, S., S. Benita, E. Coates, P. Davies and G. Penn (2007). Analysis for policy: evidence-based policy in practice. London, HM Treasury.

Cook, J. M., C. O'Donnell, S. Dinnen, J. C. Coyne, J. I. Ruzek and P. P. Schnurr (2012). "Measurement of a model of implementation for health care: toward a testable theory." Implementation Science 7(1): 59.

Damschroder, L. J., D. C. Aron, R. E. Keith, S. R. Kirsh, J. A. Alexander and J. C. Lowery (2009). "Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science." Implementation Science 4(1): 50.

Dechartres, A., L. Trinquart, I. Atal, D. Moher, K. Dickersin, I. Boutron, E. Perrodeau, D. G. Altman and P. Ravaud (2017). "Evolution of poor reporting and inadequate methods over time in 20 920 randomised controlled trials included in Cochrane reviews: research on research study." BMJ 357: j2490.

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Gagliardi, A. R., C. Marshall, S. Huckson, R. James and V. Moore (2015). "Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice." Implementation science: IS 10: 19-19.

Gagliardi, A. R., C. Marshall, S. Huckson, R. James and V. Moore (2015). "Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice." Implementation Science 10(1): 19.

GREENHALGH, T., G. ROBERT, F. MACFARLANE, P. BATE and O. KYRIAKIDOU (2004). "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations." The Milbank Quarterly 82(4): 581-629.

Greenhalgh, T., J. Wherton, C. Papoutsi, J. Lynch, G. Hughes, C. A'Court, S. Hinder, N. Fahy, R. Procter and S. Shaw (2017). "Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies." J Med Internet Res 19(11): e367.

Innvær, S., G. Vist, M. Trommald and A. Oxman (2002). "Health policy-makers' perceptions of their use of evidence: a systematic review." Journal of Health Services Research & Policy 7(4): 239-244.

Jewell, C. J. and L. A. Bero (2008). ""Developing Good Taste in Evidence": Facilitators of and Hindrances to Evidence-Informed Health Policymaking in State Government." The Milbank Quarterly 86(2): 177-208.

Kastner, M., O. Bhattacharyya, L. Hayden, J. Makarski, E. Estey, L. Durocher, A. Chatterjee, L. Perrier, I. D. Graham, S. E. Straus, M. Zwarenstein and M. Brouwers (2015). "Guideline uptake is influenced by six implementability domains for creating and communicating guidelines: a realist review." Journal of Clinical Epidemiology 68(5): 498-509.

Lewis, C. C., S. Fischer, B. J. Weiner, C. Stanick, M. Kim and R. G. Martinez (2015). "Outcomes for implementation science: an enhanced systematic review of instruments using evidence-based rating criteria." Implementation Science 10(1): 155.

Malmivaara, A. (2019). "Generalizability of findings from randomized controlled trials is limited in the leading general medical journals." Journal of Clinical Epidemiology 107: 36-41.

Montgomery, P., K. Underhill, F. Gardner, D. Operario and E. Mayo-Wilson (2013). "The Oxford Implementation Index: a new tool for incorporating implementation data into systematic reviews and meta-analyses." Journal of Clinical Epidemiology 66(8): 874-882.

National Health and Medical Research Council (NHMRC) "Guidelines for Guidelines: Implementability.".

Proctor, E., H. Silmere, R. Raghavan, P. Hovmand, G. Aarons, A. Bunger, R. Griffey and M. Hensley (2011). "Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda."

Administration and Policy in Mental Health and Mental Health Services Research 38(2): 65-76.

Shiffman, R. N., J. Dixon, C. Brandt, A. Essaihi, A. Hsiao, G. Michel and R. O'Connell (2005). "The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline implementation." BMC Medical Informatics and Decision Making 5(1): 23.

Streater, A., A. Spector, E. Aguirre, J. Stansfeld and M. Orrell (2016). "ImpRess: an Implementation Readiness checklist developed using a systematic review of randomised controlled trials assessing cognitive stimulation for dementia." BMC Medical Research Methodology 16(1): 167.

Worsley, S. D., K. Oude Rengerink, E. Irving, S. Lejeune, K. Mol, S. Collier, R. H. H. Groenwold, C. Enters-Weijnen, M. Egger and T. Rhodes (2017). "Series: Pragmatic trials and real world evidence: Paper 2. Setting, sites, and investigator selection." Journal of Clinical Epidemiology 88: 14-20.

Zuidgeest, M. G. P., P. M. J. Welsing, G. J. M. W. van Thiel, A. Ciaglia, R. Alfonso-Cristancho, L. Eckert, M. J. C. Eijkemans and M. Egger (2017). "Series: Pragmatic trials and real world evidence: Paper 5. Usual care and real life comparators." Journal of Clinical Epidemiology 90: 92-98.

C. Preliminary list of relevant tools

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Annals of Internal Medicine. 2013;158(3):200-7.

Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ: British Medical Journal. 2014;348:g1687.

Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. BMJ: British Medical Journal. 2015;350:h2147.

Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.

D. Table of excluded resources

Reference		Reason for exclusion	
1.	Alvarez E, Lavis J. Implementing health systems guidance: A workbook to	Implementation	
	support the contextualization of recommendations at the national or		
	subnational level Hamilton, Canada: McMaster Health Forum; 2016.		
2.	Australian Government Department of Health Therapeutic Goods	Not relevant to implementability	
	Administration. Australian Clinical Trial Handbook: Guidance on		
	conducting clinical trials in Australia using 'unapproved' therapeutic		
	goods. Version 2.2. Canberra: Commonwealth of Australia; 2018.		
3.	Balshem H, Curtis P, Joplin L, Justman RA, Rosenberg AB. Stakeholder	Superseded by more recent	
	Involvement in Improving Comparative Effectiveness Reviews: AHRQ and	guidance from same organisation	
	the Effective Health Care Program. AHRQ; 2011.		
4.	Barnett J, Vasileiou K, Djemil F, Brooks L, Young T. Understanding	Implementation	
	innovators' experiences of barriers and facilitators in implementation and		
	diffusion of healthcare service innovations: a qualitative study. BMC		
	Health Serv Res. 2011;11:342.		

5.	Brach C, Lenfestey N, Roussel A, Amoozegar J, Sorensen A. Will It Work Here? A Decisionmaker's Guide to Adopting Innovations. Publication No.	Published before 2009
	08-0051. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); 2008.	
6.	Brach C, Lenfestey N, Roussel A, Amoozegar J, Sorensen A. Will It Work Here? A Decisionmaker's Guide to Adopting Innovations. Publication No. 08-0051. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); 2008.	Published before 2009
7.	Brennan SE, Cumpston M, Misso ML, McDonald S, Murphy MJ, Green SE. Design and formative evaluation of the Policy Liaison Initiative: a long-term knowledge translation strategy to encourage and support the use of Cochrane systematic reviews for informing health policy. Evidence & Policy: A Journal of Research, Debate and Practice. 2016;12(1):25-52.	Primary study, systematic review is available.
8.	Breuer E, Lee L, De Silva M, Lund C. Using theory of change to design and evaluate public health interventions: a systematic review. Implementation Science. 2016;11(1):63.	Not relevant to implementability
9.	Buffet C, Ciliska D, Thomas H. Can I Use This Evidence in my Program Decision? Assessing Applicability and Transferability of Evidence2007.	Published before 2009
10.	Buffet C, Ciliska D, Thomas H. Can I Use This Evidence in my Program Decision? Assessing Applicability and Transferability of Evidence2007.	Published before 2009
11.	Buffet C, Ciliska D, Thomas H. It worked there. Will it work here? Tool for Assessing Applicability and Transferability of Evidence (A: When considering starting a new program)2011.	Implementation
12.	Buffet C, Ciliska D, Thomas H. It worked there. Will it work here? Tool for Assessing Applicability and Transferability of Evidence (B: When considering stopping a new program)2011.	Implementation
13.	Campbell M, Katikireddi SV, Hoffmann T, Armstrong R, Waters E, Craig P, et al. TIDieR-PHP: a reporting guideline for population health and policy interventions. BMJ 2018;361 k1079.	Duplicate
14.	Campbell S, Benita S, Coates E, Davies P, Penn G. Analysis for policy: evidence-based policy in practice. London: HM Treasury; 2007.	Published before 2009
15.	Carey T, Sanders G, Viswanathan M ea. Framework for Considering Study Designs for Future Research Needs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); Mar. (Methods Future Research Needs Reports, No. 8.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK95273/. 2012.	Not relevant to implementability
16.	CIHR. Knowledge User Engagement [Available from: http://www.cihr-irsc.gc.ca/e/49505.html	More detailed resource available from same organisation.
17.	Clearly Communicating Research Results across the Clinical Trials Continuum: National Institutes of Health; 2016 [Available from: https://www.nih.gov/health-information/nih-clinical-research-trials-you/clearly-communicating-research-results-across-clinical-trials-continuum.	Not relevant to implementability
18.	Cook JM, O'Donnell C, Dinnen S, Coyne JC, Ruzek JI, Schnurr PP. Measurement of a model of implementation for health care: toward a testable theory. Implementation Science. 2012;7(1):59.	Implementation
19.	Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation Science. 2009;4(1):50.	Implementation
	de Savigny D, Adam T, editors. Systems thinking for health systems strengthening. Geneva: World Health Organization; 2009.	Implementation
21.	Dechartres A, Trinquart L, Atal I, Moher D, Dickersin K, Boutron I, et al. Evolution of poor reporting and inadequate methods over time in 20 920 randomised controlled trials included in Cochrane reviews: research on research study. Bmj. 2017;357:j2490.	Duplicate

22. Dobbins M, DeCorby K, Twiddy T. A Knowledge Transfer Strategy for Public Health Decision Makers. Worldviews on Evidence-Based Nursing.	Published before 2009
 2004;1(2):120-8. 23. Edinger T, Cohen AM. A large-scale analysis of the reasons given for excluding articles that are retrieved by literature search during systematic review. AMIA Annual Symposium proceedings AMIA Symposium. 2013;2013:379-87. 	Not relevant to implementability
24. Ellen ME, Lavis JN, Horowitz E, Berglas R. How is the use of research evidence in health policy perceived? A comparison between the reporting of researchers and policy-makers. Health Res Policy Syst. 2018;16(1):64.	Not relevant to implementability
25. Feldstein AC, Glasgow RE. A Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice. Joint Commission Journal on Quality and Patient Safety. 2008;34(4):228-43.	Published before 2009
26. Fischer F, Lange K, Klose K, Greiner W, Kraemer A. Barriers and Strategies in Guideline Implementation-A Scoping Review. Healthcare (Basel, Switzerland). 2016;4(3).	Implementation
27. Forbes G, Loudon K, Treweek S, Taylor SJC, Eldridge S. Understanding the applicability of results from primary care trials: lessons learned from applying PRECIS-2. Journal of Clinical Epidemiology. 2017;90:119-26.	Not relevant to implementability
28. Gagliardi AR, Alhabib S, Group atmotGINIW. Trends in guideline implementation: a scoping systematic review. Implementation Science. 2015;10(1):54.	Implementation
29. Gagliardi AR, Brouwers MC, Bhattacharyya OK. The guideline implementability research and application network (GIRAnet): an international collaborative to support knowledge exchange: study protocol. Implement Sci. 2012;7:26.	Study protocol
30. Gagliardi AR, Marshall C, Huckson S, James R, Moore V. Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice. Implementation Science. 2015;10(1):19.	Implementation
31. Godwin M, Ruhland L, Casson I, MacDonald S, Delva D, Birtwhistle R, et al. Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. BMC Med Res Methodol. 2003;3:28.	Published before 2009
32. Gollust SE, Seymour JW, Pany MJ, Goss A, Meisel ZF, Grande D. Mutual Distrust: Perspectives From Researchers and Policy Makers on the Research to Policy Gap in 2013 and Recommendations for the Future. Inquiry: a journal of medical care organization, provision and financing. 2017;54:46958017705465.	Primary study, systematic review is available.
33. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. The Milbank Quarterly. 2004;82(4):581-629.	Published before 2009
34. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Analysing the role of complexity in explaining the fortunes of technology programmes: empirical application of the NASSS framework. BMC Medicine. 2018;16(1):66.	Not relevant to clinical trials
35. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017;19(11):e367.	Implementation
36. Gupta A, Thorpe C, Bhattacharyya O, Zwarenstein M. Promoting development and uptake of health innovations: The Nose to Tail Tool [version 1; peer review: 3 approved, 1 approved with reservations]. (https://doi.org/10.12688/f1000research.8145.1). F1000Research. 2016;5:361.	Implementation

37. Haynes B. Can it work? Does it work? Is it worth it? The testing of healthcare interventions is evolving. 1999;319(7211):652-3.	Published before 2009
38. Haynes B, Haines A. Barriers and bridges to evidence based clinical practice. BMJ. 1998;317(7153):273-6.	Published before 2009
39. He J, Du L, Liu G, Fu J, He X, Yu J, et al. Quality assessment of reporting of randomization, allocation concealment, and blinding in traditional Chinese medicine RCTs: a review of 3159 RCTs identified from 260 systematic	Specific clinical area, broader resource is available.
reviews. Trials. 2011;12:122. 40. Hyder AA, Corluka A, Winch PJ, El-Shinnawy A, Ghassany H, Malekafzali H, et al. National policy-makers speak out: are researchers giving them what they need? Health policy and planning. 2011;26(1):73-82.	Primary study, systematic review is available.
41. Innvær S, Vist G, Trommald M, Oxman A. Health policy-makers' perceptions of their use of evidence: a systematic review. Journal of Health Services Research & Policy. 2002;7(4):239-44.	Published before 2009
42. Jewell CJ, Bero LA. "Developing Good Taste in Evidence": Facilitators of and Hindrances to Evidence-Informed Health Policymaking in State Government. The Milbank Quarterly. 2008;86(2):177-208.	Published before 2009
43. Kalkman S, van Thiel GJ, Grobbee DE, van Delden JJ. Pragmatic randomized trials in drug development pose new ethical questions: a systematic review. Drug discovery today. 2015;20(7):856-62.	Not relevant to implementability
44. L&M Policy Research, Quintiles Outcome. Registry of Patient Registries Outcome Measures Framework: Literature Review Findings and Implications. OMF Literature Review Report. (Prepared under Contract No. 290-2014-00004-C.) AHRQ Publication No. 16-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2016. Available from: www.effectivehealthcare.ahrq.gov/reports/final/cfm.	Not relevant to clinical trials
45. Lavis J, Davies H, Oxman A, Denis J-L, Golden-Biddle K, Ferlie E. Towards systematic reviews that inform health care management and policymaking. Journal of Health Services Research & Policy. 2005;10(1_suppl):35-48.	Published before 2009
46. LAVIS JN, ROBERTSON D, WOODSIDE JM, McLEOD CB, ABELSON J. How Can Research Organizations More Effectively Transfer Research Knowledge to Decision Makers? The Milbank Quarterly. 2003;81(2):221-48.	Published before 2009
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48. Leavy M, Schur C, Kassamali F, Johnson M, Sabharwal R, Wallace P, et al. Development of Harmonized Outcome Measures for Use in Patient Registries and Clinical Practice: Methods and Lessons Learned. Final Report. Rockville MD: Agency for Healthcare Research and Quality; 2019. Report No.: AHRQ Publication No. 19-EHC008-EF.	Not relevant to clinical trials
49. Lewis CC, Fischer S, Weiner BJ, Stanick C, Kim M, Martinez RG. Outcomes for implementation science: an enhanced systematic review of instruments using evidence-based rating criteria. Implementation Science. 2015;10(1):155.	Implementation
50. Li T, Mayo-Wilson E, Fusco N, Hong H, Dickersin K. Caveat emptor: the combined effects of multiplicity and selective reporting. Trials. 2018;19(1):497.	Not relevant to implementability
51. Lomas J, Fulop N, Gagnon D, Allen P. On Being a Good Listener: Setting Priorities for Applied Health Services Research. The Milbank Quarterly. 2003;81(3):363-88.	Priority setting.
52. Lu Y, Yao Q, Gu J, Shen C. Methodological reporting of randomized clinical trials in respiratory research in 2010. Respiratory care. 2013;58(9):1546-51.	Specific clinical area, broader resource is available.

53. Madurasinghe VW, Group SEoboMS, Group GFobotSEC. Guidelines for reporting embedded recruitment trials. Trials. 2016;17(1):27. 54. Morestin F. Knowledge Sharing and Public Policies: A Representation of Influence Processes2015. 55. National Institute for Health and Care Excellence (NICE). Multimorbidity: clinical assessment and management. NICE; 2016. 56. Nieuwenhuis JB, Irving E, Oude Rengerink K, Lloyd E, Goetz I, Grobbee DE, et al. Pragmatic trial design elements showed a different impact on trial interpretation and feasibility than explanatory elements. J Clin Epidemiol. 2016;77:95-100. 57. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Services Research. 2019;19(1):1389. 58. Orton L, Lloyd-Williams F, Taylor-Robinson D, O'Flaherty M, Capewell S. The use of research evidence in public health decision making processes: systematic review. PLoS One. 2011;6(7):e21704. 59. O'Sullivan AK, Thompson D, Drummond MF. Collection of health-economic data alongside clinical trials: is there a future for piggyback evaluations? Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2005;8(1):67-79. 60. Otten JJ, Dodson EA, Fleischhacker S, Siddiqi S, Quinn EL. Getting research to the policy table: a qualitative study with public health researchers on engaging with policy makers. Preventing chronic disease. 2015;12:E56. 61. Page MJ, McKenzie JE, Kirkham J, Dwan K, Kramer S, Green S, et al. Bias due to selective inclusion and reporting of outcomes and analyses in systematic reviews of randomised trials of healthcare interventions. The Cochrane database of systematic reviews. 2014(10):Mr000035. 62. PCORI, PCORI; Stakeholders 2018 [Available from: https://www.pcori.org/about-us/our-programs/engagement/public-and-patient-engagement/pcoris-stakeholders. 63. PCORI (Patient Centered Ouctomes Research Institute). PCORI Dissemination	
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