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Development and Psychometric Evaluation of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol

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Manuscripts

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3 1 **Development and Psychometric Evaluation of the Implementation Science**

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5 2 **Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol**

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23 **Abstract**

24 **Introduction**

25 The need for quantitative criteria to appraise the quality of implementation research has
26 recently been highlighted to improve methodological rigor. The Implementation Science
27 Research development (ImpRes) tool and supplementary guide provide methodological
28 guidance and recommendations on how to design high-quality implementation research.
29 This protocol reports on the development of the Implementation Science Research Project
30 Appraisal Criteria (ImpResPAC) tool, a quantitative appraisal tool, developed based on the
31 structure and content of the ImpRes tool and supplementary guide, to evaluate the
32 conceptual and methodological quality of implementation research.

33 **Methods and analysis**

34 This study employs a three-stage sequential mixed-methods design. During stage 1 the
35 research team will map core domains of the ImpRes tool, guidance and recommendations
36 contained in the supplementary guide and within the literature, to ImpResPAC. In stage 2, an
37 international multi-disciplinary expert group, recruited through purposive sampling, will inform
38 the refinement of ImpResPAC, including content, scoring system and user instructions. In
39 stage 3, an extensive psychometric evaluation of ImpResPAC, that was created in stage 1
40 and refined in stage 2, will be conducted. The scaling assumptions (inter-item and item-total
41 correlations), reliability (internal consistency, inter-rater) and validity (construct and
42 convergent validity) will be investigated by applying ImpResPAC to 50 protocols published in
43 *Implementation Science*. We envisage developing ImpResPAC in this way will provide
44 implementation research stakeholders, primarily grant reviewers and educators, to
45 undertake a comprehensive, transparent and fair appraisal of the conceptual and
46 methodological quality of implementation research, increasing the likelihood of funding
47 research that will generate knowledge and contribute to the advancement of the field.

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3 49 **Ethics and dissemination:**
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6 50 This study will involve human participants. This study has been registered and minimal risk
7
8 51 ethical clearance granted by, The Research Ethics Office, King's College London (Reference
9
10 52 number MRA-20/21-20807)
11
12

13 53 **Strengths and limitations of this study:**
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- 15 54 ▪ This research will advance the field by developing a quantitative appraisal tool to allow
16
17 55 implementation research stakeholders, primarily grant reviewers and educators, to
18
19 56 undertake a comprehensive, transparent and fair appraisal of the conceptual and
20
21 57 methodological quality of implementation research, increasing the likelihood of funding
22
23 58 research that will generate knowledge and contribute to the advancement of the field.
24
25 59 ▪ Future studies should evaluate the value of ImpResPAC with implementation research
26
27 60 stakeholders that have applied the tool.
28
29 61 ▪ Although a broad range of implementation research protocols will be appraised, using
30
31 62 ImpResPAC, limiting the appraisal to protocols published in *Implementation Science*, is
32
33 63 likely to positively skew the results.
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40 65 **Keywords:**
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43 66 Implementation science; Implementation research; Research appraisal; Methodological
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45 67 quality; Psychometric evaluation.
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73 **Introduction:**

74 High-quality research is critical to knowledge accumulation and the advancement of scientific
75 fields. Over the past decade, Implementation Science (IS) has benefited from notable efforts
76 to advance the conceptual clarity of fundamental IS concepts and methodological guidance
77 and recommendations to support applied health researchers and practitioners working within
78 the field to design high-quality implementation research (1) (2) (3) (4) (5). Such advances
79 include, but are not limited to, the proposal of an effectiveness-implementation hybrid design
80 typology (1), an implementation theory and framework comparison and selection tool (6), a
81 working taxonomy of implementation outcomes (3), taxonomies of implementation strategies
82 (4) (5) (7), guidance to identify, select and tailor implementation strategies (8), and
83 repositories of implementation outcome instruments (9) (10) (11) (12) (13).

84 Despite these advances, however, practical guidance consolidating IS concepts and
85 methodological guidelines and recommendations, (e.g., design decisions to inform the
86 appropriate hybrid design selection) until recently was lacking. This gap, in part, is likely to
87 have contributed to poor quality implementation research (14), (15).

88 Recently, the Implementation Science Research Development (ImpRes) tool and
89 supplementary guide were developed, with the explicit aim to address this gap (15), ImpRes
90 was intended to support applied health researchers and those working within the field to
91 design high-quality implementation research, and consequently help educate the next
92 generation of IS researchers and build capacity within the field (15). Based on key
93 conceptual and methodological literature containing design guidance and recommendations,
94 and an expert consensus-building brainstorming process, ImpRes incorporates core IS
95 principles and concepts that researchers should consider when designing IS research –
96 including application of appropriate theories and/or frameworks, selection of implementation
97 and other types of outcomes, development of stakeholder informed implementation
98 strategies, and evaluation of health economic elements of implementation efforts. Initial

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3 99 usability testing with end-users (i.e., researchers with varying degrees of implementation
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5 100 science knowledge/expertise) showed that the ImpRes tool is useful for identifying project
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7 101 areas where implementation research is lacking and for improving the quality of
8
9 102 implementation research (15).

11
12 103 Whilst ImpRes has the potential to contribute to filling a much-needed capacity-building gap,
13
14 104 the need for a quantitative tool to appraise the quality of implementation research has
15
16 105 recently been highlighted as a further area for development of the field (14). Research
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18 106 appraisal tools allow research stakeholders (e.g., research grant panels and educators) to
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20 107 undertake a standardized, transparent, objective, and fair appraisal (16).

22
23 108 A previous attempt to use the traditional National Institutes of Health (NIH) scoring criteria to
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25 109 evaluate grant applications for implementation and improvement sciences projects, identified
26
27 110 the need for evaluation criteria capable of identifying specific strengths and weaknesses of
28
29 111 implementation studies (14). An initial effort to address this gap has recently been reported
30
31 112 by Crable et al, 2018 who developed a scoring system, '*ImplemeNtation and Improvement*
32
33 113 *Science Proposals Evaluation CriTeria* (INSPECT)', based on Proctor's 10 key ingredients in
34
35 114 high-quality implementation research grant proposals, to identify common deficiencies in
36
37 115 implementation and improvement science research proposals from a grant application
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39 116 perspective (14).

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43 117 Another example of prior efforts to quantify the quality of implementation research, by some
44
45 118 of the authors of this paper (CS, LG, LH), reported the initial development of a quantitative
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47 119 appraisal tool, based on the ImpRes tool and supplementary guide (17) (18). This initial
48
49 120 development work focused on five of the ten ImpRes domains: 1) Implementation research
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51 121 characteristics; 2) Implementation theories, frameworks and models; 3) Determinants of
52
53 122 implementation; 4) Implementation strategies; 5) Implementation outcomes. This quantitative
54
55 123 appraisal tool, structured as a rubric, applied analytic scoring to study protocols, published in
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57 124 *Implementation Science*, using a 4-point scale (ranging from '1' indicating that the protocol is
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59 125 lacking detail and of sub-optimal conceptual and methodological quality, to '4' indicating that

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3 126 the protocol provides explicit descriptions, justifications and citations from the literature and
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5 127 is of excellent conceptual and methodological quality). Initial development included applying
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7 128 the appraisal criteria to 16 implementation research protocols, published in *Implementation*
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9 129 *Science*, where all cumulative scores were expressed as a percentage of the total
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11 130 achievable score for that protocol, to indicate and allow IS protocols to be compared based
12
13 131 on conceptual and methodological strength. Intra-class correlation coefficient (ICC) tests
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15 132 indicated excellent inter-rater reliability (IRR).
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21 134 Here we build upon this early-phase study by Sweetnam et al, 2018 (17) (18) and report a
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23 135 study that will develop a complete and comprehensive tool to appraise the conceptual and
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25 136 methodological quality of implementation research, termed the Implementation Science
26
27 137 Research Project Appraisal Criteria (ImpResPAC) tool. The study aims to develop appraisal
28
29 138 criteria for the remaining five ImpRes domains: 1) Service and patient outcomes; 2)
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31 139 Unintended consequences; 3) Economic evaluation; 4) Stakeholder involvement and
32
33 140 engagement; 5) Patient and public involvement and engagement; and to refine the existing
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35 141 criteria developed by Sweetnam et al, 2018 (17) (18).
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39 142 The specific objectives of the research are as follows:

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42 143 1. To formulate an ImpResPAC expert advisory group to contribute to the refinement
43
44 144 and content of ImpResPAC.
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46 145 2. To develop a comprehensive and in-depth quantitative appraisal tool to be used by
47
48 146 implementation research stakeholders to appraise the conceptual and
49
50 147 methodological quality of IS research: ImpResPAC.
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52 148 3. To evaluate the psychometric properties (reliability and validity) and usability,
53
54 149 including the acceptability, feasibility, and appropriateness, of ImpResPAC.
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3 151 ImpResPAC will complement but extend recent efforts by Crable et al (14) who developed
4
5 152 and evaluated the 'INSPECT' tool. Whilst overlap between INSPECT and ImpResPAC will
6
7 153 exist, the two appraisal systems will differ notably in focus, depth of appraisal, and the
8
9 154 foundations upon which they are based. For example, INSPECT primarily focuses on
10
11 155 fundability whereas ImpResPAC focuses on conceptual and methodological quality of
12
13 156 implementation research. Furthermore, INSPECT operationalizes the "key ingredients" to
14
15 157 writing implementation research grant proposals developed by Proctor et al. (19) which
16
17 158 operates specifically within the National Institutes of Health (NIH) proposal scoring
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19 159 framework (20), whereas ImpResPAC will not be developed within the constraints of a single
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21 160 grant proposal scoring framework, thus its applicability will not be limited in this way.
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3 174 **Methods and analysis:**
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6 175 We will conduct a multi-stage, mixed-methods study to develop, refine, and evaluate the
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8 176 psychometric strength of ImpResPAC.
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14 178 **Stage 1: ImpResPAC development**
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16 179 ImpResPAC will map onto the ten domains of the ImpRes tool and supplementary guide
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18 180 (see Figure 1).
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21 181 As part of a previous dissertation study, five of the ImpResPAC domains were developed
22
23 182 and inter-rater reliability was assessed (17). Formal quantitative psychometric testing of the
24
25 183 content validity and concurrent validity of ImpResPAC was beyond the scope of this previous
26
27 184 work. In this research, the five previously developed domains will be subject to refinement
28
29 185 within the tool development stage of this study, and the remaining five domains will be
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31 186 developed, by the ImpResPAC development/research team. Furthermore, more extensive
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33 187 and rigorous psychometric evaluation will be performed for all ten ImpResPAC domains.
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39 189 **Figure 1. ImpRes domains to be represented in ImpResPAC (15)**
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45 191 **Stage 2: ImpResPAC Content Validation and Refinement**
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47 192 To ensure that ImpResPAC is face and content valid we will use purposive sampling to form
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49 193 an ImpResPAC expert advisory group, consisting of a number of eminent academics that
50
51 194 have made a significant contribution to the conceptual and methodological advancement of
52
53 195 one or more of the ImpResPAC domains. Experts will be asked to review and provide
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55 196 feedback, including modifications and suggestions for improvement, on the ImpResPAC
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57 197 domain(s) that they have expertise in.
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3 198 We define an expert as ‘someone widely recognized as a reliable source of knowledge,
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5 199 technique, or skill whose judgment is accorded authority and status by the public or his or
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7 200 her peers’ (21). The ImpResPAC development/research team will generate a list of experts
8
9 201 that meet the above criteria, based on our collective knowledge. Once experts have agreed
10
11 202 to participate in the study, we will encourage them to nominate additional experts, i.e.,
12
13 203 snowballing technique, whose contribution would be valuable. Once experts agree to
14
15 204 participate, they will have the option to be recognized as a contributor in the study or for their
16
17 205 participant to remain anonymous.
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23 207 Using surveys, the expert advisory group will review ImpResPAC domain(s) and items for
24
25 208 content, style and comprehensiveness. Members of the expert advisory group will be
26
27 209 presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC
28
29 210 domain(s) that they are an expert in, survey instructions, and survey questions. The survey
30
31 211 will be attached in an email to experts.
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35 212 Experts will be asked to review the ImpResPAC domain(s) and associated items for the
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37 213 domain(s) that they agree they are ‘experts’ in. Members of the expert advisory group will
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39 214 have 4 weeks to complete the survey. A reminder email will be sent two weeks after the
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41 215 survey is first sent and one week before the 4-week deadline.
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44 216 The development/research team will collate and review all comments and suggested
45
46 217 refinements to ImpResPAC and refinements will be decided via group discussions until
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48 218 consensus is reached. Once ImpResPAC is finalized, we will quantitatively assess the
49
50 219 acceptability, appropriateness and feasibility of ImpResPAC. All members of the
51
52 220 ImpResPAC expert advisory group will be invited to review the refined version ImpResPAC
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54 221 and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC via
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56 222 a follow-up survey. See additional file 1 for survey questions.
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3 224 **Stage 3: Application and Psychometric Evaluation of ImpResPAC**
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6 225 ImpResPAC, developed in stage 1 and content validated and refined based on expert
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8 226 feedback in stage 2, will be applied to 50 research protocols published in *Implementation*
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10 227 *Science* to evaluate its psychometric strength.

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13 228 Two of the study authors (CS and LH), with expertise and experience in implementation and
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15 229 improvement science research, will independently appraise the conceptual and
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17 230 methodological quality of the 50 most recently published research protocols published in
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19 231 *Implementation Science*, using ImpResPAC. We decided to appraise research protocols
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21 232 published in *Implementation Science* as it is the most well established (since 2006), highest
22
23 233 impact factor (IF) journal in the field and regarded, by researchers, practitioners and funders
24
25 234 as a key source for dissemination and implementation (D&I) research in health (22).
26
27 235 Furthermore, *Implementation Science* publishes research covering a broad array of content
28
29 236 areas and settings, making it an ideal test bed for ImpResPAC.

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35 238 *Inclusion Criteria:*

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38 239 Study protocols that describe:

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41 240 1. Effectiveness-implementation hybrid design studies (i.e., “a study design that takes a
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43 241 dual focus in assessing clinical effectiveness and implementation”) (1).
44
45 242 2. Implementation research studies (i.e., “Research focused on the adoption or uptake
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47 243 of clinical interventions by providers and/or systems of care”) (1).
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52 245 *Exclusion criteria:*

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54 246 Study protocols/proposals that describe:
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3 247 1. Theoretical or methodological research (e.g., theory development, measurement
4 development), where implementation of an evidence-based intervention is not
5 248
6 planned
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9 250 2. De-implementation studies of interventions found to be of low value, wasteful or
10 clinically ineffective. The field of de-implementation is expanding rapidly, and
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12 although there have been recent attempts to theorise the de-implementation process
13 252
14 (23), and the field is still in infancy (24). As such consensus regarding de-
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16 implementation and research guidance is lacking and further methodological
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18 development is still necessary (25). For this very reason, this subsection of IS was
19 255
20 not included in the ImpRes tool and guide and will also not be included in
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22 ImpResPAC.
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30 259 *Assessment of the validity and reliability of ImpResPAC*
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34 261 We will employ an item exploratory factor analysis (EFA) to the polychoric matrix of the 10
35 262 ImpResPAC domains to determine and confirm scale factor structures (construct validity). A
36 263 varimax rotation will be applied to improve the interpretability of the factors obtained. We will
37 264 use three criteria to select the final factors: i) The scree plot ii) eigenvalues >1 and iii) >90%
38 265 of total variance explained by the factors. ImpResPAC will be applied to 50 protocols for
39 266 pragmatic reasons, as this equates to the minimum number of observations (50), required
40 267 when conducting EFA (26).
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51 269 Convergent validity will be further examined by estimating the correlation between
52 270 ImpResPAC dimension with the total scores of the INSPECT scale (14) as both scoring
53 271 criteria rate the quality of proposed implementation science research. Spearman's
54 272 correlation coefficients will be calculated and interpreted as follows: >0.90: excellent
55 273 relationship, 0.71-0.90: good, 0.51-0.70: fair, 0.31-0.50: weak, and <0.30: none (28).
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We are expecting fair to good correlations, as excellent correlations would indicate that ImpResPAC is a duplication of INSPECT. A comparison of ImpResPAC and INSPECT domains, presented in Table 1, indicates clear similarities between a number of domains (i.e., ImpResPAC domains 1 – 4), a degree of similarities between some domains (i.e., ImpResPAC domains 5 – 9), and no apparent similarities between some domains (i.e., ImpResPAC domain 10). Given the varying degrees of content overlap between ImpResPAC and INSPECT domains, as described in details above, we hypothesize that there will be a fair to good relationship (correlation coefficient r : 0.31-0.70) between global ImpResPAC and INSPECT scores.

Cronbach's alpha coefficient will be used to evaluate the reliability (internal consistency) of the ten domains of ImpResPAC, as it evaluates the extent to which the domains within a scale are inter-correlated with one another and thus seem to measure the same concept. It's value ranges from 0 to 1 and internal consistency is suggested to be acceptable when Cronbach's alpha is at least 0.70 (28). Inter-rater reliability will be assessed using Criterion of Lin's $\rho \geq 0.70$ to indicate acceptable reliability. A weighted kappa score will also be calculated for each ImpResPAC domain to provide details on the test–retest and inter-rater reliability. A criterion of weighted kappa ≥ 0.40 will be used to indicate acceptable domain level reliability. Precision will be assessed to test how well each domain fits within its proposed scale (28). Corrected domain-total correlations of < 30 will indicate poor fit of items within the ImpResPAC total score (30). Each ImpResPAC item will be correlated both with its own global domain score total and with the other global domain totals. Each component will require higher correlation with its own domain than other ImpResPAC domains to demonstrate precision.

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301 **Patient and Public Involvement:**

302 Patients or the public were not involved in the design, conduct or reporting plans of this
303 research.

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For peer review only

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323 **Table 1. Comparison of domains included in INSPECT versus ImpResPAC**

	ImpResPAC domains <i>(Informed by ImpRes tool and guide, Hull et al (15).</i>	INSPECT domains <i>(Informed by 'ten key ingredients', Proctor et al (19).</i>
<i>ImpResPAC domains with clear overlap in domains (1 - 4).</i>		
1	Implementation theories, frameworks and models	Conceptual model and theoretical justification
2	Stakeholder involvement and engagement	Stakeholder priorities and engagement in change
3	Patient and public involvement (PPI) and engagement	
4	Implementation strategies	Implementation strategy/process
<i>ImpResPAC domains with some degree of overlap in domains (5 – 9).</i>		
5	Implementation research characteristics	The care gap or quality gap
6	Determinants of implementation contextual factors	Setting's readiness to adopt new services/treatments/programs
7	Economic evaluation	Feasibility of proposed research design and methods
8	Service and patient outcomes	Measurement and analysis section
9	Implementation outcomes	
<i>ImpResPAC domains with no apparent overlap in domains (10).</i>		
10	Unintended consequences	<i>No comparable/similar domain</i>
	<i>No comparable/similar domain</i>	Policy/funding environment; leverage or support for sustaining change
	<i>No comparable/similar domain</i>	Team experience with setting
	<i>No comparable/similar domain</i>	The evidence-based treatment to be implemented

324 *Key: ImpResPAC domain 1-4: clear overlap in domains; ImpResPAC domain 5-9: Some degree*
 325 *of overlap in domains; ImpResPAC domain 10: No apparent overlap in domains*

326

327 Discussion

328 This study will develop, refine, content validate, and evaluate the psychometric strength (i.e.,
329 the reliability and validity) of an expert derived tool, ImpResPAC, to appraise the conceptual
330 and methodological quality of implementation research. The proposed research will fill an
331 important gap in our ability, as a field, to conduct a comprehensive, transparent, systematic
332 and in-depth quantitative appraisal of implementation research. Purposively sampling
333 experts to form an international ImpResPAC expert advisory group to refine and content
334 validate ImpResPAC, will ensure appropriate appraisal criteria, relevant to the conceptual
335 and methodological quality of implementation research, is developed, which will allow an in-
336 depth, comprehensive appraisal of implementation research. Feedback on the acceptability,
337 feasibility and appropriateness of ImpResPAC will also be sought from the ImpResPAC
338 expert advisory group.

339

340 Previous research suggests that researchers seeking to design implementation research find
341 it challenging to distinguish between implementation research and efficacy and effectiveness
342 research and consequently fail to design high-quality implementation research (4). With the
343 availability of the ImpRes tool and supplementary guide, consolidating methodological
344 guidelines and recommendations, researchers are better equipped to design high-quality
345 implementation research proposals. We envisage ImpResPAC will provide funding bodies
346 with a standardized and transparent method to differentiate high and low-quality
347 implementation research. In addition, we also anticipate that ImpResPAC could be
348 incorporated into training materials and applied retrospectively by educators as a
349 standardized appraisal tool across IS programs to quantitatively assess implementation
350 research projects submitted by students.

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3 352 Although INSPECT already exists as a standardized appraisal tool for implementation
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5 353 research proposals, we plan to develop a complementary, yet conceptually distinct tool that
6
7 354 focuses exclusively on conceptual and methodological quality of IS research proposals. As
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9 355 such, ImpResPAC scoring domains will differ to INSPECT domains, as highlighted in Table
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11 356 1. For example, *team experience with setting, treatment, and implementation process* is one
12
13 357 of the ten *domains* of the INSPECT tool, however the ImpRes tool and supplementary guide,
14
15 358 and consequently ImpResPAC, will not contain criteria measuring this domain as team
16
17 359 experience is not a direct measure of conceptual or methodological quality of IS research.
18
19 360 Similarly, ImpResPAC will contain criteria that INSPECT does not explicitly appraise. For
20
21 361 example, ImpResPAC will appraise whether research teams plan to evaluate unintended
22
23 362 consequences of implementation in addition to exploring and quantifying the anticipated
24
25 363 benefits of implementation. Furthermore, the level of detail at which implementation research
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27 364 will be appraised using the two scoring systems will differ substantially. For example,
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29 365 INSPECT provides an overall appraisal of the *measurement and analysis* of IS research
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31 366 proposals, however the ImpRes guide, and consequently ImpResPAC, will contain three
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33 367 domains relating to measurement and analysis; 1) service and patient outcomes; 2)
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35 368 implementation outcomes; and 3) economic evaluation, providing a much more detailed and
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37 369 focused appraisal of the outcomes typically assessed in implementation research.
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45 371 INSPECT operationalized grant proposal criteria proposed by Proctor's et al 'key
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47 372 ingredients', which were developed nearly a decade ago (i.e., 2012) (19), whereas
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49 373 ImpResPAC will identify conceptual and methodological strengths and weakness in IS
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51 374 projects taking account of the conceptual and methodological developments that have taken
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53 375 place in more recent years. As such, ImpResPAC will include and operationalize key
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55 376 methodological guidelines and recommendations that simply did not exist nearly a decade
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57 377 ago. ImpResPAC will operationalize, for example, the key methodological and conceptual
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59 378 guidelines and recommendations that have been described in the ImpRes tool and guide, as

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3 379 well as guidelines suggested by our international expert advisory panel, and key literature
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5 380 published since the development of the ImpRes tool and guide.
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11 382 This study has a number of limitations. We acknowledge that in order to truly test the value
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13 383 of ImpResPAC, it will be preferable to seek feedback from implementation research
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15 384 stakeholders who have had the opportunity to apply the tool in practice, but this is beyond
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17 385 the scope of this research. Future studies should evaluate the value of ImpResPAC with
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19 386 implementation research stakeholders that have applied the tool. Secondly, although the
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21 387 implementation research protocols that will be appraised, using ImpResPAC, will cover a
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23 388 broad range of content areas and settings, appraising protocols published in *Implementation*
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25 389 *Science*, is likely to positively skew the results (i.e., it is fair to assume that only high-quality
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27 390 IS protocols will have been published in *Implementation Science*). This is a specific and
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29 391 inherent challenge with the planned research, as access to implementation research
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31 392 protocols rejected from journals and unsuccessful grant proposals submitted to funding
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33 393 bodies are not publicly available and unattainable for obvious reasons.
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40 395 High-quality implementation research is key to advancing the field and improving the
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42 396 adoption, implementation, sustainment and scale-up of evidence-based interventions. This
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44 397 research will advance the field by developing a quantitative appraisal tool, which we believe
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46 398 will be of immediate use and value to IS research stakeholders (e.g., grant reviewers and
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48 399 educators), to undertake a comprehensive, transparent and fair appraisal of the conceptual
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50 400 and methodological quality of implementation research.
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6 405 This study will involve human participants. This study has been registered and minimal risk
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8 406 ethical clearance granted by, The Research Ethics Office, King's College London (Reference
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10 407 number MRA-20/21-20807)
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18
19 410 CS and LH initially conceptualized and designed this study. IB made significant contribution
20
21 411 to the design of the psychometric evaluation section. NS, LG, RD, ZK, AB and AH all made
22
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24
25 413 authors read and approved the final manuscript.
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13
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32 439 **List of abbreviations**
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35 440 **EFA:** Exploratory Factor Analysis
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38 441 **ICC:** Intra-class Correlation Coefficient
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41 442 **ImpRes:** Implementation Science Research development
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44 443 **ImpResPAC:** Implementation Science Research Project Appraisal Criteria
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46 444 **INSPECT:** ImplemeNtation and Improvement Science Proposals Evaluation CriTeria
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49 445 **IRR:** Inter-Rater Reliability
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52 446 **IS:** Implementation Science
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55 447 **NIH:** National Institutes of Health
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13 476 **Additional Files**
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16 477 Additional file 1: ImpResPAC Survey Questions (Stage 2: ImpResPAC Content
17 478 Validation and Refinement Expert Advisory Group Survey Questions)
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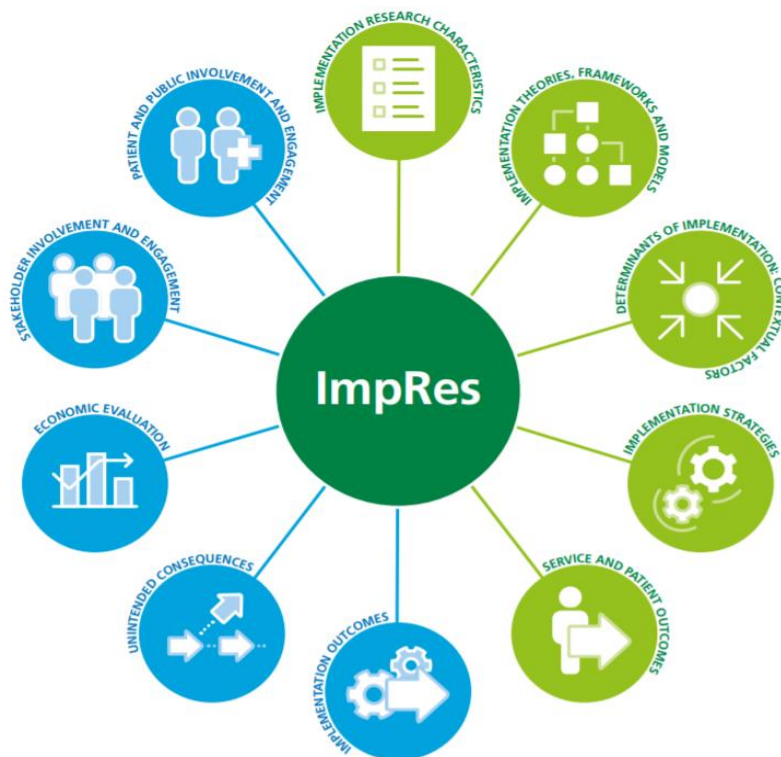
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Table 1. Comparison of domains included in INSPECT versus ImpResPAC

	ImpResPAC domains <i>(Informed by ImpRes tool and guide, Hull et al (15).</i>	INSPECT domains <i>(Informed by ‘ten key ingredients’, Proctor et al (19).</i>
<i>ImpResPAC domains with clear overlap in domains (1 - 4).</i>		
1	Implementation theories, frameworks and models	Conceptual model and theoretical justification
2	Stakeholder involvement and engagement	Stakeholder priorities and engagement in change
3	Patient and public involvement (PPI) and engagement	
4	Implementation strategies	Implementation strategy/process
<i>ImpResPAC domains with some degree of overlap in domains (5 – 9).</i>		
5	Implementation research characteristics	The care gap or quality gap
6	Determinants of implementation contextual factors	Setting’s readiness to adopt new services/treatments/programs
7	Economic evaluation	Feasibility of proposed research design and methods
8	Service and patient outcomes	Measurement and analysis section
9	Implementation outcomes	
<i>ImpResPAC domains with no apparent overlap in domains (10).</i>		
10	Unintended consequences	<i>No comparable/similar domain</i>
	<i>No comparable/similar domain</i>	Policy/funding environment; leverage or support for sustaining change
	<i>No comparable/similar domain</i>	Team experience with setting
	<i>No comparable/similar domain</i>	The evidence-based treatment to be implemented

Key: ImpResPAC domain 1-4: clear overlap in domains; ImpResPAC domain 5-9: Some degree of overlap in domains; ImpResPAC domain 10: No apparent overlap in domains

Figure 1. ImpRes domains to be represented in ImpResPAC (15)



Review only

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Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Each member of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions.

Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool.

The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, each member of the expert advisory group will be sent a survey and asked to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC.

Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Based on the significant contribution you have made to the conceptual and methodological advancement of implementation research, in particular relating to the characteristics of implementation research, we would like your feedback on the ***Implementation Research Characteristics*** domain of ImpResPAC.

We would also like your feedback on the ***Unintended Consequences*** domain of ImpResPAC. Although a separate domain, it is very much linked to design of implementation research and the ***Implementation Research Characteristics*** domain. If, after reviewing the ***Unintended Consequences*** domain, you feel that you don't have the expertise to provide feedback, you can choose to provide feedback on the Implementation Research Characteristics domain only.

ImpResPAC contains 10 domains representing core implementation science principles and concepts, including:

- (1) Implementation Research Characteristics
- (2) Implementation Theories, Frameworks and Models
- (3) Determinants of Implementation: Contextual Factors
- (4) Implementation Strategies
- (5) Service and Patient Outcomes
- (6) Implementation Outcomes
- (7) Unintended Consequences
- (8) Economic Evaluation
- (9) Stakeholder Involvement and Engagement
- (10) Patient and Public Involvement and Engagement.

We appreciate that you may have expertise relating to other ImpResPAC domains, if you believe that you have expertise relating to any other ImpResPAC domain(s), please let us know and we will share these with you to enable you to provide feedback on these ImpResPAC domains.

Survey instructions

We would like you to review and provide feedback, including modifications and suggestions for improvement, on the 'Implementation Research Characteristics' ImpResPAC domain and associated items, presented in the table below. Following review of the domain items, you will then be asked to complete 5 questions regarding domain content, style and comprehensiveness. You will also be asked to

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provide feedback relating to the scoring scale and anchors and user instructions. We request your comments and suggestions for improvements to be made using the comment and track changes functions in word.

Overview of ImpResPAC

ImpResPAC aims to be a comprehensive and in-depth quantitative appraisal tool to evaluate the conceptual and methodological quality of implementation research. ImpResPAC contains 10 domains representing core implementation science principles and concepts (detailed above). For each domain, we have identified a number of items that we believe indicate high-quality implementation research.

We hope that ImpResPAC will advance the field of implementation science by providing a quantitative appraisal tool that can be used by a wide range of implementation research stakeholders, primarily grant reviewers and educators working within the field, to comprehensively appraise the conceptual and methodological quality of implementation research.

ImpResPAC user instructions

The ImpResPAC tool contains 10 domains representing core implementation science principles and concepts. Each domain contains a number of items that are indicative of high-quality implementation research. Each ImpResPAC domain, and associated items, should be considered in the context of the aims and objectives, scope and resources of the research project in question. As such, it is possible that one or more ImpResPAC domains, and associated items, will not be applicable. You are not expected to score each item within each domain, rather a single score for each applicable ImpResPAC domain should be provided.

For each applicable domain, the scores should be added together, to calculate a global score indicating the conceptual and methodological quality of the implementation project. For example, if 7 ImpResPAC domains are applicable, the global score would be out of a maximum score of 35 (7 domains x maximum domain score of 5 = 35).

Please note you are not expected to provide a score as part of completing this survey

Domain scoring scale and anchors

1 = Very poor: Proposed project fails to adequately address all items

2 = Poor: Proposed project fails to adequately address most items

3 = Satisfactory: Proposed project addresses some items adequately

4 = Good: Proposed project addresses most items adequately/fully

5 = Excellent: Proposed project fully addresses all items

N/A = domain considered not applicable given the aims, objectives, scope and resources of the project.

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Part A: Survey questions

1. (a) Do the domain items represent and reflect high-quality conceptual and methodological elements of implementation research characteristics? Yes/no
(b) If no, please use track changes in the table above to provide amendments/suggestions for improvement.
2. (a) Are there any items missing from the domain? Yes/no
(b) If yes, please use track changes in the table above to suggest additional items for inclusion.
3. (a) Is the item wording clear? Yes/no
(b) If no, please use track changes in the table above to suggest amendments/improvements.
4. (a) Are the ImpResPAC user instructions (p.2) adequate and clear?
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.
5. (a) Is the scoring scale and associated anchors (p.2) appropriate and clear? Yes/no
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

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Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool

Thank you for your initial feedback on Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. After careful consideration of the feedback received from the expert advisory group, the ImpResPAC research/development group have refined the ImpResPAC tool.

On a scale of 1 – 5 please rate your level of agreement with the following statements on the acceptability, appropriateness and feasibility of the ImpResPAC tool.

Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory (Proctor et al, 2011). With this definition in mind, please rate the acceptability of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(i) The ImpResPAC Tool Acceptability						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an acceptable tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an acceptable tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an acceptable tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an acceptable tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising						

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implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not acceptable for use for this purpose.

Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem (Proctor et al, 2011). With this definition in mind, please rate the appropriateness of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(ii) The ImpResPAC Tool Appropriateness						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an appropriate tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an appropriate tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an appropriate tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an appropriate tool to be used for educational purposes e.g.,						

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incorporating into training materials or quantitatively appraising implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not appropriate for use for this purpose.

Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting (Proctor et al, 2011). With this definition in mind, please rate the feasibility of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(iii) The ImpResPAC Tool Feasibility						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is a feasible tool to be used in the appraisal of grant applications.						
b) ImpResPAC is a feasible tool for researchers, to appraise the methodological and conceptual quality of their research						
c) ImpResPAC is a feasible tool for practitioners, to appraise the methodological and conceptual quality of their project.						

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d) ImpResPAC is a feasible tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not feasible for use for this purpose.

Do you have any additional comments you will like to make about ImpResPAC?

BMJ Open

Development and Psychometric Evaluation of the Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol

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Manuscripts

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3 **1 Development and Psychometric Evaluation of the Implementation Science**
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5 **2 Research Project Appraisal Criteria (ImpResPAC) tool: A Study Protocol**
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23 **Abstract**

24 **Introduction**

25 The need for quantitative criteria to appraise the quality of implementation research has
26 recently been highlighted to improve methodological rigor. The Implementation Science
27 Research development (ImpRes) tool and supplementary guide provide methodological
28 guidance and recommendations on how to design high-quality implementation research.
29 This protocol reports on the development of the Implementation Science Research Project
30 Appraisal Criteria (ImpResPAC) tool, a quantitative appraisal tool, developed based on the
31 structure and content of the ImpRes tool and supplementary guide, to evaluate the
32 conceptual and methodological quality of implementation research.

33 **Methods and analysis**

34 This study employs a three-stage sequential mixed-methods design. During stage 1 the
35 research team will map core domains of the ImpRes tool, guidance and recommendations
36 contained in the supplementary guide and within the literature, to ImpResPAC. In stage 2, an
37 international multi-disciplinary expert group, recruited through purposive sampling, will inform
38 the refinement of ImpResPAC, including content, scoring system and user instructions. In
39 stage 3, an extensive psychometric evaluation of ImpResPAC, that was created in stage 1
40 and refined in stage 2, will be conducted. The scaling assumptions (inter-item and item-total
41 correlations), reliability (internal consistency, inter-rater) and validity (construct and
42 convergent validity) will be investigated by applying ImpResPAC to 50 protocols published in
43 *Implementation Science*. We envisage developing ImpResPAC in this way will provide
44 implementation research stakeholders, primarily grant reviewers and educators, to
45 undertake a comprehensive, transparent and fair appraisal of the conceptual and
46 methodological quality of implementation research, increasing the likelihood of funding
47 research that will generate knowledge and contribute to the advancement of the field.

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2
3 49 **Ethics and dissemination:**
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5

6 50 This study will involve human participants. This study has been registered and minimal risk
7
8 51 ethical clearance granted by, The Research Ethics Office, King's College London (Reference
9
10 52 number MRA-20/21-20807). Participants will receive written information on the study via
11
12 53 email and will provide e-consent if they wish to participate. We will use traditional academic
13
14 54 modalities of dissemination (e.g., conferences, publications).
15
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19
20 56 **Strengths and limitations of this study:**
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- 22 57 - This study will develop and evaluate the psychometric properties of a quantitative
23
24 58 appraisal tool, the Implementation Science Research Project Appraisal Criteria
25
26 59 (ImpResPAC) tool, to evaluate the quality of implementation research.
27
28 60 - Input from a multi-disciplinary, international expert group will inform the development of
29
30 61 ImpResPAC.
31
32 62 - Our definition of 'experts' in this study could exclude the perspectives of other
33
34 63 stakeholder groups that could be useful and how the tool might be valued by groups
35
36 64 excluded in the initial development process.
37
38 65 - ImpResPAC will enable users to undertake a comprehensive, transparent, and fair
39
40 66 appraisal of the conceptual and methodological quality quality of implementation
41
42 67 research.
43
44 68 - Some limitations to the study design include the lack of public and patient involvement,
45
46 69 due to lack of funding to involve patient and the public in the research.
47
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51 70

52
53 71 **Keywords:**
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55
56 72 Implementation science; Implementation research; Research appraisal; Methodological
57
58 73 quality; Psychometric evaluation.
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4
56 75 **Introduction:**
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8
9 76 High-quality research is critical to knowledge accumulation and the advancement of scientific
10
11 77 fields. Over the past decade, Implementation Science (IS) has benefited from notable efforts
12
13 78 to advance the conceptual clarity of fundamental IS concepts and methodological guidance
14
15 79 and recommendations to support applied health researchers and practitioners working within
16
17 80 the field to design high-quality implementation research (1) (2) (3) (4) (5). Such advances
18
19 81 include, but are not limited to, the proposal of an effectiveness-implementation hybrid design
20
21 82 typology (1), an implementation theory and framework comparison and selection tool (6), a
22
23 83 working taxonomy of implementation outcomes (3), taxonomies of implementation strategies
24
25 84 (4) (5) (7), guidance to identify, select and tailor implementation strategies (8), and
26
27 85 repositories of implementation outcome instruments (9) (10) (11) (12) (13).

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31 86 Despite these advances, however, practical guidance consolidating IS concepts and
32
33 87 methodological guidelines and recommendations, (e.g., design decisions to inform the
34
35 88 appropriate hybrid design selection) until recently was lacking. This gap, in part, is likely to
36
37 89 have contributed to poor quality implementation research (14), (15).

38
39
40 90 Recently, the Implementation Science Research Development (ImpRes) tool and
41
42 91 supplementary guide were developed, with the explicit aim to address this gap (15), ImpRes
43
44 92 was intended to support applied health researchers and those working within the field to
45
46 93 design high-quality implementation research, and consequently help educate the next
47
48 94 generation of IS researchers and build capacity within the field (15). Based on key
49
50 95 conceptual and methodological literature containing design guidance and recommendations,
51
52 96 and an expert consensus-building brainstorming process, ImpRes incorporates core IS
53
54 97 principles and concepts that researchers should consider when designing IS research –
55
56 98 including application of appropriate theories and/or frameworks, selection of implementation
57
58 99 and other types of outcomes, development of stakeholder informed implementation
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3 100 strategies, and evaluation of health economic elements of implementation efforts. Initial
4
5 101 usability testing with end-users (i.e., researchers with varying degrees of implementation
6
7 102 science knowledge/expertise) showed that the ImpRes tool is useful for identifying project
8
9 103 areas where implementation research is lacking and for improving the quality of
10
11 104 implementation research (15).

12
13
14 105 Whilst ImpRes has the potential to contribute to filling a much-needed capacity-building gap,
15
16 106 the need for a quantitative tool to appraise the quality of implementation research has
17
18 107 recently been highlighted as a further area for development of the field (14).

19
20
21 108 Practical tools to improve the quality of reporting have been shown to improve research
22
23 109 reporting (e.g., the development of the Consolidated Standards of Reporting Trials
24
25 110 (CONSORT) checklist, for the reporting of randomised controlled trials (RCTs), (16) (17)
26
27 111 (18). Research appraisal tools allow research stakeholders (e.g., research grant panels and
28
29 112 educators) to undertake a standardized, transparent, objective, and fair appraisal (19).

30
31
32 113 A previous attempt to use the traditional National Institutes of Health (NIH) scoring criteria to
33
34 114 evaluate grant applications for implementation and improvement sciences projects, identified
35
36 115 the need for evaluation criteria capable of identifying specific strengths and weaknesses of
37
38 116 implementation studies (14). An initial effort to address this gap has recently been reported
39
40 117 by Crable et al, 2018 who developed a scoring system, '*ImplemeNtation and Improvement*
41
42 118 *Science Proposals Evaluation CriTeria* (INSPECT)', based on Proctor's 10 key ingredients in
43
44 119 high-quality implementation research grant proposals, to identify common deficiencies in
45
46 120 implementation and improvement science research proposals from a grant application
47
48 121 perspective (14).

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52 122 Another example of prior efforts to quantify the quality of implementation research, by some
53
54 123 of the authors of this paper (CS, LG, LH), reported the initial development of a quantitative
55
56 124 appraisal tool, based on the ImpRes tool and supplementary guide (20) (21) as part of a
57
58 125 master's dissertation project. Due to time constraints and scope of the master's dissertation
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3 126 project, this initial development work focused on five of the ten ImpRes domains: 1)
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5 127 Implementation research characteristics; 2) Implementation theories, frameworks and
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7 128 models; 3) Determinants of implementation; 4) Implementation strategies; 5) Implementation
8
9 129 outcomes. These domains were considered to be most relevant and specific to
10
11 130 implementation research, whereas the other domains (e.g., service and patient outcome),
12
13 131 while still relevant to implementation research, overlap over research types (e.g.,
14
15 132 effectiveness research).

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18 133 This quantitative appraisal tool, structured as a rubric, applied analytic scoring to study
19
20 134 protocols, published in *Implementation Science*, using a 4-point scale (ranging from '1'
21
22 135 indicating that the protocol is lacking detail and of sub-optimal conceptual and
23
24 136 methodological quality, to '4' indicating that the protocol provides explicit descriptions,
25
26 137 justifications and citations from the literature and is of excellent conceptual and
27
28 138 methodological quality). Initial development included applying the appraisal criteria to 16
29
30 139 implementation research protocols, published in *Implementation Science*, where all
31
32 140 cumulative scores were expressed as a percentage of the total achievable score for that
33
34 141 protocol, to indicate and allow IS protocols to be compared based on conceptual and
35
36 142 methodological strength. The resulting Intra-class correlation coefficient (ICC) was in the
37
38 143 excellent inter-rater reliability (IRR) range: ICC: 0.85 (22).

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45 145 Here we build upon this early-phase study by Sweetnam et al, 2018 (20) (21) and report a
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47 146 study that will develop a complete and comprehensive tool to appraise the conceptual and
48
49 147 methodological quality of implementation research, termed the Implementation Science
50
51 148 Research Project Appraisal Criteria (ImpResPAC) tool. The study aims to develop appraisal
52
53 149 criteria for the remaining five ImpRes domains: 1) Service and patient outcomes; 2)
54
55 150 Unintended consequences; 3) Economic evaluation; 4) Stakeholder involvement and
56
57 151 engagement; 5) Patient and public involvement and engagement; and to refine the existing
58
59 152 criteria developed by Sweetnam et al, 2018 (20) (21).
60

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3 153 The specific objectives of the research are as follows:
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5

- 6 154 1. To formulate an ImpResPAC expert advisory group to contribute to the refinement
7
8 155 and content of ImpResPAC.
9
10 156 2. To develop a comprehensive and in-depth quantitative appraisal tool to be used by
11
12 157 implementation research funders to appraise the conceptual and methodological
13
14 158 quality of IS research: ImpResPAC.
15
16 159 3. To evaluate the psychometric properties (reliability and validity) and usability,
17
18 160 including the acceptability, feasibility, and appropriateness, of ImpResPAC.
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23
24 162 ImpResPAC will complement but extend recent efforts by Crable et al (14) who developed
25
26 163 and evaluated the 'INSPECT' tool. Whilst overlap between INSPECT and ImpResPAC will
27
28 164 exist, the two appraisal systems will differ notably in focus, depth of appraisal, and the
29
30 165 foundations upon which they are based. For example, INSPECT primarily focuses on
31
32 166 fundability because it is based on grant proposal criteria whereas ImpResPAC, based on the
33
34 167 ImpRes tool and guide, focuses on conceptual and methodological quality of implementation
35
36 168 research. Furthermore, INSPECT operationalizes the "key ingredients" to writing
37
38 169 implementation research grant proposals developed by Proctor et al. (19) which operates
39
40 170 specifically within the National Institutes of Health (NIH) proposal scoring framework (23),
41
42 171 whereas ImpResPAC will not be developed within the constraints of a single grant proposal
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44 172 scoring framework, thus its applicability will not be limited in this way.
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54 175 **Methods and analysis:**

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56 176 We will conduct a multi-stage, mixed-methods study to develop, refine, and evaluate the
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58 177 psychometric strength of ImpResPAC.
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179 Stage 1: ImpResPAC development (September 2021 – November 2021)

180 ImpResPAC will map onto the ten domains of the ImpRes tool and supplementary guide
181 (see Figure 1).

182 As part of a previous study, five of the ImpResPAC domains were developed and inter-rater
183 reliability was assessed (20). Formal quantitative psychometric testing of the content validity
184 and concurrent validity of ImpResPAC was beyond the scope of this previous work. In this
185 research, the five previously developed domains will be subject to refinement within the tool
186 development stage of this study, and the remaining five domains will be developed, by the
187 ImpResPAC development/research team.

188

189 Figure 1. ImpRes domains to be represented in ImpResPAC (15)

190

**191 Stage 2: ImpResPAC Content Validation and Refinement (December 2021 – December
192 2022)**

193 To ensure that ImpResPAC is face and content valid we will use purposive sampling to form
194 an ImpResPAC expert advisory group, consisting of a number of eminent academics across
195 the world that have made a significant contribution to the conceptual and methodological
196 advancement of one or more of the ImpResPAC domains. Experts in each domain will be
197 asked to review and provide feedback, including modifications and suggestions for
198 improvement, on the ImpResPAC domain(s) that they have expertise in.

199 We define an expert as 'someone widely recognized as a reliable source of knowledge,
200 technique, or skill whose judgment is accorded authority and status by the public or his or
201 her peers' (24). The ImpResPAC development/research team will generate a list of experts
202 that meet the above criteria, based on our collective knowledge. Once experts have agreed

1
2
3 203 to participate in the study, we will encourage them to nominate additional experts, i.e.,
4
5 204 snowballing technique, whose contribution would be valuable. Once experts agree to
6
7 205 participate, they will have the option to be recognized as a contributor in the study or for their
8
9 206 participant to remain anonymous. We expect to identify 70 - 100 experts globally in the field
10
11 207 of implementation science. We hope experts, both academics and practitioners, working in
12
13 208 high-, middle- and low-income countries will participate.
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19 210 Using surveys, the expert advisory group will review ImpResPAC domain(s) and items for
20
21 211 content, style and comprehensiveness. Members of the expert advisory group will be
22
23 212 presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC
24
25 213 domain(s) that they are an expert in, survey instructions, and survey questions. The survey
26
27 214 will be attached in an email to experts.
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29

30 215 Experts will be asked to review the overview of ImpResPAC, ImpResPAC user instructions
31
32 216 and ImpResPAC domain(s) and associated items for the domain(s) that they agree they are
33
34 217 'experts' in. Members of the expert advisory group will have 4 weeks to complete the survey.
35
36 218 A reminder email will be sent two weeks after the survey is first sent and one week before
37
38 219 the 4-week deadline.
39
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41 220 The development/research team will collate and review all comments and suggested
42
43 221 refinements to ImpResPAC and refinements will be decided via group discussions until
44
45 222 consensus is reached. Once ImpResPAC is finalized, we will quantitatively assess the
46
47 223 acceptability, appropriateness and feasibility of ImpResPAC. All members of the
48
49 224 ImpResPAC expert advisory group will be invited to review the refined version ImpResPAC
50
51 225 and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC (all
52
53 226 domains) via a follow-up survey. Experts will be given the option of providing feedback on
54
55 227 the domains that they provided feedback on in Stage 1 (survey A) or if they wish, providing
56
57 228 feedback on the entire tool. See additional file 1 for survey questions.
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6 230 **Stage 3: Application and Psychometric Evaluation of ImpResPAC (January 2023 –**
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8 231 **July 2023)**
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11 232 ImpResPAC, developed in stage 1 and content validated and refined based on expert
12
13 233 feedback in stage 2, will be applied to 50 research protocols published in *Implementation*
14
15 234 *Science* to evaluate its psychometric strength.
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18 235 Two of the study authors (CS and LH), with expertise and experience in implementation and
19
20 236 improvement science research, will independently appraise the conceptual and
21
22 237 methodological quality of the 50 most recently published research protocols published in
23
24 238 *Implementation Science*, using ImpResPAC. We decided to appraise research protocols
25
26 239 published in *Implementation Science* as it is the most well established (since 2006), highest
27
28 240 impact factor journal in the field and regarded, by researchers, practitioners and funders as a
29
30 241 key source for dissemination and implementation research in health (25). Furthermore,
31
32 242 *Implementation Science* publishes research covering a broad array of content areas and
33
34 243 settings, making it an ideal test bed for ImpResPAC.
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37 244
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40 245 *Inclusion Criteria:*
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43 246 Study protocols that describe:
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46 247 1. Effectiveness-implementation hybrid design studies (i.e., “a study design that takes a
47
48 248 dual focus in assessing clinical effectiveness and implementation”) (1).
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50 249 2. Implementation research studies (i.e., “Research focused on the adoption or uptake
51
52 250 of clinical interventions by providers and/or systems of care”) (1).
53
54 251
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56
57 252 *Exclusion criteria:*
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59 253 Study protocols/proposals that describe:
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3 254 1. Theoretical or methodological research (e.g., theory development, measurement
4 development), where implementation of an evidence-based intervention is not
5 255
6 planned
7 256
8
9 257 2. De-implementation studies of interventions found to be of low value, wasteful or
10 clinically ineffective. The field of de-implementation is expanding rapidly, and
11 258
12 although there have been recent attempts to theorise the de-implementation process
13 259
14 (26), and the field is still in infancy (27). As such consensus regarding de-
15 260
16 implementation and research guidance is lacking and further methodological
17 261
18 development is still necessary (28). For this very reason, this subsection of IS was
19 262
20 not included in the ImpRes tool and guide and will also not be included in
21 263
22 ImpResPAC.
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30 266 *Assessment of the validity and reliability of ImpResPAC*
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34 268 We will employ an item exploratory factor analysis (EFA) to the polychoric matrix of the 10
35 269 ImpResPAC domains to determine and confirm scale factor structures (construct validity). A
36 270 varimax rotation will be applied to improve the interpretability of the factors obtained. We will
37 271 use three criteria to select the final factors: i) The scree plot ii) eigenvalues >1 and iii) >90%
38 272 of total variance explained by the factors. ImpResPAC will be applied to 50 protocols for
39 273 pragmatic reasons, as this equates to the minimum number of observations (50), required
40 274 when conducting EFA (29).
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51 276 Convergent validity will be further examined by estimating the correlation between the global
52 277 ImpResPAC dimension with the global scores of INSPECT (14) as both scoring criteria rate
53 278 the quality of proposed implementation science research. Spearman's correlation
54 279 coefficients will be calculated and interpreted as follows: >0.90: excellent relationship, 0.71-
55 280 0.90: good, 0.51-0.70: fair, 0.31-0.50: weak, and <0.30: none (30).
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5 282 We are expecting fair to good correlations, as excellent correlations would indicate that
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7 283 ImpResPAC is a duplication of INSPECT. A comparison of ImpResPAC and INSPECT
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9 284 domains, presented in supplementary material indicates clear similarities between a number
10
11 285 of domains (e.g., 'Theories, frameworks and models' domain of ImpResPAC and
12
13 286 'Conceptual model and theoretical justification' element of INSPECT), a degree of similarities
14
15 287 between some domains (e.g., Determinants of implementation: contextual factors' domain of
16
17 288 ImpResPAC and 'Feasibility of proposed research design and methods' element of
18
19 289 INSPECT), and no apparent similarities between some domains (e.g., 'Patient and Public
20
21 290 Involvement' domain of ImpResPAC, which has no similarities to INSPECT elements).
22
23 291 Given the varying degrees of content overlap between ImpResPAC and INSPECT domains,
24
25 292 as described in detail above, we hypothesize that there will be a fair to good relationship
26
27 293 (correlation coefficient r : 0.31-0.70) between global ImpResPAC and INSPECT scores.
28
29 294
30
31 295 Cronbach's alpha coefficient will be used to evaluate the reliability (internal consistency) of
32
33 296 the ten domains of ImpResPAC, as it evaluates the extent to which the domains within a
34
35 297 scale are inter-correlated with one another and thus seem to measure the same concept. It's
36
37 298 value ranges from 0 to 1 and internal consistency is suggested to be acceptable when
38
39 299 Cronbach's alpha is at least 0.70 (30). Inter-rater reliability will be assessed using Criterion
40
41 300 of Lin's $\rho \geq 0.70$ to indicate acceptable reliability. A weighted kappa score will also be
42
43 301 calculated for each ImpResPAC domain to provide details on the test-retest and inter-rater
44
45 302 reliability. A criterion of weighted kappa ≥ 0.40 will be used to indicate acceptable domain
46
47 303 level reliability. Precision will be assessed to test how well each domain fits within its
48
49 304 proposed scale (30). Corrected domain-total correlations of < 30 will indicate poor fit of items
50
51 305 within the ImpResPAC total score (30). Each ImpResPAC item will be correlated both with
52
53 306 its own global domain score total and with the other global domain totals. Each component
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3 307 will require higher correlation with its own domain than other ImpResPAC domains to
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5 308 demonstrate precision.
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11 310 **Patient and Public Involvement:**
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13 311 Patients or the public were not involved in the design, conduct or reporting plans of this
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15 312 research.
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21 314 **Discussion**
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23
24 315 This study will develop, refine, content validate, and evaluate the psychometric strength (i.e.,
25
26 316 the reliability and validity) of an expert derived tool, ImpResPAC, to appraise the conceptual
27
28 317 and methodological quality of implementation research. The proposed research will fill an
29
30 318 important gap in our ability, as a field, to conduct a comprehensive, transparent, systematic
31
32 319 and in-depth quantitative appraisal of implementation research. Purposively sampling
33
34 320 experts to form an international ImpResPAC expert advisory group to refine and content
35
36 321 validate ImpResPAC, will ensure appropriate appraisal criteria, relevant to the conceptual
37
38 322 and methodological quality of implementation research, is developed, which will allow an in-
39
40 323 depth, comprehensive appraisal of implementation research. Feedback on the acceptability,
41
42 324 feasibility and appropriateness of ImpResPAC will also be sought from the ImpResPAC
43
44 325 expert advisory group.
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50 327 Previous research suggests that researchers seeking to design implementation research find
51
52 328 it challenging to distinguish between implementation research and efficacy and effectiveness
53
54 329 research and consequently fail to design high-quality implementation research (4). With the
55
56 330 availability of the ImpRes tool and supplementary guide, consolidating methodological
57
58 331 guidelines and recommendations, researchers, practitioners and students are better
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1
2
3 332 equipped to design high-quality implementation research proposals. We envisage
4
5 333 ImpResPAC primarily being used by funding bodies as a standardized and transparent
6
7 334 method to differentiate high and low-quality implementation research and identify areas for
8
9 335 improvement before funding decisions are made. In addition, we also envisage that
10
11 336 ImpResPAC will be useful to educators that are tasked with appraising implementation
12
13 337 projects submitted by students/learners, especially in educational settings where the ImpRes
14
15 338 tool and guide informed the curriculum. We plan to explore whether another potential
16
17 339 application of ImpResPAC would be for implementation researchers, practitioners and
18
19 340 students/learners to use ImpResPAC as a quality assurance step, to self-assess a funding
20
21 341 application or implementation project, prior to submission.
22
23

24
25 342 Although INSPECT already exists as a standardized appraisal tool for implementation
26
27 343 research proposals, we plan to develop a complementary, yet conceptually distinct tool that
28
29 344 focuses exclusively on conceptual and methodological quality of IS research proposals. As
30
31 345 such, ImpResPAC scoring domains will differ to INSPECT domains, as highlighted in
32
33 346 supplementary material (additional file 2). For example, *team experience with setting,*
34
35 347 *treatment, and implementation process* is one of the ten elements of the INSPECT tool,
36
37 348 however the ImpRes tool and supplementary guide, and consequently ImpResPAC, will not
38
39 349 contain criteria measuring this domain as team experience is not a direct measure of
40
41 350 conceptual or methodological quality of IS research. Similarly, ImpResPAC will contain
42
43 351 criteria that INSPECT does not explicitly appraise. For example, ImpResPAC will appraise
44
45 352 whether research teams plan to evaluate unintended consequences of implementation in
46
47 353 addition to exploring and quantifying the anticipated benefits of implementation.
48
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50 354 Furthermore, the level of detail at which implementation research will be appraised using the
51
52 355 two scoring systems will differ substantially. For example, INSPECT provides an overall
53
54 356 appraisal of the *measurement and analysis* of IS research proposals, however the ImpRes
55
56 357 guide, and consequently ImpResPAC, will contain three domains relating to measurement
57
58 358 and analysis; 1) service and patient outcomes; 2) implementation outcomes; and 3)
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3 359 economic evaluation, providing a much more detailed and focused appraisal of the
4
5 360 outcomes typically assessed in implementation research. The initial mapping of the ImpRes
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7 361 tool and supplementation guide to develop the ImpResPAC tool (stage 1) and a detailed
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9 362 comparison of ImpResPAC tool domain items (initial mapping) and the INSPECT tool
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11 363 element items can be found in supplementary material (additional file 2).

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17 365 INSPECT operationalized grant proposal criteria proposed by Proctor's et al 'key
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19 366 ingredients', which were developed nearly a decade ago (i.e., 2012) (19), whereas
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21 367 ImpResPAC will identify conceptual and methodological strengths and weakness in IS
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23 368 projects taking account of the conceptual and methodological developments that have taken
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25 369 place in more recent years. As such, ImpResPAC will include and operationalize key
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27 370 methodological guidelines and recommendations that simply did not exist nearly a decade
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29 371 ago (1) (8) (10) (31) (32) (33) (34) (35) (36) (37). ImpResPAC will operationalize, for
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31 372 example, the key methodological and conceptual guidelines and recommendations that have
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33 373 been described in the ImpRes tool and guide, as well as guidelines suggested by our
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35 374 international expert advisory panel, and key literature published since the development of
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37 375 the ImpRes tool and guide.

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44 377 This study has a number of limitations. We acknowledge the importance of public and
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46 378 patient involvement in the design of implementation research, but the study we report here is
47
48 379 not funded and did not have the funds to involve patient and the public in the research. We
49
50 380 strongly recommend that any future ImpResPAC research, including further validation and
51
52 381 utilisation, includes patient and public involvement. Secondly, we acknowledge that in order
53
54 382 to truly test the value of ImpResPAC, it will be preferable to seek feedback from
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56 383 implementation research stakeholders who have had the opportunity to apply the tool in
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58 384 practice, but this is beyond the scope of this research. Future studies should evaluate the

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3 385 value of ImpResPAC with implementation research stakeholders that have applied the tool.
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5 386 Thirdly, our definition of 'experts' (someone widely recognized as a reliable source of
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7 387 knowledge, technique, or skill whose judgment is accorded authority and status by the public
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9 388 or his or her peers) could exclude useful perspectives of stakeholder groups. Lastly,
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11 389 although the implementation research protocols that will be appraised, using ImpResPAC,
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13 390 will cover a broad range of content areas and settings, appraising protocols published in
14
15 391 *Implementation Science*, is likely to positively skew the results (i.e., it is fair to assume that
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17 392 only high-quality IS protocols will have been published in *Implementation Science*). This is a
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19 393 specific and inherent challenge with the planned research, as access to implementation
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21 394 research protocols rejected from journals and unsuccessful grant proposals submitted to
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23 395 funding bodies are not publicly available and unattainable for obvious reasons.
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30 397 High-quality implementation research is key to advancing the field and improving the
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32 398 adoption, implementation, sustainment and scale-up of evidence-based interventions. This
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34 399 research will advance the field by developing a quantitative appraisal tool, which we believe
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36 400 will be of immediate use and value to IS research stakeholders (e.g., grant reviewers and
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38 401 educators), to undertake a comprehensive, transparent and fair appraisal of the conceptual
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40 402 and methodological quality of implementation research.
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45 405 **Ethics and dissemination:**

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49 406 This study will involve human participants. This study has been registered and minimal risk
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51 407 ethical clearance granted by, The Research Ethics Office, King's College London (Reference
52
53 408 number MRA-20/21-20807). Participants will receive written information on the study via
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55 409 email and will provide e-consent if they wish to participate. We will use traditional academic
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57 410 modalities of dissemination (e.g., conferences, publications).
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56 412 **Authors' contributions:**
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9 413 CS and LH initially conceptualized and designed this study. IB made significant contribution
10 414 to the design of the psychometric evaluation section. NS, LG, RD, ZK, AB and AH all made
11 415 significant contributions to the framing, editing, revisions, and content of the manuscript. All
12 416 authors read and approved the final manuscript.

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5556 434 **Competing interests statement:**
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3 435 NS is the director of the London Safety and Training Solutions Ltd, which offers training in
4
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6
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16 440 3836 words (excluding title page, abstract, references, tables or acknowledgements)
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21
22 442 **List of abbreviations**

23
24
25 443 **EFA:** Exploratory Factor Analysis

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27 444 **ICC:** Intra-class Correlation Coefficient

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30 445 **ImpRes:** Implementation Science Research development

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33 446 **ImpResPAC:** Implementation Science Research Project Appraisal Criteria

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36 447 **INSPECT:** ImplemeNtation and Improvement Science Proposals Evaluation CriTeria

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39 448 **IRR:** Inter-Rater Reliability

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42 449 **IS:** Implementation Science

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44 450 **NIH:** National Institutes of Health
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54 476 Ioannis Bakolis
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58 478 **Additional Files**
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3 479 Additional file 1: ImpResPAC Survey Questions (Stage 2: ImpResPAC Content Validation
4 and Refinement Expert Advisory Group Survey Questions)
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7 481 Additional file 2: Comparison of ImpResPAC tool (initial version developed in stage 1) and
8 the INSPECT tool.
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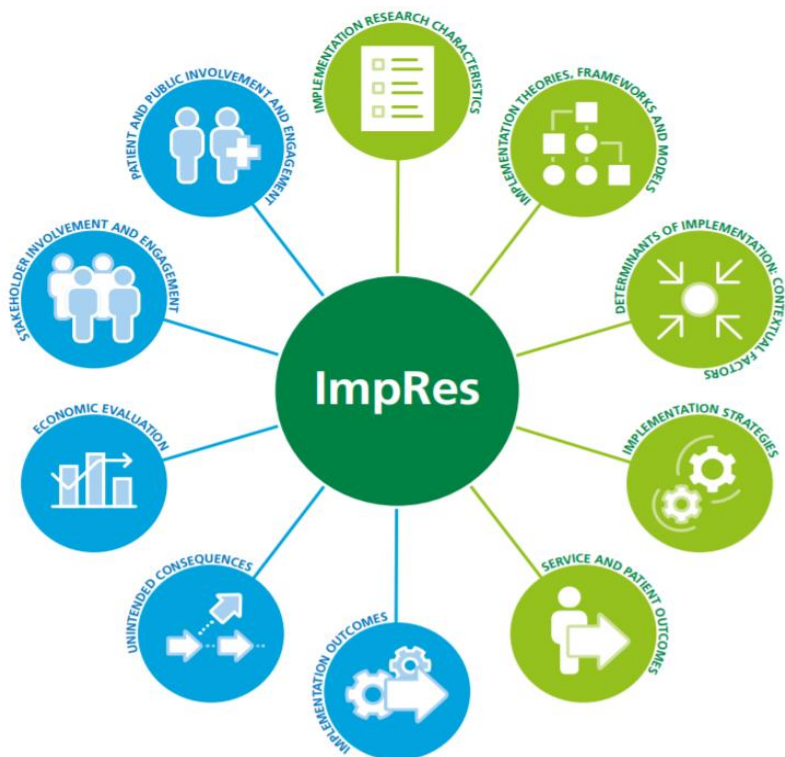
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Figure 1. ImpRes domains to be represented in ImpResPAC (15)



Review only

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Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Each member of the expert advisory group will be presented with an overview of ImpResPAC, ImpResPAC user instructions, the ImpResPAC domain(s) that they are an expert in, survey instructions, and survey questions.

Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool.

The development/research team will collate and review all comments and suggested refinements to ImpResPAC and refinements will be decided via group discussions until consensus is reached. Once ImpResPAC is finalized, each member of the expert advisory group will be sent a survey and asked to review the refined version ImpResPAC and provide feedback on the acceptability, appropriateness and feasibility of ImpResPAC.

Part A: Survey to review ImpResPAC domains and items for content, style and comprehensiveness.

Based on the significant contribution you have made to the conceptual and methodological advancement of implementation research, in particular relating to the characteristics of implementation research, we would like your feedback on the ***Implementation Research Characteristics*** domain of ImpResPAC.

We would also like your feedback on the ***Unintended Consequences*** domain of ImpResPAC. Although a separate domain, it is very much linked to design of implementation research and the ***Implementation Research Characteristics*** domain. If, after reviewing the ***Unintended Consequences*** domain, you feel that you don't have the expertise to provide feedback, you can choose to provide feedback on the Implementation Research Characteristics domain only.

ImpResPAC contains 10 domains representing core implementation science principles and concepts, including:

- (1) Implementation Research Characteristics
- (2) Implementation Theories, Frameworks and Models
- (3) Determinants of Implementation: Contextual Factors
- (4) Implementation Strategies
- (5) Service and Patient Outcomes
- (6) Implementation Outcomes
- (7) Unintended Consequences
- (8) Economic Evaluation
- (9) Stakeholder Involvement and Engagement
- (10) Patient and Public Involvement and Engagement.

We appreciate that you may have expertise relating to other ImpResPAC domains, if you believe that you have expertise relating to any other ImpResPAC domain(s), please let us know and we will share these with you to enable you to provide feedback on these ImpResPAC domains.

Survey instructions

We would like you to review and provide feedback, including modifications and suggestions for improvement, on the 'Implementation Research Characteristics' ImpResPAC domain and associated items, presented in the table below. Following review of the domain items, you will then be asked to complete 5 questions regarding domain content, style and comprehensiveness. You will also be asked to

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provide feedback relating to the scoring scale and anchors and user instructions. We request your comments and suggestions for improvements to be made using the comment and track changes functions in word.

Overview of ImpResPAC

ImpResPAC aims to be a comprehensive and in-depth quantitative appraisal tool to evaluate the conceptual and methodological quality of implementation research. ImpResPAC contains 10 domains representing core implementation science principles and concepts (detailed above). For each domain, we have identified a number of items that we believe indicate high-quality implementation research.

We hope that ImpResPAC will advance the field of implementation science by providing a quantitative appraisal tool that can be used by a wide range of implementation research stakeholders, primarily grant reviewers and educators working within the field, to comprehensively appraise the conceptual and methodological quality of implementation research.

ImpResPAC user instructions

The ImpResPAC tool contains 10 domains representing core implementation science principles and concepts. Each domain contains a number of items that are indicative of high-quality implementation research. Each ImpResPAC domain, and associated items, should be considered in the context of the aims and objectives, scope and resources of the research project in question. As such, it is possible that one or more ImpResPAC domains, and associated items, will not be applicable. You are not expected to score each item within each domain, rather a single score for each applicable ImpResPAC domain should be provided.

For each applicable domain, the scores should be added together, to calculate a global score indicating the conceptual and methodological quality of the implementation project. For example, if 7 ImpResPAC domains are applicable, the global score would be out of a maximum score of 35 (7 domains x maximum domain score of 5 = 35).

Please note you are not expected to provide a score as part of completing this survey

Domain scoring scale and anchors

1 = Very poor: Proposed project fails to adequately address all items

2 = Poor: Proposed project fails to adequately address most items

3 = Satisfactory: Proposed project addresses some items adequately

4 = Good: Proposed project addresses most items adequately/fully

5 = Excellent: Proposed project fully addresses all items

N/A = domain considered not applicable given the aims, objectives, scope and resources of the project.

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Part A: Survey questions

1. (a) Do the domain items represent and reflect high-quality conceptual and methodological elements of implementation research characteristics? Yes/no
(b) If no, please use track changes in the table above to provide amendments/suggestions for improvement.
2. (a) Are there any items missing from the domain? Yes/no
(b) If yes, please use track changes in the table above to suggest additional items for inclusion.
3. (a) Is the item wording clear? Yes/no
(b) If no, please use track changes in the table above to suggest amendments/improvements.
4. (a) Are the ImpResPAC user instructions (p.2) adequate and clear?
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.
5. (a) Is the scoring scale and associated anchors (p.2) appropriate and clear? Yes/no
(b) If no, please provide your reasoning below and use track changes to suggest amendments/improvements.

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Part B: Survey to assess for acceptability, appropriateness and feasibility of the refined version of the ImpResPAC tool

Thank you for your initial feedback on Implementation Science Research Project Appraisal Criteria (ImpResPAC) tool. After careful consideration of the feedback received from the expert advisory group, the ImpResPAC research/development group have refined the ImpResPAC tool.

On a scale of 1 – 5 please rate your level of agreement with the following statements on the acceptability, appropriateness and feasibility of the ImpResPAC tool.

Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory (Proctor et al, 2011). With this definition in mind, please rate the acceptability of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(i) The ImpResPAC Tool Acceptability						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an acceptable tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an acceptable tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an acceptable tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an acceptable tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising						

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implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not acceptable for use for this purpose.

Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem (Proctor et al, 2011). With this definition in mind, please rate the appropriateness of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(ii) The ImpResPAC Tool Appropriateness						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is an appropriate tool to be used in the appraisal of grant applications.						
b) ImpResPAC is an appropriate tool for researchers, to appraise the methodological and conceptual quality of their research.						
c) ImpResPAC is an appropriate tool for practitioners, to appraise the methodological and conceptual quality of their project.						
d) ImpResPAC is an appropriate tool to be used for educational purposes e.g.,						

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incorporating into training materials or quantitatively appraising implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not appropriate for use for this purpose.

Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting (Proctor et al, 2011). With this definition in mind, please rate the feasibility of the ImpResPAC tool, to assess the conceptual and methodological quality of implementation science research, for this purpose.

(iii) The ImpResPAC Tool Feasibility						
	1	2	3	4	5	6
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I do not feel able to answer this due to lack of knowledge and/or experience in this area.
a) ImpResPAC is a feasible tool to be used in the appraisal of grant applications.						
b) ImpResPAC is a feasible tool for researchers, to appraise the methodological and conceptual quality of their research						
c) ImpResPAC is a feasible tool for practitioners, to appraise the methodological and conceptual quality of their project.						

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d) ImpResPAC is a feasible tool to be used for educational purposes e.g., incorporating into training materials or quantitatively appraising implementation projects.						
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Optional: If you rated 4 or 5 for questions (a) – (d), please explain why the ImpResPAC tool is not feasible for use for this purpose.

Do you have any additional comments you will like to make about ImpResPAC?

ImpResPAC stage 1 Results: Initial mapping of ImpRes tool and guide to develop ImpResPAC, compared with INSPECT element items

- Below is a comparison of ImpResPAC domain items and INSPECT element items.
- Rows with bolded font, have some level of overlap (high, medium or low).
- Rows with non-bolded font and grey cells in one column have no overlap between tools.
- **Key:**
 - **High level of overlap:** the ImpResPAC domain items overlap directly with the INSPECT element item, covering the same principles.
 - **Medium level of overlap:** the ImpResPAC domain item covers a similar principle as the INSPECT element item, but not the same.
 - **Low level of overlap:** the ImpResPAC domain items does not directly overlap with the INSPECT element item, but the domain and element has principles in common.

Additional File 2: ImpResPAC and INSPECT comparison (initial mapping completed as stage 1 of the study)

<i>ImpResPAC (initial mapping)</i>		<i>INSPECT (14)</i>		<i>Level of overlap:</i>
Domain:	Item wording (score of 5 – given if the proposed project fully addresses all items):	Element:	Item wording (score of 3 – highest score available, given for an element if all of the criteria requirements are met):	
Implementation research characteristics	The project explicitly seeks to address an implementation problem; it clearly describes the associated quality of care gap and evidence-based intervention identified to address the problem.	The care or quality gap	Explicit, well thought out description of the potential for improvement.	High
Implementation research characteristics	Clear, detailed, and strong justification provided to support the proposed project, supported by appropriate literature, and/or local data. If literature has been used to support the proposed project, this is up-to-date and has been critically appraised.	The care or quality gap	Clearly defined quality gap is supported by local setting data (i.e., evidence of chart review or other preliminary data) and appropriate citations from the literature.	High
		The care or quality gap	Proposed implementation and/or improvement study is clearly linked to a safety net setting.	None
Implementation research characteristics	Implementation aims and objectives are explicitly and clearly articulated and align with the proposed project design, methods, and measures.			None

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3	Implementation research characteristics	Implementation stage(s) of the proposed project and the associated activities planned at each stage are described in detail.		None
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6	Implementation research characteristics	Design of the proposed project is clearly and comprehensively described and positioned along the effectiveness-implementation research continuum (e.g., hybrid type 1, 2, 3, or pure implementation) and aligns appropriately to the aims and objectives of the project.		None
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11	Implementation research characteristics	Clear rationale is provided for choice of research design supported by literature and/or local data (e.g., hybrid type 1 design will provide data justifying that the clinical intervention has strong face validity supporting applicability in a new setting, population, or delivery method).	Feasibility of proposed research design and methods	The proposed study includes appropriate methods, interventions, and other components that are achievable as a pilot study and are justified against potential alternatives.
12				Low
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18	Theories, Frameworks, Models Domain	Clear, detailed, and strong justification is provided to support the selection of implementation theories, models and/or frameworks (framework hereafter), supported by appropriate literature, and/or data from implementation site(s)	Conceptual model and theoretical justification	An implementation and/or improvement science-specific conceptual model or framework is clearly described, with theoretical constructions explicitly described within the proposed setting, population, and intervention contexts.
19				High
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22	Theories, Frameworks, Models Domain	The chosen implementation framework(s) inform and structure all aspects of the proposed project (i.e., project design, aims and objectives, data collection, including measures, and data analysis, where relevant).	Conceptual model and theoretical justification	The implementation and/or improvement science-specific conceptual model or framework is used to frame the proposed study in all aspects including the study questions, aims/objectives, hypotheses, process, and outcome measures.
23				High
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26			Conceptual model and theoretical justification	Some discussion may refer and describe how study findings would build upon or otherwise contribute to theory or the larger implementation and/or improvement science fields.
27				None
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30	Theories, Frameworks, Models Domain	Constructs/elements/domains of implementation framework(s) are measured using psychometrically robust and/or pragmatic instruments.		None
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33	Theories, Frameworks, Models Domain	If frameworks are applied pragmatically (i.e., not in its entirety), clear and strong justification is provided.		None
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37	Theories, Frameworks, Models Domain	Proposed adaptations (above and beyond pragmatic application) to chosen frameworks are clearly and comprehensively described and strong justification is provided.		None
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Theories, Frameworks, Models Domain	If more than one framework is proposed, the unique contribution of each is described.			None
Determinants of implementation: contextual factors	The project aims to prospectively identify factors likely to hinder or facilitate implementation efforts.			None
Determinants of implementation: contextual factors	Detailed and strong justification is provided to support the identification and selection of the chosen implementation framework, supported by appropriate literature.			None
Determinants of implementation: contextual factors	Clear and detailed description and justification is provided of suggested adaptations to the intervention and/or implementation strategy (if applicable). Adaptations are based on implementation determinants and maintain the core features of the intervention.			None
Determinants of implementation: contextual factors	Clear and detailed description of how implementation determinants will be identified.	Feasibility of proposed research design and methods	Potential barriers to implementation are clearly identified with potential plans to overcome those barriers.	High
Determinants of implementation: contextual factors	An appropriate theory, framework, or model (framework hereafter) has been selected to identify and understand the factors affecting implementation success or failure.			Medium
Determinants of implementation: contextual factors	The project aims to prospectively identify factors likely to hinder or facilitate implementation efforts.	Feasibility of proposed research design and methods	Explicitly describes preliminary data on the assessed organizational and political capacity and readiness for implementation (assessment completed prior to application/pilot).	Low
Determinants of implementation: contextual factors	Clear and detailed description of how implementation determinants will be identified.	Feasibility of proposed research design and methods	Preliminary capacity and readiness assessments were completed using a scale with established validity and reliability, or a scale that has undergone some validity and reliability testing.	Low
			May include strategies for how those opposed to change in the study setting will be involved with or have their concerns addressed by study processes or components.	None

1				Evidence of support (e.g., letters from the study setting that address how the proposed study aligns with the organization's priorities/policies).	None
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7	Implementation Strategies	Implementation strategies are described in sufficient detail to allow replication.	Implementation strategy/process	Explicitly describes how implementation strategies will be observed or empirically tested.	Medium
8	Implementation Strategies	Implementation strategies will be (or have been) selected and tailored to overcome identified barriers to implementation and/or harness identified facilitators.			None
9	Implementation Strategies	Clear description of the methods used to select implementation strategies.			None
10	Implementation Strategies	Explicitly states the implementation outcome(s) that are targeted for improvement by the implementation strategy.			None
11	Implementation Strategies	Implementation strategy selection is theoretically and/or empirically justified, supported by relevant literature.	Implementation strategy/process	Explicitly describes and theoretically justifies the implementation strategies.	High
12	Implementation Strategies	Intention to involve patients and the public in the identification and selection of implementation strategies.			None
13	Implementation Strategies	Intention to involve stakeholders in the identification and selection of implementation strategies.			None
14			Implementation strategy/process	Explicitly describes how implementation strategies link to the stated aims/setting/outcome measures of the proposed study.	None
15			Implementation strategy/process	Implementation strategies are feasible given the pilot study timeline and budget constraints.	None
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17	Service and Patient Outcomes	The degree of focus placed on measuring service and/or patient outcomes is guided by the strength of the evidence for the intervention in question.			None
18	Service and Patient Outcomes	Explicit alignment between service and/or patient outcomes to be collected and the proposed project aims and objectives.			None
19	Service and Patient Outcomes	Clear and explicit evidence that stakeholders were involved or will be involved in the selection of service and/or patient outcomes to be evaluated.			None
20	Service and Patient Outcomes	Explicit awareness that service and/or patient outcomes are not sufficient for understanding implementation success or failure.			None
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Service and Patient Outcomes	A clear and detailed description of service and/or patient outcome data analysis plan is presented and is linked to implementation outcome data analysis plans.			<i>None</i>
Implementation outcomes	The proposed project includes the evaluation of implementation outcome(s).	Measurement and analysis section	Outcomes described are implementation and/or improvement science-related.	High
Implementation outcomes	The implementation outcomes of interest align with the project aims and objectives.	Measurement and analysis section	Outcomes are clearly linked to the proposed study aims.	High
Implementation outcomes	Where quantitative implementation outcome instrument(s) are proposed to be used to assess implementation outcome(s), evidence of its psychometric strength is provided.	Measurement and analysis section	Measurement and data analytic plans robustly describe how all variables and outcomes will be measured and are appropriate for the proposed study through clear theoretical justification.	High
Implementation outcomes	Clear and explicit evidence that stakeholders were involved, or will be involved, in the identification and selection of relevant and important implementation outcomes to be evaluated.			<i>None</i>
Implementation outcomes	Clear and explicit evidence that patients/public were involved, or will be involved, in the identification selection of relevant and important implementation outcomes to be evaluated.			<i>None</i>
Implementation outcomes	The measurement method, unit of analysis and time point(s) of implementation outcome data collection are appropriate for the proposed project's aims and objectives.	Measurement and analysis section	The unit of analysis is appropriate for the proposed study.	High
Implementation outcomes	A clear and detailed description of implementation outcome data analysis plan is presented and is linked to service and patient outcomes data analysis, if applicable.			<i>None</i>
Unintended Consequences	Discussion of the intention to explore unintended consequences (including unexpected benefits, unexpected drawbacks and perverse results) that might occur as a result of implementation efforts.			<i>None</i>
	Project is designed to allow for the identification and effective management of unintended consequences.			<i>None</i>
Economic Evaluation	The type of economic evaluation and the economic project question has been clearly articulated.			<i>None</i>

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Economic Evaluation	The perspective of the economic evaluation is clearly stated and justified in relation to the context of the research and the time horizon over which resource impacts and patient/population outcomes are to be evaluated is clearly indicated.			None
Economic Evaluation	There is a clear statement of how patient/population health outcomes are to be quantified.			None
Economic Evaluation	The approach to measurement of resource use (including resources used in implementation) and to costing resource use is clearly stated, including data sources.	Feasibility of proposed research design and methods	The budget and timeline are appropriate.	Low
Economic Evaluation	The methodological approach to evaluation and the approach to measurement of resource use (including resources used in implementation) and to costing resource use (including data sources) is clearly stated.			None
Economic Evaluation	The approach to sensitivity analysis to evaluate the robustness of conclusions to uncertainty around the value of key implementation, clinical, epidemiological and economic parameters is indicated.			None
Economic Evaluation	Clear and explicit recognition of implementation strategy cost during implementation phase and beyond initial implementation phase (scale up phase).			None
Stakeholder Involvement and Engagement		Stakeholder priorities, engagement in change	Comprehensive description of who all of the identifiable stakeholders are.	None
Stakeholder Involvement and Engagement		Stakeholder priorities, engagement in change	Clear understanding of stakeholder concerns related to the intervention as evidenced by a stakeholder analysis plan that describes how the applicant will collect comprehensive information on stakeholders' interests, interrelations, influences, preferences, and priorities.	None
Stakeholder Involvement and Engagement	Evidence that stakeholders were engaged and/or involved in developing the project proposal and are part of the research team.	Stakeholder priorities, engagement in change	Detailed description of how stakeholders were involved in the conceptual design of the intervention and in considering the implementation strategies, process, and outcomes.	High

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Stakeholder Involvement and Engagement	Clear and explicit evidence of intention to engage and/or involve stakeholders in all relevant later stages of the project.			<i>None</i>
Stakeholder Involvement and Engagement	Clear and explicit rationale/purpose of engagement and/or involvement provided.			<i>None</i>
Stakeholder Involvement and Engagement	Informed by stakeholder preferences and priorities, the project proposes to be a partnership between researchers and relevant stakeholder(s) based upon shared power.	Stakeholder priorities, engagement in change	An explicit agreement (such as memorandum of understanding) or evidence of collaboration between the stakeholders and the applicant that is explained with relevance to the proposed study process and how findings will be communicated.	Medium
Stakeholder Involvement and Engagement	Engagement and/or involvement methods are well described and appropriate.			<i>None</i>
Patient and Public Involvement	Evidence that patient, service users and the public were engaged and/or involved in developing the project proposal and are part of the research team.			<i>None</i>
Patient and Public Involvement	Clear and explicit evidence of intention to engage and/or involve patient, service users and the public in all relevant later stages of the project.			<i>None</i>
Patient and Public Involvement	Clear and explicit rationale/purpose of engagement and/or involvement provided.			<i>None</i>
Patient and Public Involvement	Informed by patient, service users and the public preferences and priorities, the project proposes to be a partnership between researchers and relevant patient, service users and the public based upon shared power.			<i>None</i>
Patient and Public Involvement	Engagement and/or involvement methods are well described and appropriate.			<i>None</i>
		Team experience with setting, treatment, and implementation process	Clearly describes how team experience relates to the study setting, treatment, and processes.	<i>None</i>

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		Team experience with setting, treatment, and implementation process	Team description, biographical sketches, resumes/CVs depict a multidisciplinary skillset relevant to the proposed study setting, treatment, processes, and other needs.	<i>None</i>
		Team experience with setting, treatment, and implementation process	Staffing plan facilitates successful study completion without necessitating CIIS support.	<i>None</i>
		Team experience with setting, treatment, and implementation process	Clearly describes strengths of the research environment including resources and infrastructure.	<i>None</i>
		Team experience with setting, treatment, and implementation process	If principal investigator is considered junior or early career or novice to implementation science, senior leadership outside of CIIS has been identified to support study completion with mentoring and/or consultation.	<i>None</i>
		Policy/funding environment; leverage of support for sustaining change	The internal/external policy trends and/or funding environment are clearly described.	<i>None</i>
		Policy/funding environment; leverage of support for sustaining change	Potential impact of the intervention is explicitly linked to relevant policies and funding issues associated with a safety net setting.	<i>None</i>

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		Policy/funding environment; leverage of support for sustaining change	The dissemination plan for study findings indicates what and how a contribution will be made to the broader policy level and safety net setting.	<i>None</i>
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For peer review only