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Will it work here? A realist approach to local decisions about implementing interventions evaluated as effective elsewhere

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3 **Will it work here? A realist approach to local decisions about implementing interventions**
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5 **evaluated as effective elsewhere**
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Keywords: generalisability; transferability; transportability; need assessment; evaluation

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3 **Will it work here? A realist approach to local decisions about implementing interventions**
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10 **Abstract**
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14 There is increasing interest in what evidence is needed to inform decisions about transporting
15 interventions evaluated as effective to new settings. There has been less attention to how local
16 decision-makers decide whether to implement such interventions immediately or subject to further
17 evaluation. Using the example of school-based social and emotional learning, we consider this
18 drawing on realist methods. We suggest decisions need to assess existing evaluations not merely in
19 terms of whether the intervention was effective but also: how the intervention was implemented
20 and what contextual factors affected this (drawing on process evaluation); and for whom the
21 intervention was effective and through what mechanisms (drawing on mediation, moderation and
22 qualitative comparative analyses from primary studies and/or systematic reviews). We contribute
23 new insights to local needs assessments, suggesting that these should assess: the potential,
24 capability, contribution and capacity present in the new setting for implementation; and whether
25 similar 'aetiological mechanisms' underlie adverse outcomes locally as in previous evaluations. We
26 recommend that where there is uncertainty concerning whether an intervention can feasibly be
27 implemented this indicates the need for piloting of implementation. Where there is uncertainty
28 concerning whether implementation of the intervention will trigger intended mechanisms, this
29 suggests the need for a new effectiveness trial. Where there is uncertainty concerning whether
30 intervention mechanisms, even if triggered, will generate the intended outcomes, this suggests that
31 decision-makers may need to look to other types of intervention as being needed for their setting
32 instead.
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59 **239 words**
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What is already known on this topic?

- There is increasing interest in what evidence is needed to inform decisions about transferring interventions evaluated as effective to new settings.
- Existing work suggests the importance of considering the importance of context and implementation when evaluating interventions to inform assessments of intervention transfer.

What does this paper add to the literature?

- There has been less attention to how local decision-makers decide whether to implement such interventions immediately or subject to further evaluation.
- We contribute new insights concerning the contents of local needs assessments, suggesting that these should assess: the potential, capability, contribution and capacity present in the new setting for implementation; and whether similar 'aetiological mechanisms' underlie adverse outcomes locally as in previous evaluations.

Will it work here? A realist approach for local decisions about implementing interventions evaluated as effective elsewhere

Introduction

Complex interventions (those with multiple elements that interact with each other and/or with context¹) should be evaluated not merely in terms of whether they are effective in one setting but also whether they might be successfully transported to other contexts.² There is increasing interest in what evidence evaluations need to generate, and systematic reviews need to synthesise, to inform such decisions.³⁻⁷ It is only recently that there has been attention to how local decision-makers decide whether interventions evaluated as effective elsewhere will be suitable for their setting.⁸ For example, Escoffery et al highlighted the importance of assessing risk behaviours and determinants in the new setting and identifying suitable interventions which align with these.⁹ Movsisyan et al highlighted the importance of assessing evidence for the effectiveness of candidate interventions across contexts, as well as likely capacity and feasibility in the new context.¹⁰ However, existing literature does not detail the information that is required to determine which interventions best fit with a setting in terms of capacity for implementation and scope for effectiveness. Nor do they consider in detail how the theorised mechanisms of an existing intervention need to be assessed to determine its potential in a new context.

There has been still less attention to the question of what further piloting and evaluation is required when interventions are transferred to new settings. Aarons et al argue for 'borrowing strength' from evidence from earlier outcome evaluations to allow for evaluation in a new setting to focus on process rather than outcomes, but do not provide detail of how such decisions can be made beyond assessment of similarity of population and intervention mechanisms in the new context.¹¹ We describe an approach to considering these questions, drawing on realist approaches to evaluation,

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3 and suggesting what sorts of evidence and information local decision-makers need to draw on.³ Our
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5 focus in this paper is about how local decision-making can assess the potential of interventions
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7 evaluated elsewhere for working in their settings, rather than how such interventions might then
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9 need to be adapted.
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14 Deciding whether to move to full implementation or first undertake piloting and evaluation has
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16 important consequences. Opting for further piloting and evaluation when an intervention is already
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18 'good to go' would waste time and money on unnecessary evaluation that adds little to the evidence
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20 base. Potential beneficiaries who find themselves in control groups or outside of studies would be
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22 denied effective intervention. For example, parenting interventions generate important benefits for
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24 parents and children across settings and may not need extensive piloting when transferred to new
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26 settings.¹² However, opting for immediate implementation of an intervention which is not fit for
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28 local purpose would also waste time and money, and could harm participants directly or by
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30 displacing more effective interventions.¹³ For example, after-school activities aiming to prevent
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32 teenage pregnancy have been found to be effective in some settings, ineffective in others and
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34 harmful in some.¹⁴⁻¹⁶
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41 The key concept is 'equipoise', usually defined as uncertainty regarding benefits.¹⁷ In the context of a
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43 previously evaluated intervention being considered for implementation in a new setting, equipoise
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45 refers to remaining uncertainty about whether or not the intervention will be more effective than
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47 usual treatment in the new setting. As well as what is usual treatment in the new setting, this will
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49 depend on whether the intervention can be feasibly and acceptably delivered, reach potential
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51 beneficiaries and generate outcomes in the new setting. The picture is complicated by the fact that
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53 local decision-makers will generally want to know about the size of effects and the costs associated
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55 with the intervention to assess whether it is worth the money. Thus, judgements about equipoise
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57 are neither simple (they involve multiple factors) nor easy (they are questions of probability not
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3 binary distinctions), and cannot be reduced to decisions based on effects demonstrated in previous
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5 evaluation.
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10 **Realist approach to local decisions about implementing interventions evaluated as effective**
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16 How should local decision-makers decide whether or not to proceed to full implementation of a
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18 previously evaluated intervention? We use the example of the proposed implementation in US
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20 elementary schools of a school-based social and emotional learning curriculum, which has been
21
22 previously evaluated as effective in promoting mental health across various settings.
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27 We take a realist approach. Realist evaluators focus not merely on what works, but on what works
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29 for whom and under what conditions.^{3 18} Interventions are understood to provide resources which
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31 actors and recipients use, which might then trigger a variety of intervention mechanisms which may
32
33 or may not generate outcomes. The use of intervention resources, the mechanisms thus triggered
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35 and the extent to which mechanisms generate outcomes will vary between contexts.
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40 For example, it might be the case that social and emotional skills curricula are more feasible to
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42 deliver in some schools and with some students more than others. The mechanisms that such
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44 interventions trigger (students understanding and managing their emotions and relationships with
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46 others) might be sufficient to generate significant mental health benefits in some settings but not
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48 others. They might improve mental health where deficits in these personal skills are an important
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50 part of the 'aetiological mechanisms' underlying poor mental health, but not in settings where
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52 broader structural factors, such as very high rates of violence, are more important aetiological
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54 mechanisms. By 'aetiological mechanisms', we refer to the mechanisms that generate certain
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56 outcomes in a setting in the absence of intervention, in contrast to 'intervention mechanisms', which
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3 which aim to disrupt, over-ride or compensate for aetiological mechanisms to change the pattern of
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5 outcomes in a setting.
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10 Below, we discuss several scenarios concerning implementation and effectiveness to consider where
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12 local implementation of a previously evaluated intervention is most likely to be successful. For both
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14 implementation and effectiveness, we first ask if the intervention has been evaluated in contexts like
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16 the new context being considered, and then we ask if the current context has the specific features
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18 required for the intervention to be successful.
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23 **Low-uncertainty scenario**

24 Implementation

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32 Implementation is most likely to be feasible and acceptable and reach potential beneficiaries in a
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34 new setting when two conditions are met (figure 1, which builds on that included in the Medical
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36 Research Council guidance on process evaluation¹⁹). Firstly, there is evidence from existing process
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38 evaluation(s) conducted in settings and to populations which resemble those present in the new
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40 setting (regarding factors that are likely to influence implementation) that the intervention was
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42 feasible and acceptable to deliver and achieved reach. Ideally, evaluations will also provide evidence
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44 about what factors supported implementation. Evaluations can usefully document what was needed
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46 to support feasibility in the context of the evaluation using existing frameworks.²⁰ In the case of
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48 social and emotional learning, for example, there is evidence that implementation is feasible and
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50 acceptable and achieves reach, and evidence that implementation is enabled by the involvement of
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52 school leaders championing the intervention, the availability of training, and broad ownership of the
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54 intervention among staff.^{21 22}
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3 Secondly, successful implementation in the new setting will be more likely when local information
4 suggests that key factors enabling implementation are also present in the new setting. As well as
5 factors identified in previous evaluations, enabling factors can also be identified from generic
6 implementation frameworks.^{2 23} The general theory of implementation suggests that successful
7 implementation is promoted through: 'potential' (providers possessing the desire and ability needed
8 for delivery); 'capability' (the intervention being workable and possible to integrate into existing
9 systems); 'contribution' (providers being able to work together to make sense of the intervention,
10 commit to its delivery, coordinate their actions and reflect on progress); and 'capacity' (local
11 structures, norms, roles and material resources supporting implementation). Local information on
12 whether such factors are present locally might come from: consultations or surveys with local
13 stakeholders; audits of knowledge, skills, equipment and other resources; existing guidelines for
14 practice; audits or evaluations of local practice; and observations of local services.⁵ Although some of
15 this information may already exist, some might need to be newly collected as part of needs
16 assessment for the new intervention.
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34 35 36 37 Effectiveness 38 39 40

41 Assuming that implementation is possible, whether this will translate into effectiveness will depend
42 on two factors. Firstly, it is more likely when existing evaluations report effectiveness drawing on
43 multiple, rigorous studies so that we have evidence of replicability and more precise estimations of
44 effects. Evaluations will ideally also indicate how the intervention works and for whom. Within
45 studies, light might be shed on this by qualitative evidence, mediation analyses or
46 subgroup/moderation analyses.^{10 24} Within systematic reviews, evidence might be provided by
47 subgroup analyses, meta-regression or qualitative comparative analysis.²⁵ Ideally, existing evidence
48 will also indicate the size of effects, the cost-effectiveness of interventions and the balance between
49 benefits and harms.
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5 In the case of social and emotional learning, there is evidence from multiple studies that this
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7 intervention impacts on positive mental health and evidence from mediation analyses that this
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9 occurs via enhancement of social and emotional skills.^{26 27} Furthermore, there is some evidence from
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11 meta-regressions across studies that this is most likely to occur in the USA (perhaps because such
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13 interventions are well aligned with US culture), and with older compared to younger elementary-
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15 school students.^{28 29} There is also evidence that such interventions are cost-effective,³⁰ do not
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17 hamper academic education and in fact promote educational attainment.³¹
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23 Secondly, we can be more confident that an intervention will generate effects in a new setting if
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25 local information suggests that similar intervention mechanisms will be triggered which will generate
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27 similar outcomes. This is more likely when the current standard of treatment in the new setting is
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29 similar to that received by the control group in previous evaluation. It is also more likely when
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31 similar 'aetiological mechanisms' underlie risks in the new setting as those present in previous
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33 evaluation. Ideally, this would be assessed by comparing each setting in terms of epidemiological
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35 context: the risk factors for the outcomes of interest in each setting.^{4 9 32} In the case of social and
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37 emotional learning, we would compare the original and new setting in terms of the prevalence of
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39 deficits in social and emotional skills and whether these are risk factors for poorer mental health.³³
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46 Comparable evidence may not always be available. Instead, the presence of similar aetiological
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48 mechanisms across settings may need to be inferred based on socio-demographic similarities
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50 between populations. While this might generally provide a reasonable guide, such assumptions will
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52 sometimes be wrong, particularly where patterns of risk are in flux perhaps associated with major
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54 social or technological change. Hence, we suggest that, where there are concerns that aetiological
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56 mechanisms might differ, local needs assessment should explore this, starting with rapid qualitative
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3 assessments and moving on to new epidemiological assessments of risk factors, depending on the
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5 degrees of uncertainty and urgency.³⁴
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10 Now let us consider scenarios where local implementation of a previously evaluation outcome is less
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12 likely to be feasible or generate similar outcomes.
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16 **Higher-uncertainty scenario**

17 18 19 20 21 Implementation 22 23 24

25 The first scenario is where there is uncertainty about implementation. Existing evaluations may not
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27 have been done in similar settings. They might have been done but identify barriers to
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29 implementation that may arise in the new setting, or identify facilitators that are unlikely to be
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31 present in the new setting. Evidence from consultations with local stakeholders or surveys, audits,
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33 guidelines for practice or observations might suggest important barriers to delivery. Considering the
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35 example of the school-based social and emotional literacy intervention: consultations with head- or
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37 classroom-teachers may suggest variable commitment to the intervention; audits of teacher skills
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39 might indicate deficits; analyses of school capacity might suggest that staff lack the time, autonomy,
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41 resources and/or senior support to deliver the intervention; or observations might indicate that
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43 classrooms are too disrupted by student misbehaviour for good implementation.³⁵
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50 In such scenarios, piloting of the feasibility of delivery before any full implementation is indicated.

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52 Piloting might involve steps to address potential barriers to optimise implementation. It may be
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54 possible to address challenges arising from provider capacity or other influences on implementation
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56 feasibility to ensure the intervention can be delivered locally. But piloting will need to assess this,
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3 monitoring fidelity and using qualitative research to explore factors affecting feasibility. Local
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5 adaptations might be required.^{36 37}
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10 Effectiveness

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14 Uncertainty about whether the intervention will be effective might occur for two reasons. Firstly, it
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16 might be due to uncertainty that the intervention will trigger the expected mechanisms. Existing
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18 evaluations may report effectiveness but be from settings or populations that do not closely
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20 resemble those found locally. Local information might suggest that the intervention will not be
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22 successful in triggering mechanisms locally. In the case of school-based social and emotional
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24 education, consultations with teachers might suggest that classroom-based interactions won't
25
26 develop students' social and emotional skills because of concerns about student attendance or
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28 engagement. Consultation with parents or students might suggest that the social and emotional
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30 skills that the intervention promotes do not align with local social norms.
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37 Secondly, there may be evidence that intervention mechanisms, even if triggered, will not generate
38
39 intended outcomes. This will be the case if different aetiological mechanisms are operating locally.
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41 Surveys or routine data might suggest that: rates of mental health problems among students are
42
43 already low; deficits in social and emotional skills are uncommon; or deficits in social and emotional
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45 skills are not significant risk factors for mental health problems. Needs assessments might suggest
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47 that, even if students develop social and emotional skills, other local aetiological mechanisms might
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49 swamp these intervention mechanisms: for example, if there are high rates of local violence or
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51 abuse. In such situations, intervention mechanisms may not disrupt the aetiological mechanisms
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53 underlying poor mental health. Some of the above information may not already be available,
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55 necessitating new research, starting with consultations with local stakeholders and moving on to
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57 quantitative surveys if significant uncertainties remain and if time and resources allow.
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5 In terms of what actions are suggested, where the concern is about whether intervention activities
6 will trigger mechanisms, this suggests the need at least for a new effectiveness trial potentially
7 focused on an intervention adapted for local context. Where the concern is that the potential
8 intervention mechanisms, even if triggered, will not disrupt local aetiological mechanisms or be
9 swamped by other aetiological mechanisms, then local decision-makers may decide to seek entirely
10 different interventions.
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21 Discussion

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25 We have aimed to develop guidance to help local decision-makers assess whether to implement
26 interventions evaluated as effective elsewhere. We have stressed the importance of assessing
27 existing evaluation evidence not merely in terms of what works overall but also: a) how successfully
28 and with what reach interventions are implemented and what factors enable this (drawing on
29 process evaluations); and b) what works for whom and how (drawing on mediation, moderation
30 and/or qualitative comparative analyses within primary studies or systematic reviews).
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41 Informed by our realist approach, we have contributed new insights to what is required of local
42 needs assessments. First, we suggest that these should examine factors relating to the local
43 potential, capability, contribution and capacity for implementation of the intervention. We recognise
44 that such evidence will often not already exist and recommend the value of consultations with local
45 stakeholders, surveys and audits in providing such information. Second, we have suggested that
46 local needs assessment should where possible consider whether similar 'aetiological mechanisms'
47 underlie adverse outcomes in a new setting compared with those of previous evaluations. We
48 recognise that this can be challenging. Assessments about comparability should ideally be based on
49 research assessing the prevalence and strength of risk factors for the outcomes of interest
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3 comparing the new setting to the settings of original evaluation. However, at minimum, similarities
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5 or differences in aetiological mechanisms might instead be imperfectly inferred through similarities
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7 and differences in socio-demographic characteristics between populations.
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12 We have suggested that where there is substantial uncertainty as to whether an intervention can be
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14 implemented in a new setting, this indicates the need for piloting the feasibility, acceptability and
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16 reach of implementation. Where there is uncertainty that implementation will trigger intended
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18 intervention mechanisms then this suggests the need for a new effectiveness trial. When there is
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20 uncertainty about whether intervention mechanism, even when triggered, will generate the
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22 intended outcomes, this suggests that decision-makers may need to look to other types of
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24 intervention instead for their setting.
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31 One limitation of our approach is that it is focused on scenarios where there is existing evidence on
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33 the intervention in question. In reality, there will be cases where an intervention is being considered
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35 for implementation in a setting when there is not evidence from multiple recent studies. In such
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37 cases, there will be much stronger arguments that new controlled trials of outcomes are needed
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39 before any delivery at scale. Furthermore, while we have recognised that evaluations must consider
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41 the size of effects, cost-effectiveness and the balance between benefits and harms, our various
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43 scenarios generally focus on simpler questions of whether interventions are effective or not, to
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45 avoid over-complicating our analysis. While our focus has been on complex interventions and
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47 social/psychological mechanisms, we recognise that biological systems are complex and so our
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49 framework might also apply to clinical interventions, in an era of personalised medicine, co-
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51 morbidities and global pandemic.³⁸
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58 Our focus has been on assessing whether an intervention feasible to deliver and effective in one
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60 context might be so in another. We have not addressed the question of unintended outcomes

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3 including harms. Based on previous work, we would however recommend that reviews of existing
4 evidence and consultations with local stakeholders consider such possibilities. These might suggest
5 the need to drop the intervention where harms are considered substantial, likely and unavoidable,
6 or adapting and evaluating the intervention where they are considered less substantial or likely and
7 more avoidable.³⁹
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17 It might sometimes be decided to move to implementation of an intervention in a new setting even
18 without firm evidence that this is locally appropriate, for example in response to emergencies arising
19 from humanitarian crises and epidemics. In such cases, evidence might still be collected in parallel to
20 preparations for delivery to inform refinements to the intervention and decisions about the extent
21 and focus of accompanying evaluation and monitoring.⁴⁰
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46 **Competing Interest**

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48 None declared.
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Figure 1: How implementation triggers intervention mechanisms which disrupt aetiological mechanisms to generate outcomes and how this is influenced by context

