

Developing whole-school mental health and wellbeing intervention through pragmatic formative process evaluation: A case-study of innovative local practice within the School Health Research Network

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Abstract

Background: The evidence-base for whole school approaches aimed at improving student mental health and wellbeing remains limited. This may be due to a focus on developing and evaluating de-novo, research led interventions, while neglecting the potential of local, contextually-relevant innovation that has demonstrated acceptability and feasibility. This study reports a novel approach to modelling and refining the theory of a whole-school restorative approach, alongside plans to scale up through a national educational infrastructure in order to support robust scientific evaluation.

Methods: A pragmatic formative process evaluation was conducted of a routinized whole-school restorative approach aimed at improving student mental health and wellbeing in Wales.

Results: The study reports seven phases of the pragmatic formative process evaluation that may be undertaken in the development and evaluation of interventions already in routine practice: 1) identification of innovative local practice; 2) scoping review of evidence-base to identify existing intervention programme theory; outcomes; and contextual characteristics that influence programme theory and implementation; 3) establishment of a Transdisciplinary Action Research (TDAR) group; 4) co-production of an initial intervention logic model with stakeholders; 5) confirmation of logic model with stakeholders; 6) planning for intervention refinement; and 7) planning for feasibility and outcome evaluation. The phases of this model may be iterative and not necessarily sequential.

Conclusions: Formative, pragmatic process evaluations support researchers, policy-makers and practitioners in developing a robust scientific evidence-base for acceptable and feasible local innovation that does not have a clear evidence base. The case of a whole-school restorative approach provides a case example of how such an evaluation may be undertaken.

Background

In recent years there has been a rapid expansion in the number of frameworks available to support the development, modelling and prototyping of complex population health interventions (1, 2). Despite offering important theoretical, methodological and pragmatic guidance, these frameworks have been largely applied to the development of de novo, research-led interventions rather than to the approaches already in routine practice.

There are distinct benefits of evaluating locally embedded interventions, which have not yet been fully exploited. First, intervention development frameworks privilege co-production, particularly in regard to developing intervention models that couple stakeholders' understanding of the problem with scientific evidence. Evaluation of embedded local innovations offers insight into stakeholders' theorisation of the problem, as they are likely developed in response to these contextually informed understandings. Second, in accordance with realist (3-5) and complex systems perspectives (6, 7), intervention outcomes should be understood as being the result of interactions between the intervention's causal mechanisms and the context into which they are introduced. In the case of routine practice, much of the dynamic interplay between these mechanisms and context are already emergent. This makes it possible move beyond hypothetical assumptions about how an intervention might operate when introduced to a specific context or how the system will (re)orientate itself following this disruption. Third, acceptability will likely already have transpired, and variations in engagement across different stakeholders may be apparent.

Pragmatic formative process evaluations have been proposed as an approach to guide the retrospective modelling and refinement of locally embedded innovations (8). Derived from frameworks used to develop de novo interventions, suggested phases of evaluation include but are not limited to: conduct of a review to map the nature of the problem and potential intervention responses; establishment of a stakeholder groups to govern the intervention development process; co-production of intervention materials; testing and adapting the intervention in context; and progression to feasibility and/or outcome evaluation (1, 2). However, additional stages likely need consideration with routinised approaches, notably the initial identification of local innovative practice and the iterative process of engaging stakeholders in modelling programme theory where it has been developed by local practitioners. Transdisciplinary action research approaches have been identified as a way of cultivating and sustaining collaborations to support such additional activities, and will be significant to the pragmatic evaluation approach (9).

Despite their potential value, there is a paucity of empirical examples of how to conduct pragmatic formative process evaluations of complex population health interventions. The present article aims to address this gap by a presenting a worked example. It describes the evaluative phases undertaken, reflects upon the limitations of the process, recognises the challenges encountered and provides recommendations for the future improvement of the research design. The study draws upon a secondary-school based restorative practice intervention as a case example for testing and developing this approach.

Intervention: Secondary-school based restorative practice

The intervention is a system-level approach to restorative practice that has been delivered in a secondary school in Wales since 2008. Restorative practices include relationship-focused actions, which can be implemented at the targeted, universal or whole school level to impact upon a range of outcomes, including mental health and wellbeing (10, 11). They often comprise a suite of activities spanning the range of socio-ecological domains (i.e. intrapersonal; interpersonal; organisational; community). A central tenet is to encourage individuals to take responsibility for their actions, with positive engagement in conflict resolution and relationship repair being key to the approach (12). Notable contextual influences and their impact on programme theory and implementation practices have not been fully articulated in the existing evidence base. Neither has unintended or potentially iatrogenic pathways.

Methods

A seven phased framework was applied to model and refine the intervention and plan potential for further feasibility and outcome testing. These were 1) identification of innovative local practice; 2) scoping review to identify programme theory; contextual characteristics; implementation and outcomes; 3) establishment of a TransDisciplinary Action Research (TDAR) group; 4) co-production of intervention logic model with stakeholders; 5) confirmation of logic model with stakeholders 6) planning for intervention refinement; and 7) planning for feasibility and outcome evaluation. These stages are presented in detail in the results, with the methodology focusing on the sample frame and research methods.

Case study

The study comprised case study methodology with one mixed gender secondary school in Wales, which had undertaken innovative practice around student mental health and wellbeing. The school serves students aged 11-18 years and had more than 1500 registered students in 2016. It has below average student Free School Meal eligibility (FSM) (2016 three year Welsh average 17.3%), which is routinely used as a proxy measure for socio-economic deprivation. It has an above average proportion of students achieving 5 General Certificate of Secondary Education (GCSEs) at Grade A*-C including English/Welsh and Mathematics (2016 Welsh average 57.9%) (13). GCSEs are statutory tests taken in Year 11 (age 15-16 years) in England and Wales. The school was identified and recruited via the national School Health Research Network infrastructure (14). On identification of the school a scoping review was undertaken to verify the innovative practice under consideration by confirming that school-based restorative approaches, while variable, tend to have underpinning programme theories that are associated with student-level health outcomes and no major tendencies to iatrogenic effects or exacerbation of inequalities (15).

Participant sample and recruitment

Staff and students participated in data generated at Phase 4 and 5. The demographic characteristics of participants are presented in Table 1. Students were purposively sampled for maximum variation in gender and age. A total number of 22 students participated, with 8 students contributing to data generation at both Phase 4 and 5. Staff members were similarly sampled to ensure maximum variation. Of the eighteen staff taking part, 9 participated at both Phase 4 and 5. Where possible researchers sought to retain consistency in participation across the phases, but did request the school to recruit additional individuals at Phase 5 to encourage new reflections. Staff and students were recruited through the study gatekeeper who was a member of the TransDisciplinary Action Research (TDAR) group. This individual was a member of staff in the Senior Leadership Team with responsibility for pastoral support, including the school's implementation of the restorative practice approach. They were provided with the sample frame to ensure diversity in participants.

Data collection

Focus groups were selected as the most appropriate method, anticipating that participant interaction would expose inconsistencies in understandings of the intervention and context. Two focus groups were held with students and two with staff. Focus groups lasted an average of one hour 12 minutes. Two researchers moderated them. Focus groups focused on modelling and refining the intervention through logic model construction. An initial, candidate logic model was developed by the TDAR group from the extant research evidence. It was used to start discussion and was built upon throughout the focus groups. The topic guide considered: perceived programme theory; contextual characteristics; experiences of implementation; outcomes; and recommendations for future enhancements. The logic model was refined after Phase 4 and presented at Phase 5 to elicit areas of consensus, areas of non-consensus, and continued uncertainties. Data were generated in April 2016 (Phase 4) and July 2016 (Phase 5).

Ethical Procedures

Ethical approval for the study was provided by [Ethics Committee]. All participants were provided with information sheets prior to study commencement, along with the opportunity to ask any questions. Written informed consent was obtained from all participants, with opt-out guardian consent being secured for students.

Data Analysis

Data were audio recorded, transcribed verbatim and reviewed for accuracy. Data collection and analysis were conducted concurrently, with the data from focus groups at Phase 4 being used to inform the questions asked during phase 5. Thematic analysis was conducted (16). Data were initially coded according to the main domains of a logic model (e.g. programme theory; context; implementation; and outcomes). De novo codes were also developed. Coding was undertaken by one researcher and verified by a second. Codes were compared and contrasted to develop themes. The two corpuses of data (Phase 4 and Phase 5) were initially considered independently of each other. Themes were then compared across the data to understand changes that emerged through the process of logic modelling and refinement. The final set of themes were confirmed by the wider research team. NVivo10 software was used to support analyses (17).

Results

The present results describe the seven phases of the framework used to identify, model and possibly refine the case of local innovation, in addition to planning for potential scale up for further feasibility and outcome testing (Figure 1). These phases are not intended to be sequential but iterative and not necessarily sequential.

1. Identification of Innovative Local Practice

The first phase is to identify innovative local practice that warrants progression to modelling, possible refinement and outcome evaluation. The researchers identified the case study intervention through the DECIPHer research centre hosted School Health Research Network infrastructure (SHRN) (14). The network comprised 165 of all secondary schools in Wales (N=212) at the time of study, with representation from all 22 local authority areas. The Network seeks to optimise research collaboration between researchers, policy-makers and practitioners. One of the central mechanisms to encourage collaborative working is through a programme of knowledge exchange activities, including webinars and stakeholder meetings. At regional meetings, researchers present study data whilst practitioners share examples of innovative practice to improve staff and student health and wellbeing. The case study innovation had been presented at a stakeholder event, with the school gatekeeper following up the potential for research collaboration with the SHRN Manager. The Manager identified a relevant academic contact with the requisite expertise to assess the fit of the intervention with the centre's research priorities, formulate preliminary research questions, consider an appropriate research design, and draw together a research team.

Given the characteristics of the local innovation and its history of implementation in the school, a pragmatic formative progress evaluation was decided upon. Criteria for informing this decision was: 1) *Feasibility of programme theory modelling*: The researchers questioned if an "intervention" (regardless of type) was in use and that a programme theory, contextual characteristics, implementation and outcomes could be characterised. The school had been recognised as delivering sector-leading, best practice in restorative practice and had been awarded a Restorative Service Quality Mark (RSQM) in 2010. As a consequence of this external validation the researchers felt that there was clear delivery of a restorative practice intervention. 2) *Feasibility of implementation and scale-up*: The researchers established that the restorative practice had been routinely used and resourced for a substantial period of time (i.e. eight years). The researchers further considered the future traction of the intervention and if it could be scaled-up for evaluation beyond the single case study schools, or was so contextually contingent no replication was feasible. There was no indication that the school was atypical so the intervention could not be transported to other secondary schools, and the school had been increasingly invited to share their practices with other schools at a national level due to being recognised as sector leading; 3) *Research Co-production*: The researchers consulted with the school to ensure they were prepared to participate in a research study and would potentially be committed to future research.

2. Scoping review to identify programme theory; outcomes; contextual characteristics that influence programme theory and implementation

The second phase is to engage in a scoping or systematic review of the existing scientific research to develop a preliminary understanding of the intervention. This can inform the development of an initial logic model, which can serve as the basis to model the real-world case example. A review further supports consideration of the effects of such interventions, and potential iatrogenic pathways that might be attended to in the primary research (15).

Programme Theory and Outcomes: Across the studies there was a lack of specificity around the underpinning programme theory. Rather there were broad principles of how restorative approaches may work, largely through the building, maintaining and restoring of relationships, where individuals take responsibility for their actions and positively engage in relationship repair and conflict resolution (10, 11). This may be further supported by changes in classroom management practices and school ethos. The INCLUSIVE intervention provides one of the most theoretically informed approaches (12, 18), hypothesising that through restorative practices students are more likely to engage with schools' pedagogic practices and embrace rules and ethos. As a result, school connectedness increases and relationships improve. A range of activities at the targeted, universal and whole-school level can be considered as restorative. The approach may be most effective when it is fully adopted at the system level (19, 20).

Evaluations of school based restorative approaches have identified a range of measurable intervention outcomes (12, 19, 21, 22). At the student level these include improving mental health and wellbeing (12), social and emotional competencies, including empathetic attitudes and self-esteem (23), improved academic attainment (22), reduced bullying (23) and fewer school exclusions (21, 22). There has been limited consideration of staff level outcomes and iatrogenic pathways remain largely underdeveloped.

Contextual characteristics that influence implementation and programme theory: The researchers mapped key system-level characteristics that might inhibit the programme across different contexts and prevent planned implementation. The Context and Implementation of Complex Intervention Framework (CICI) (24) was used as a framework for mapping context and implementation. As these are often not fully considered when modelling interventions, Table 2 provides a worked example of how they were understood based on the evidence-base. Although existing research findings did not map onto all of the CICI domains, a number of influences emerged across papers. *Epidemiological:* Implementation is strengthened by an increase in the prevalence of bullying within the specified context, leading to more support for such approaches (22, 23). *Political:* There is increased support for restorative approaches where there is alignment with political/policy priorities, which has often led to direct government funding (12, 19, 21, 25). *Ethical:* Restorative approaches are congruent with a belief in a fair and just society where citizens are respected. In such circumstances they are viewed as a more ethical approach to punitive or criminalised responses (21). {Wong, 2011 #15}

3. Establishment of a Transdisciplinary Action Research Group (TDAR)

The third phase is to establish a TDAR Group, which is intended to support the effective collaboration between diverse stakeholders (26). Within the existing literature, this approach emphasises co-production where non-academics are active agents in research and strives for equal, mutually beneficial and reciprocal relationships that value public, practitioner and policy-maker knowledge and experience to the same degree as academic knowledge (27). It is underpinned by the principles of action research, and its tenets has been increasingly deployed in guidance around intervention development to ensure that approaches are maximally responsive to the contexts and populations where they are to be implemented (1). While dominant terminology uses the term transdisciplinary, it may be more useful to think more in terms of creating a trans-professional group that draws together different professional identities, such as policy-makers, local education authority representatives, researchers, teachers and of course students. Within a pragmatic formative process evaluation, TDAR can help to bring a comprehensive and nuanced understanding of the intervention that is being modelled, in addition to a rich awareness of the context in which it has been originally delivered.

A Transdisciplinary Action Research Group (TDAR) comprising diverse researchers (i.e. sociology, public health, psychology and epidemiology) and members of the school community who were on the Senior Management Team. The group comprised eight members. It should be noted that students were not represented, meaning that their perspective was only accommodated during the research. Future studies should better represent the target population in the TDAR group. The group met routinely throughout the duration of the study. Its function was to oversee study conduct, ensure that the study design and processes were being shaped by practice perspectives, support the development of an initial candidate logic model and to build relationships to support knowledge translation. It further aided the decision-making about future evaluation (Phase 7), where stakeholders could share views on the value of information from an outcome evaluation and the different types of evidence that would support practice moving forward.

4. Co-production of Intervention Logic Model with Stakeholders

The fourth phase is the co-production of a logic model with key stakeholders to identify the underpinning programme theory, contextual characteristics, implementation practices and outcomes. Participants developed the logic model from the initial construction undertaken by the TDAR group following the scoping review. The Wisconsin template was used (28). The output of the logic model from both Phase 4 and Phase 5 is presented Table 3. A more detailed consideration of context and implementation, as mapped across the CICI framework, is presented in Table 4.

Programme theory: Both staff and students stated confidence and self-efficacy as being important to the programme theory. Students spoke about feeling between equipped to take ownership of their learning, ask for help, and take risks with complex topics, which was largely a consequence of involvement in classroom and school-level decision making. Meanwhile staff suggested that improvements in confidence in the classroom, combined with having the opportunity and skills to express their thoughts and feelings following student conflict, had reduced stress:

STAFF FG1;3: So ... it certainly has made a difference in terms of my wellbeing, giving me more confidence within the classroom ... it's not just looking after student wellbeing, but also staff wellbeing.

The central mechanism for both of these groups of stakeholders was a change in relationships. Students mentioned peer relationships frequently, while staff emphasised relationships between staff and students: In the later instance, one member of staff suggested that circle time redresses power imbalances, creating more supportive interactions:

STAFF FG2; 14- ...the starting with them ... with them was to sort of have a circle time in and listen to them. Find out what they need from me and let them know what I need from them. Erm, and just ... just not being afraid really to sort of break down any barriers between sort of thoughts and feelings ...

Through a shift towards trustworthy and responsive relationships, the school was considered to offer a more positive and supportive culture. These changes led to students experiencing increased school connectedness. This process was further enhanced through a distributed leadership model, involving students in key decision making, such as the design of a new building or appointment of a staff member, with one commenting '*we've had a huge impact with everything in school.*'

Additionally, students felt that the instilling of restorative practices had improved the school's reputation in the community, and relative to other local schools. This had enhanced school connectedness and thus motivation to engage in positive behaviours and improve academic attainment:

STUDENT FG1;5: Because when I first came to the school, ... we were known as "down the hill" and now it's "the comp". Like things have changed. ...

Beyond intended causal pathways, participants considered iatrogenic pathways, which have largely been overlooked in the previous modelling of restorative approaches. This identification illustrates the particular strength of co-production and learning from interventions already in routine practice. For example, participants indicated that the school's improved reputation following adoption of the intervention had led to over-subscription, which had limited access in the community and placed a resource burden on the school.

Outcomes: Logic modelling indicated three key sets of outcomes, which are largely congruent with existing restorative approaches. For both student and staff the reported primary outcome was improved student mental health and wellbeing:

STUDENT FG1; 2- I think wellbeing in the school is kind've increased massively ..,I've got a brother who is 5 years older than me but he came to this school as well and he's told me stories about how there used to be fights every week and people would set off fire extinguishers... then you look at our school now and honestly I'd be surprised if I heard about a fight because it just doesn't happen anymore...(laughs) yeah it's not common any more. I think generally school life has transformed and everything is more positive now. I rarely hear people talk badly about teachers um, everything here seems to be more positive and I think that contributes to all the points these guys have brought up about feeling secure and happy in the environment.

Additional outcomes are presented in Table 3.

Contextual characteristics that influence implementation and programme theory: Drawing on the factors identified in the scoping review, the co-production process explored key contextual features that could support the implementation of the intervention and ensure the programme theory worked as intended. These factors were often explained in relation to the reason why restorative practices were initiated.

Epidemiological: Data indicated that the school had reached a tipping point, and preparedness for change was due to perceptions of increasingly poor levels of mental health and wellbeing and high levels of fixed-term and permanent exclusions. Existing practices based on merit and punishment were considered punitive and ineffectual in addressing the problem:

STAFF FG1; 2: ...we were just finding we were going round and round and round in circles and not really making progress.

Political: The policy context in Wales was increasingly orientated to support the prioritisation of mental health and wellbeing of children and young people, particularly within the educational context. The Well-being of Future Generations Act (2015) in Wales has mandated organisational and culture change to enhance mental health related outcomes. Meanwhile the Donaldson educational review on curriculum reform has outlined six key priorities, such as wellbeing, alongside an acknowledgement of the synergy between wellbeing and educational outcomes (Donaldson, 2016). Although in the case study school, restorative practice had been implemented for 8 years prior to data collection in 2016, and advance of these political and educational changes, these policy priorities supported its continued implementation. *Socio-economic:* Participants acknowledged that the case study school had a lower than national average level of free school meal entitlement and a high level of academic achievement. Thus, whilst the school cannot necessarily be characterised as atypical, there was acknowledgment that the intervention may be more difficult to implement in a more challenging context with higher levels of disadvantage:

STAFF FG1; 6 – I think there's more focus on students' perspectives here um, which students value more. Generally the behaviour here is better than at schools that I've taught at previously, though I'd say those schools are working within a different concepts, there are inherently gonna be more issues because of the intake that they have.

Socio-cultural: Participants identified entrenched pedagogic practices that were the antitheses of restorative approaches, namely punitively orientated interactions with students. There was indication that staff could orientate to the default approach, which could lead to extensive variation in practice:

STAFF FG1;2 – varied yeah, it is varied across the school: you can see a restorative conversation happening in quite a negative tone in one space, but in another it can be very effective so...and that's hard for young people as well because young people say "I've just had a restorative" (said in an angry voice) and actually it's like hang on a second, that's not a restorative

Participants also suggested potential incongruence between the social and emotional competencies required for the effective delivery of a restorative approach, and a socio-cultural context that did not always privilege vulnerability and emotional openness. To mitigate against such issues, participants identified the importance of senior leadership vision and commitment as part of the implementation plan to ensure realignment of the school ethos with the restorative practice approach and staff commitment to training and delivery. Moreover, the school adopted a rather organic diffusion process, initially securing training to a small team of pastoral staff to ensure their buy in and capacity for modelling the approach before expanding to more diverse professional roles. Eventually working groups were established to ensure continued change to the socio-cultural context, with a Behaviour Research Group reviewing how the restorative practices could be sensitively translated into the setting.

5. Confirmation of Logic Model with Stakeholders

The fifth phase of the process entails confirmation of the logic model with stakeholders. Commonly studies present logic model development as a static phase, but to ensure meaningful co-production multiple opportunities for input are required. The second round of data collection with participants provided clarity on a number of uncertainties that remained following Phase 4 and elicited aspects of the intervention and context that had not yet been identified. In particular, participants focused on the socio-ecological domains beyond the inter-personal, notably family and community level processes. For example, family-based activities emerged, particularly the delivery of parenting skills, to ensure some congruence between the school ethos and family dynamic:

STAFF FG2;13: We're working with parents on the approach we would take in school particularly where children have reflected and said 'well if I did that at home this is what would happen ...or this is what I see at home. And that ongoing communication and collaboration with parents is really important and it's quite a long journey for some.

Taken together, Phase 4 and Phase 5 provided a nuanced and contextually sensitive understanding of the local innovation.

6. Planning for Intervention Refinement

The sixth phases progresses to planning for intervention refinement where required. A knowledge exchange event was hosted at the school in order to feedback the study findings and discuss the logic model generated during Phase 4 and 5 (Figure 2). The purpose and impacts of the meeting were fourfold. First, it aimed to provide an additional opportunity to discuss the intervention and verify that the research team who interpreted the data, and the TDAR group who supported this process, had an adequate understanding of the intervention. Second, by highlighting remaining areas of uncertainty or challenges with delivering the intervention, stakeholders were able to identify where further intervention refinement was required and where barriers needed to be addressed to ensure that proposed the programme theory was being activated as intended. Third, the event served to strengthen partnership between stakeholders. Fourth, it

aimed to reassert the emotional investment of the school (29). To progress to further evaluation, where the school may be required to support the sharing and delivery of practices within other institutions, it was deemed important for the school feel committed to both the intervention and research. Reflecting with stakeholders provided a positive experience that renewed enthusiasm, with many commenting on how much the school had achieved since the initial introduction of the intervention.

A central issue to reflect upon at this stage, is the potential for different stakeholder groups to have different perspectives on what the refinements are required. In the present case example, there were no significant disagreements and discussion generally focused on removing implementation barriers. However, this issue may arise and the processes for resolving potential conflict needs further consideration.

While the co-production literature is important in recognising the need to take account of all perspectives, the notion of functional fidelity may have practical use in helping accommodate a range of different needs and understandings. This recommends that changes to interventions can be permitted and activities can be flexible as long as the central programme theory is being activated (6, 30). In refining an intervention then, the focus may be on expanding activities or providing different versions of components for different stakeholders in accordance with their needs. The extent to which these refinements support the programme theory can guide what is permitted.

This approach does not come without its own challenges, as they may not be a single programme theory in operation, and different stakeholders can have different interpretations of how an intervention works. Hence achieving modifications to ensure the programme theory is activated can be problematic, and in this case there may need to be several iterations of modelling and refinement to reach an understanding of a theory that most closely approximates the mechanisms that are being activated in the context.

7. Planning for Outcome Evaluation

The seventh phase comprises planning for future outcome evaluation if appropriate. Where outcome evaluation is warranted, the type of evaluation would be most suitably assessed against the phases of evaluation prescribed by the MRC: pilot and feasibility trial, a randomised controlled trial; natural experiment or other quasi-experimental design; and then longer-term implementation evaluation (3, 31). Further work is required to refine decision-making about the most suitable evaluation approach, and an a priori progression criteria similar to that used in feasibility trials may be helpful. Potential criteria to be considered are: 1) The evaluability of the intervention(32); 2) The Value of Information (VOI), which weighs the cost of obtaining evidence against the need for certainty amongst stakeholders (33); and 3) the applicability of the existing evidence. For example, Aarons et al. have developed a framework for 'borrowing evidence', which assesses the similarities of different interventions and contexts to see if the outcomes of evaluations conducted elsewhere have relevance in the new context in question(34).

In the present case study, planning is primarily being conducted through the TDAR group, drawing on both practice and academic expertise. The SHRN infrastructure offers a particular opportunity to continue with pragmatically orientated innovation evaluation, through the conduct of a pragmatic feasibility and outcome trial. As of 2020 the network includes 100% of the 212 state-funded schools in Wales, providing a complete sample frame for randomisation. A sample of students at each participating school complete bi-annual surveys of their health and wellbeing, and provided data is collected at appropriate times, these surveys could be exploited as the data source for outcome measurement. As popular innovations, such as that selected for the case study, are gaining traction within systems, it is imperative that we have responsive study designs. Use of routine data, such as that collected through the SHRN survey data offers such responsiveness, although the evidence generated is arguably less scientifically robust than that provided by RCTs.

Discussion

In recent years there has been a proliferation of guidance on the development of complex population health interventions (1, 2). Such frameworks have primarily focused on the modelling of de-novo interventions. To date there has been more limited consideration of the retrospective development of local innovations that are already routinised. Such approaches offer a fruitful opportunity for future research. They have demonstrated some evidence of feasibility, as well as the challenges associated with embedding a new approach. With increased interest in the notion of interventions as being contextually contingent, there has been a range of theoretical and methodological consideration of how best to integrate a focus on context into developmental and evaluation processes (24, 35, 36). In the event of routinised practice, many of these contextual contingencies are already emergent or even established. Thus, beyond offering an opportunity to develop contextually sensitive, feasible and acceptable interventions, such studies offer significant insight into the systems that innovations are aiming to disrupt.

The case study intervention, a school-based restorative practice approach addressing student mental health and wellbeing, demonstrates the utility of pragmatic formative process evaluations. To date there have been a range of restorative interventions, including that reported in the recent INCLUSIVE trial (12, 18). While many of these studies have started to map key system influences that may moderate the intervention's programme theory, the case study is particularly insightful as it presents established contextual characteristics eight years into intervention implementation. These include key socio-cultural factors, such as the entrenched educational ethos and pedagogic approaches (37). Such findings also illustrate the importance of attending to intervention maintenance, and the ongoing resource required to ensure continued contextual fit. Use of context mapping frameworks, such as the CICI framework, across studies reporting on different phases of diffusion will enable researchers to understand the evolution of contextual factors and how interventions may respond to and accommodate them (24)

The seven phases of intervention modelling and refinement are particularly focused on the elicitation of contextual characteristics. To this end, meaningful co-production must serve as a central feature. As with other developmental frameworks, establishment of TDAR group is recommended to ensure that a diverse range of stakeholders invested in the intervention are adequately represented (2, 26). The presence of this group can help ensure that phases of evaluation privilege co-production, that policy and practice stakeholders are able to make a meaningful contribution and that the modelled intervention captures a multiplicity of experiences and perspectives.

Pragmatic formative process evaluation also responds to the ever-present issue of incongruence in the needs of policy-makers and practitioners and the reality of conducting scientifically robust evaluations. One of the key tensions is the timeliness of generating research evidence, and a perceived lack of responsiveness in the research community. Efforts to resolve these arguably incompatible needs have increasingly focused on quasi-experimental designs, with natural experiments being used to evaluate policy innovation (38). While such designs may not provide the same level of scientific robustness as randomised controlled trials, they do allow for the generation of pragmatic and relevant evidence. The present framework for pragmatic formative process evaluation supports this direction of travel by privileging with the wealth of local innovation that has already gained traction within real world settings.

Limitations

There are a number of limitations that should be acknowledged. First, as identified in existing developmental models focused on co-production, there is uncertainty about the extent of opportunity provided for stakeholders to contribute in order to ensure a rounded and nuanced understanding of the intervention (2). This may be a consequence of the study design privileging the researchers' perspectives by commencing with the review and synthesis of existing literature. Equally the three phases of stakeholder engagement may be inadequate in practice, and they may need to be continually repeated until the logic model is fully refined and there is consensus. Second, the representativeness of the case study school should be considered, as it had a lower than average level of free school meal entitlement, a higher than average level of academic attainment and was large in size. The field of implementation has been increasingly concerned with the generalizability of evidence when interventions are scaled-up or scaled-out (34), and there are implications about whether the intervention could be embedded within the system functioning of schools with different socio-economic profiles. For example, study participants felt it would be challenging to deliver the intervention in more socio-economically deprived settings, while extant research suggests that the quality of staff-students relationships is actually more of a priority in schools of a lower socio-economic status (39). Third, while maximum variation in sampling within the case study was pursued, the sample is limited by those who were prepared to participate. Interviews were largely conducted with students engaged in classroom level activities, with fewer individuals who had received one-to-one support within the restorative approach. Equally, data was not available on additional student level characteristics that may have influenced perceptions of the intervention (e.g. school connectedness) and these were not addressed during sampling. Fourth, the composition of the student focus groups, which were heterogenous in gender and school years may have inhibited the sharing of contrasting views, rather encouraging students to conform to predominant norms.

Conclusions

The present study provides an empirically worked example of a pragmatic formative process evaluation to support researchers, policymakers and practitioners in the modelling, possible refinement and outcome evaluation of interventions already in routine practice. This phased framework serves as a complement to the emerging range of guidance for the development of de-novo population health interventions (1, 2), by addressing the specific developmental phases required for working with locally embedded innovation. It also responds to increased policy and practice needs, where evaluation needs to be responsive to the rapid emergence of new innovation. Further methodological and empirical work is needed to apply and refine the framework with different health outcomes, populations and settings.

Abbreviations

Transdisciplinary Action Research (TDAR) group; Free School Meal eligibility (FSM); General Certificate of Secondary Education (GCSE), School Health Research Network infrastructure (SHRN); Restorative Service Quality Mark (RSQM); Context and Implementation of Complex Intervention Framework (CICF)

Declarations

Ethics approval and consent to participate: Ethical approval was obtained from [University] School of Medicine Research Ethics Committee. Written informed consent was obtained from all participants.

Consent for publication: Not applicable

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Authors' contributions: NG, AW, KMcE, MR, SR, SM, RE obtained funding and developed the study protocol. NG obtained ethical approvals. AW facilitated access to the case study school, recruited study participants, and facilitated access for the research to be conducted in the school. NG, KMcE, HS collected data. NG, HL, KMcE, HS, RE analysed data. NG, HL, AW, KMcE, MR, SR, SM, RE interpreted data. NG and RE drafted the manuscript. All authors contributed and approved the final manuscript.

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Tables

Table 1: Demographic Characteristics of Case Study Participants at Phase 4 and Phase 5

	Phase 4		Phase 5		<i>Participants who took part in both Phase 4 and 5</i>	
	Group 1	Group 2	Group 1	Group 2	<i>Group 1</i>	<i>Group 2</i>
Students						
Total students	8	7	8	7	1	7
Gender						
Male	5	4	5	4	-	4
Female	3	3	3	3	1	3
Year group						
Year 7	1	2	2	-	-	-
Year 8	1	3	3	2	-	2
Year 9		-	-	3	-	3
Year 10	1	2	2	2	1	2
Year 11	2	-	-	-	-	-
Year 12	2	-	1	-	-	-
Year 13	1	-	N/A ^a	N/A	N/A	N/A
Staff						
Total staff	6	7	8	5	5	4
Gender						
Male	1	1	-	-	-	-
Female	5	6	8	5	5	4
Role						
Support staff ^b	3	1	3	1	2	-
Teaching staff	1	1	1	2	1	-
Form tutor	1	1	-	-	2	2
Leadership role ^c	1	3	2	2	-	-
School governor	-	1	-	-	-	-
Admin staff	-	-	1	-	-	-

^aYear 13 no longer at school in July 2016

^bSupport staff members work in the support center

^cLeadership staff members include heads of year, heads of faculty

Table 2: Setting, context and implementation feature of restorative practice interventions from evidence-base (24)

Reference, type of paper	Setting ^a	Context ^b	Implementation				
			Implementation Theory ^c	Implementation Process ^d	Implementation Strategy ^e	Implementation Agents ^f	Implementation Outcomes ^g
Bitel (2005) National evaluation report (21)	28 schools: 19 restorative & 9 control, mixed urban and rural locations and mixed in England and Wales, UK	<p><i>Political:</i> National commitment to addressing bullying and anti-social behaviour.</p> <p><i>Ethical:</i> Britain values the idea of citizenship - included in PSHE, part of the educational curriculum.</p>	Unclear	Intervention components varied, process of implementation unclear, but involved collaborations with youth offending teams and training.	Schools determined the restorative approach they chose to adopt; senior leadership commitment	Government funding, youth offending team staff, school staff, third sector staff (e.g. Connexions), students, parents	High levels of staff and student satisfaction with approach; whole school approach seen as more effective to address antisocial behaviour than partial adoption.
Bonell et al (2015; 2019) Randomised controlled pilot trial; effectiveness trial (12, 18)	8 schools with "satisfactory" performance as determined by the schools regulatory body (Ofstead), in London and south east England, UK	<p><i>Political:</i> WHO recognition of bullying and significant impact on adolescent health.</p> <p>British policy context and national initiatives aim to reduce bullying in schools - e.g. 2009 Steer review reported on wide variation in approaches taken by schools to address bullying.</p>	Unclear	Schools recruited to take part in pilot trial, intervention inputs provided and school responsible for implementing these.	Intervention inputs: funding, school needs assessment, external facilitator to build commitment among staff, specialist training or staff, training for students.	Funding body, external facilitator, staff and students at schools.	Intervention inputs reported as acceptable to staff and students.
Kane et al (2009) (25) McClusky et al (2008) (19) Pilot evaluation report	18 schools with varying rates of exclusion across 3 local authorities in Scotland, UK. Schools situated across rural and urban locations with varying degrees of deprivation. Mix of primary, secondary and one special school.	<p><i>Political:</i> Scotland has distinctive social history and educational priorities that draw on humanistic perspectives and sociological understandings of schooling and academic attainment.</p> <p>Most local authorities practice restorative justice to complement Children's Hearing</p>	Unclear	Initiation of restorative practice through a government funded pilot scheme; adaptation of restorative practice to local school needs depending on existing ethos and practice; adaptation of school processes in some schools.	Training and skill development of school, staff and pupils rather than use of external facilitators.	Scottish government; local authorities; primary and secondary schools; staff and students.	Mixed responses from staff across different schools regarding acceptability of the approach. Some evidence of uptake, but unclear acceptability of implementation processes.

		<p>system. Policy context well aligned with restorative principles – including new initiative in 2002: Better Behaviour, Better Learning</p> <ul style="list-style-type: none"> • <i>Ethical</i>: Recognition that restorative practice is fair and just e.g. approaches advocated 					
Skinns et al (2009) (22) Evaluation report	6 Mixed comprehensive schools (700-1200 pupils) in South Bristol, UK	<p><i>Epidemiological</i>: Local: South Bristol location chosen, as schools here had the highest rates of exclusion across all schools in Wales and England. Schools described as “problematic”.</p>	Culture change stimulated either by policy change, or by initially testing the approach before committing to adopting it at system level.	Different processes: one school integrated approach into school policies and focused on all staff training; other schools aimed to embed practice in small “pockets”	Training provided for staff at two levels	Community interest group, funders, schools, students	Quality of restorative practice reported to be higher in schools that adopted a whole schools approach vs those that adopted “pockets” of practice; mixed reception by staff to the model
Wong et al (2011) (23) Natural experiment	4 secondary schools with equivalence academic attainment records in Hong Kong	<p><i>Epidemiological</i>: Increase in bullying at school in Hong Kong</p> <ul style="list-style-type: none"> • <i>Ethical</i>: Social preference not to criminalise bullying and aggression in Hong Kong 	Unclear	Unclear	All staff trained in a whole school restorative approach.	Unclear, but varied. The one school that fully adopted the approach trained staff and students.	Of 4 schools, 1 school adopted approach fully, 2 adopted partially and 1 did not adopt approach; Unclear how implementation was experienced.

^a The specific physical location in which the intervention is put into practice; ^b Socio-economic, socio-cultural, ethical, legal, political epidemiological, geographical domains; ^c Attempts to explain the causal mechanisms of implementation; ^d Social processes through which interventions are operationalized in an organization or community; ^e Methods and means to ensure the adoption and sustainment of interventions; ^f Individuals and organisations engaged with deciding to implement a given intervention, implementing it or receiving it; ^g The result or implication of the implementation effort

Table 3: Logic model for Restorative Practice Intervention

Inputs	Whole school restorative activities	Programme Theory (1)	Programme Theory (2)	Outcomes
Initiation funding	Individual-level <i>Student-staff:</i> Restorative conversations; Student needs-led approach to learning	Intra-personal skill development - empathy, accountability		Primary outcome: improved student mental health and wellbeing (physical, emotional, social).
Staff training in restorative approach	<i>Student-student:</i> Peer mentoring <i>Staff-staff:</i> Peer mentoring	Enhanced confidence, self-efficacy and sense of achievement in learning among students		Improved staff mental health and wellbeing: reduction in staff absence due to illness.
Policy and systems alignment	Group level <i>Classroom:</i> Circle time; Rotational seating plans	Enhanced confidence, self-efficacy and reduced stress among staff		Increase in student attendance.
Benchmarking	<i>Staff:</i> Circle time structure for meetings and policy development	Trustworthy,, supportive, respectful relationships between:	School connectedness for students and staff	Reductions in student suspension & permanent exclusion.
	<ul style="list-style-type: none"> • Student-staff • Student-student • Staff-staff 		Student engagement in learning and pride in success.	Reduction in referrals to youth justice for students.
	<ul style="list-style-type: none"> • Distributive leadership • Language of school reflects restorative principles • Student involvement in high stakes school level decisions, e.g. school development planning. • Memes diffuse ideas across the school, e.g. school motto: "learning to lead our lives", values part of common language of school. 	Improved relationships between school and community.	Enhanced school reputation in community and student/staff pride in school.	Reduction in bullying (but also more reports of inappropriate behaviour).
	Community level	Improved relationships between school and families		School culture - supportive, welcoming, trustworthy, safe and secure - promotes integrated learning academic attainment
	<ul style="list-style-type: none"> • Engagement with families • Engagement with local community 			School oversubscription
Contextual characteristics that influence implementation and programme theory				
School level		Re-enforce and promote cultural shift	Undermine or threaten cultural shift	
		<ul style="list-style-type: none"> • On-going senior leadership support and investment • Monitoring and evaluating • Self-assessment and development e.g. inset day meetings • Revision of policy documents as active process 	<ul style="list-style-type: none"> • Staff changes - challenge with continuity • Sub-culture of staff resistance - challenge with consistency 	
Policy and political level		Contextual drivers that value restorative approach, e.g. the Donaldson review recommending curriculum reform in Wales	Contextual factors that threaten the approach, e.g. school accountability measures that focus on student results at the exclusion of other metrics.	

Table 4: Setting, Context and Implementation Features of Restorative Practice Intervention (24)

Setting ^a	Context ^b	Implementation				
		Implementation Theory ^c	Implementation Process ^d	Implementation Strategy ^e	Implementation Agents ^f	Implementation Outcomes ^g
<p>Mixed comprehensive, secondary school (1700 students) in Monmouthshire, Wales. Approx. one quarter of students live in England. Lower than the national average in terms of social deprivation.</p> <p><i>Interactions</i></p> <p>Perception among external stakeholders that restorative practice can work in the school because relatively low social deprivation, with less antisocial behaviour. Also assumption of greater cohesion in family and community groups.</p>	<p><i>Contextual features</i></p> <p>International: OECD countries compare academic attainment of school students using the Programme for International Student Assessment (PISA)</p> <ul style="list-style-type: none"> Regional: Wales score the lowest of UK countries on PISA rankings, below the OECD countries. Strong policy focus to enhance academic attainment. Regional: Independent curriculum review in Wales the recommended changes in approach to attainment and focuses on promotion of health and wellbeing. Regional: New legislation in Wales “Well-being of Future Generations Act, 2015” sets legislative frame for public bodies to act in a sustainable way. And one that promotes health and wellbeing. <p><i>Interactions</i></p> <ul style="list-style-type: none"> Embedding of restorative practice as core part of pedagogy well aligned with 	<p>Diffusion of innovation, where restorative practice introduced by the senior leadership and recognition given to staff groupings that would adopt the intervention at different times and in different ways, e.g. “early” vs. “late” adopters.</p> <p>Theory used to guide and frame experience of implementation over time. Senior leadership use terminology to explain process.</p>	<p>Implementation process described as “organic”. Started with staff engagement and moved to re-alignment of school policies and clarification of school values through to establishing restorative practice in the form of routines that will sustain the intervention.</p>	<p>Funding, training of staff and students, focus on engagement of innovators and early adopters, use of form tutors to build staff-student class relationship, curriculum review, policy and systems alignment</p> <p>Strategy involves embedding organisational structures that sustain restorative practice e.g. staff selection, expectation of staff training, the way in which staff meetings are conducted, classroom routines, how the student council is run, expectation of student involvement in high stakes decisions, “memes” e.g. school motto and values and the active linking of these to guide behavioural expectations</p>	<p>Government funding, school staff, governors, students, parents, multi-agency workers</p>	<p>Intervention is fully embedded in the school.</p>

<p>Welsh curriculum review and with new legislative context, but competing pressures regarding academic attainment and school regulatory body targets create opposing tensions and demands.</p> <ul style="list-style-type: none"> Structures to sustain the intervention require reflexive practice and adaptability, and these mechanisms for, part of the intervention (on-going monitoring, review and training) 					
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^a The specific physical location in which the intervention is put into practice; ^b Socio-economic, socio-cultural, ethical, legal, political epidemiological, geographical domains; ^c Attempts to explain the causal mechanisms of implementation; ^d Social processes through which interventions are operationalized in an organization or community; ^e Methods and means to ensure the adoption and sustainment of interventions; ^f Individuals and organisations engaged with deciding to implement a given intervention, implementing it or receiving it; ^g The result or implication of the implementation effort

Figures

1. Identification of innovative local practice
2. Scoping review to identify need; programme theory; contextual characteristics; implementation; and outcomes
3. Establishment of a TransDisciplinary Action Research (TDAR) group
4. Co-production of intervention logic model with stakeholders;
5. Confirmation of logic model with stakeholders
6. Planning for intervention refinement
7. Planning for feasibility and outcome evaluation

Figure 1

Procedure for conducting the pragmatic formative process evaluation for intervention development and evaluation

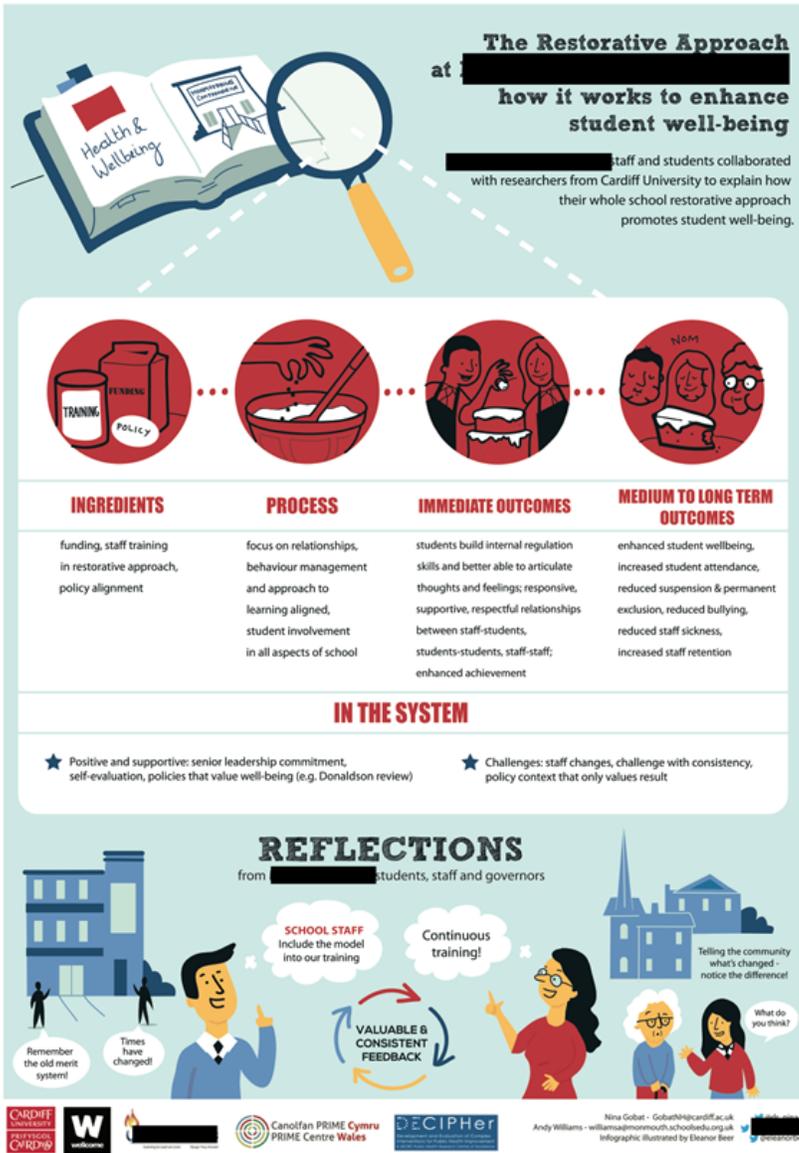


Figure 2

Visual minutes of the whole school restorative approach logic model and stakeholder reflections.