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Developing a 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 We conducted a pragmatic formative process evaluation 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 researchers, policy-makers and practitioners may undertake in the development and evaluation of interventions already in routine practice: 1) identification of innovative local practice; 2) scoping review to identify intervention theory of change; antecedent and emergent 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. The phases of this model are seen as being iterative. 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 an exemplar of how such an evaluation may be undertaken.

Developing a 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:** We conducted a pragmatic formative process evaluation 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 researchers, policy-makers and practitioners may undertake in the development and evaluation of interventions already in routine practice: 1) identification of innovative local practice; 2) scoping review to identify intervention theory of change; antecedent and emergent 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. The phases of this model are seen as being iterative. **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 an exemplar of how such an evaluation may be undertaken.

Key words: Process evaluation; intervention development; restorative approach; schools-based intervention; mental health; methodology

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 (Wight et al. 2016; Hawkins et al. 2017). Despite offering important theoretical, methodological and pragmatic guidance, these frameworks have been applied mainly to the development of de novo, research-led interventions rather than to the retrospective modelling and refinement of approaches already in routine practice.

There are distinct benefits of evaluating locally embedded interventions, which have not yet been fully exploited by the research community. 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 meaningful engagement with stakeholders' theorisation of causal pathway as the innovation is a response to their contextually informed understanding of the problem. Such interventions will also indicate how mechanisms of change and implementation practices may be operationalised within real world settings. In accordance with realist (Fletcher et al. 2016; Pawson 2013; Pawson and Tilley 1997) and complex systems perspectives (Hawe et al. 2004, 2009), we can suggest that intervention outcomes are generated through the interaction of causal mechanisms and contextual characteristics. In the case of routine practice, much of the dynamic interplay between an intervention's theory of change and context are already emergent. This allows us to 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. Through this empirically informed understanding we can then work with stakeholders to identify system modifications required to support intervention functionality, or intervention modifications that will enhance contextual fit without compromising the theory of change.

Pragmatic formative process evaluations have been proposed as an approach to guide the retrospective modelling and refinement of routinised interventions (Evans et al. 2015). Serving as a hermeneutic tool, the proposed evaluation states a number of evaluation phases that can be derived from frameworks used to develop de novo interventions. These include but are not limited to: conduct of a review to map the

nature of the problem and potential intervention responses; establishment of a Transdisciplinary Action Research (TDAR) group 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 (Hawkins et al. 2017; Wight et al. 2016). However, additional stages likely need consideration in pragmatic formative process evaluations. These may include the identification of local innovative practice and the iterative processes of engaging stakeholders in intervention theorisation and modelling where ownership lies with local practitioners.

To date there remains a paucity of empirically worked examples of how to conduct pragmatic formative process evaluations of complex population health interventions. The present study starts to address this gap. It presents the phases undertaken in identifying a routinised school-based restorative practice intervention and establishing a TDAR group to oversee the theorisation, modelling and confirmation of the local innovation, in addition to planning for future feasibility or outcome evaluation. The intervention is a system-level approach to restorative practice that has been delivered in a secondary school in Wales since 2008. It comprises a suite of activities spanning the range of socio-ecological domains (i.e. intrapersonal; interpersonal; organisational; community), with the primary aim of improving student mental health and wellbeing. The underpinning theory of change, contextual influences, implementation practices secondary outcomes and potential unintended pathways had not been fully articulated prior to this study.

Methods

A seven phased framework was applied to model and refine the intervention and plan further feasibility and outcome testing. These were 1) identification of innovative local practice; 2) scoping review to identify intervention theory of change; antecedent and emergent contextual characteristics; implementation and outcomes; 3) establishment of a TDAR group; 4) co-production of an intervention logic model with stakeholders; 5) confirmation of the 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 (Yazan 2015). The case selected was one mixed gender secondary school in Wales which had undertaken innovative practice around student mental health and wellbeing. This school serves students aged 11-18 years. 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, and an above average proportion of students achieving 5 GCSEs at Grade A*-C including English/Welsh and Mathematics (2016 Welsh average 57.9%) (Welsh Government 2018). The school was identified and recruited via the national School Health Research Network infrastructure. On identification of the school, a scoping review was undertaken to verify innovation selection by confirming that school-based restorative approaches tend to have underpinning theories of change that are associated with improved student-level health outcomes and no major tendencies to unintended effects or exacerbation of inequalities (C. Bonell et al. 2015).

Participant sample and recruitment

Staff and students across the case study school provided data at phase 4 and 5. The demographic characteristics of participants at each phase 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 also purposively sampled to for maximum variation in role and length of employment. Of the 18 staff involved, 9 participated at both phase 4 and 5. Where possible we sought to retain consistency in participation across the phases but did recruit additional individuals at phase 5 to encourage new reflections. Staff and students were recruited through the study gatekeeper, who was also a member of the research team. This individual was provided with the sample frame to ensure diversity in participants. Two members of the school's leadership team were also interviewed.

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 from the extant research evidence, which was used to start discussion. The topic guide considered: perceived theory of change; outcomes; implementation; key contextual characteristics; experiences of intervention delivery/participation; 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 obtained. All participants were provided with information sheets prior to study commencement with the opportunity to ask any questions. Written informed consent was obtained from all participants, with opt-out guardian consent also being secured for all students.

Data Analysis

Data were audio recorded, transcribed verbatim and reviewed for accuracy. Data collection and analysis were conducted iteratively, with the data from focus groups at phase 4 being used to inform the questions asked during phase 5. Thematic analysis was conducted (Braun et al. 2014). Data were initially coded for pre-specified codes that mapped onto the main domains of a logic model (e.g. theory of change; implementation; contextual characteristics). Additional codes were developed in vivo. Coding was undertaken by one researcher and verified by a second. Codes were compared and contrasted to develop themes. The two corpus 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 candidate themes was

confirmed by the wider research team. NVivo10 software was used to support analyses (QSR International 2008).

RESULTS

The results describe the seven phased framework utilised to identify, model and refine the whole-school based restorative approach (Figure 1). These phases are not intended to be sequential but iterative, with stages 4 and 5 particularly necessitating revisiting on a number of occasions.

1. Identification of Innovative Local Practice

The first phase is to identify innovative local practice that warrants progression to theoretical modelling, refinement and outcome evaluation. We identified the case study intervention through the DECIPHer research centre hosted School Health Research Network infrastructure (SHRN) (Murphy et al. 2018). SHRN comprised 165 of all secondary schools in Wales (N=212) at the time of study, with representation from all 22 local authority areas. It seeks to optimise research collaboration between researchers, policy-makers and practitioners, particularly in regard to knowledge translation. 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 health and wellbeing. The case study intervention 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 relevant academic contacts to further scope out collaboration and assess the suitability of pursuing evaluation of this specific approach.

On deciding to progress with a research collaboration, we considered the following key aspects of the intervention, system and extant research: 1) *Feasibility of theory modelling:* We questioned if we could establish that an "intervention" (regardless of type) was in use and that we could, in conjunction with stakeholders, characterise intervention theory, outcomes, implementation and key contextual characteristics. 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 we felt that there was clear delivery of a restorative approach and there was adherence to core processes. 2) *Feasibility of implementation and scale-up:* We established that the restorative practice had been routinely used and resourced for a substantial period of time (8 years). We further considered the future traction of the intervention and if it could be scaled-up for evaluation beyond the single case, 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 indeed 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:* We consulted with the school that they were prepared to participate in a research study and would potentially be committed to future research.

2. *Scoping review to identify intervention theory of change; outcomes; antecedent and emergent contextual characteristics implementation*

The second phase involves a scoping review of the existing scientific research to develop a preliminary understanding of the intervention and to construct an initial logic model, which can serve as a normative referent to model the real-world case example. A review also supports consideration of the effects of such interventions, and potential unintended pathways that should be attended to in the primary research (Chris; Bonell et al. 2015). Table 2 presents key retrieved studies from our scoping exercise that describe restorative approaches and conducted process and/or outcome evaluations.

Theory of Change and Outcomes: Across the studies there was a lack of specificity around the underpinning theory of change. 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 relationships repair and conflict resolution. (Hopkins 2006; Morrison et al. 2005). 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 (C. Bonell et al. 2015), 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, with modification across settings to align with localised problems (McCluskey et al. 2008; Shaw 2007). Evaluations of school based restorative approaches have identified a range of measurable intervention outcomes (Bitel 2005; C. Bonell et al. 2015; McCluskey et al. 2008; Skinns and Hough 2009). At the student level these are: mental health and wellbeing (C. Bonell et al. 2015); social and emotional competencies, including empathetic attitudes and self-esteem (Wong et al. 2011); academic attainment (Skinns and Hough 2009), incidences of bullying (Wong et al. 2011); and school exclusions (Skinns and Hough 2009; Bitel 2005). There has been limited consideration of staff level outcomes. Unintended pathways remain largely underdeveloped.

Antecedent and emergent contextual characteristics implementation: We mapped key system-level characteristics that might interact with the theory of change across different contexts and modify planned implementation. We employed the Context and Implementation of Complex Intervention Framework (CICI) (Pfadenhauer et al. 2017) as a hermenutic tool for mapping contextual and implementation factors (Table 2). Although the extant evidence base did not map onto all specified domains, a number of influences emerged across papers. *Epidemiological:* Implementation had been supported by an increase in the prevalence of bullying within the specified context, leading to more support for such approaches (Skinns and Hough 2009; Wong et al. 2011). *Political:* There had been increased support for restorative approaches due to an alignment with political/policy priorities, which had often led to direct government funding (C. Bonell et al. 2015; Bitel 2005; Kane et al. 2009; McCluskey et al. 2008). *Ethical:* Restorative approaches reflected belief in a fair and just society where citizens are respected. Such interventions are viewed as a more ethical approach than punitive or criminalised responses (Bitel 2005).

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

The third phase is establishment of a TDAR Group, which is intended to support the cultivation and sustaining of effective collaboration between research, policy, frontline staff and community stakeholders (Stokols 2006; Stokols et al. 2013). TDAR groups facilitate co-production as non-academics are active agents in research and they strive for equal, mutually beneficial and reciprocal relationship that value public, practitioner and policy-maker knowledge and experience to the same degree as academic knowledge (Heaton et al. 2016). These groups have increasingly been deployed in guidance around intervention development to ensure that approaches are maximally responsive to the contexts and populations where they are to be implemented (Wight et al. 2016). Within a pragmatic formative process evaluation, TDAR groups 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. We established a TDAR group comprising researchers and members of the school community, which routinely met throughout the duration of the study to guide research conduct. The group also supported planning around dissemination and consideration of future evaluation.

4. *Co-production of Intervention Logic Model with Stakeholders*

The fourth phase involves co-production of a logic model with key stakeholders to identify the underpinning theory of change, outcomes, and contextual characteristics that impact upon causal pathways and implementation practices. Participants developed the logic model from the initial construction undertaken by researchers following the scoping review, and using the Wisconsin template (Wisconsin-Extension 2018). The output of the logic model from both phase 4 and phase 5 is presented Table 3. A more detailed consideration of pertinent contextual factors, as mapped across the CICI framework, is presented in Table 4.

Theory of change: Participants identified the range of activities that a school may undertake at the individual, group, organisational and community level, with interactions across these levels. The central mechanism activated by these activities is a change in the nature of relationships, particularly between

staff and students: For example, circle time redresses power imbalances, creating more supportive interactions:

> ***Staff member:*** *...the starting with them ... was to have a circle time 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, which was explained as the central process underpinning observed outcomes. This 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*.'

Outcomes: Logic modelling indicated three key sets of medium-term outcomes, which are largely congruent with existing restorative approaches. First, both student and staff reported feeling that the intervention had improved student mental health and wellbeing:

> ***Student (year 10):*** *I think wellbeing in the school has 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.*

Second, there was indication of improved staff wellbeing, with participants claiming increased confidence, whilst having the opportunity and skills to express their thoughts and feelings following student conflict had reduced stress:

Staff member: *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.*

Third, was a range of educational outcomes, relating to attainment, attendance and fixed-term and permanent exclusions. Involvement in classroom and school level decision-making, combined with support teacher-student relationships, was considered to develop students' confidence to take ownership of their learning, request help when required, and take risks with more complex topics as they were less concerned about making mistakes: Improved relationships had also motivated some students to attend school more frequently. Additionally, students felt instilling of restorative practices had improved the school's reputation in the community, and relative to other local schools, which had increased school connectedness, and thus motivation to engage in positive behaviours and improve academic attainment:

Student (year 9): *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 positive intervention outcomes, participants considered potential harms, which have largely been overlooked in 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 a restorative approach had led to over-subscription and placed a resource demand on the school.

Antecedent and emergent contextual characteristics and implementation: Drawing on the factors identified in the scoping review as a starting point, the co-production process explored key contextual features that participants felt impacted on implementation and the theory of change. *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 member: *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). *Socio-economic:* Participants acknowledged that the case study school had a lower than national average level of free school entitlement and 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 member: *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, they're 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 were indications that staff could orientate to the default approach, which could lead to extensive variation in practice:

Staff member: *– 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 approach and staff commitment to training and delivery. Moreover, the school adopted an organic diffusion process, initially securing training to a small team of pastoral staff to ensure their buy in and capacity for modelling the restorative 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 higher level of the socio-ecological domains rather than inter-personal aspects, 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 relational dynamic:

> ***Staff member:*** *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.*

Additional processes and activities elicited during this phase are presented in Table 3.

6. *Planning for Intervention Refinement*

The sixth phase shifts towards prospective intervention developmental work, and planning for the refinement of intervention. We hosted a knowledge exchange event at the school site 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 reach consensus and verifying the underpinning causal mechanisms of the intervention, ensuring that the research team who interpreted the data, and the TDAR group who support this process, had an adequate understanding of the intervention. Second, by highlighting where there remain 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 causal pathways were not being disrupted. Third, the event served to strengthen partnership between researchers and the school. Fourth was to reassert the emotional investment of stakeholders, which is important to the continued delivery of the intervention (Rogers 2010). To progress to further evaluation, where the school may be required to support the sharing and delivery of practices within other institutions, we deemed it important that 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.

7. Planning for Outcome Evaluation

The seventh phase comprises planning for future outcome evaluation if appropriate. In some instances the prior developmental phases may necessitate revisiting multiple times before phase 7 can be considered. Where outcome evaluation is warranted, the type of evaluation would be most suitably assessed against the phases of evaluation proscribed by the MRC: pilot and feasibility trial, a randomised controlled trial; natural experiment or other quasi-experimental design; and then longer-term implementation evaluation (Fletcher et al. 2016; Peter. Craig et al. 2008). In this case study, planning is primarily being conducted through the TDAR group, drawing on both practice and academic expertise to assess if the intervention is sufficiently understood to progress to outcome evaluation and

the appropriate study design that might be employed. The SHRN infrastructure offers a particular opportunity to continue with pragmatically orientated innovation evaluation, through the conduct of pragmatic development, feasibility, effectiveness and implementation studies. As of 2018 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 outcomes. As popular innovations, such as that selected for the case study, are often gaining traction within systems, it is imperative that we have responsive study designs. Exploitation of routine data, such as that collected through the SHRN survey data offers such responsivity, although the evidence generated is 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 (Wight et al. 2016; Hawkins et al. 2017). 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 interventions 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 (Pfadenhauer et al. 2017; Craig P et al. 2018; G. Moore et al. 2018). In the event of routinised practice, many of these contextual contingencies are already emergent or even established, allowing us to foreground contextual factors. Thus, beyond offering a fortuitous opportunity to develop contextually sensitive, feasible and acceptable interventions, such studies offer significant insight into the systems that we are aiming to disrupt.

The case study intervention, a school-based restorative 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 those evaluated in the INCLUSIVE trial (C. Bonell et al. 2015; Bonell et al. 2018). While many of these studies have started to map key system influences that may moderate the intervention's theory of change, this case study is particularly insightful as it presents established contextual characteristics eight years into intervention implementation. Interestingly, many of the challenges around implementation are enduring, and reflect issues with school-based mental health interventions identified within the context of outcome evaluations. These include key socio-cultural factors, such as the entrenched educational ethos and pedagogic approaches (Humphrey et al. 2013). Such findings also illustrate the importance of the active and dynamic process of 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 allow us to see the evolution of contextual factors and how interventions may respond to and accommodate them (Pfadenhauer et al. 2017)

The seven phases of intervention modelling and refinement are particularly focused on the elicitation of these contextual contingencies. To ensure this, meaningful co-production must serve as a central feature. As with other developmental frameworks, we recommend establishment of TDAR group to ensure that the diverse range of stakeholders invested in the intervention are adequately represented (Stokols 2006; Hawkins et al. 2017). Presence of this group can help ensure that phases of evaluation privilege co-production and 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 conducted scientifically robust evaluation. One of the key tensions between these domains is the timeliness of generating research evidence, and a perceived lack of responsiveness by the research community. Efforts to resolve these inconsistent needs have increasingly focused on quasi-experimental designs, with natural experiments being used to evaluate policy innovation (P.; Craig et al. 2012). 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 research by privileging with the wealth of local innovation that has already gained traction within real world settings.

There are a number of limitations that should be acknowledged, both in relation to the proposed framework for conducting a pragmatic formative process evaluation and the specified case study. First, as identified in existing developmental models focused on co-production, there remain uncertainties about the extent of opportunities provided for stakeholders to contribute to ensure a rounded and nuanced understanding of the intervention (Hawkins et al. 2017). In the current framework, three opportunities were provided. This may be inadequate in practice, and we would encourage the iterative use of the model 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 and higher than average level of academic attainment. The field of implementation has been increasingly concerned with the generalizability of evidence when interventions are scaled-up or scaled-out (Aarons et al. 2017), 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 more challenging to deliver the intervention in more socio-economically deprived settings, whilst extant research suggests that the quality of staff-students relationships is actually more of a priority in schools of a lower socio-economic status (G. F. Moore et al. 2017). Third, while maximum variation in sampling within the case study was pursued, the sample is limited by those who were prepared to participate. In particular, we mainly interviewed students who were engaged in classroom level activities, with fewer individuals who had received one-to-one support within the restorative approach.

Conclusions

The present study provides an empirically worked example of a pragmatic formative process evaluation to support researchers, policymakers and practitioners in the modelling, 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 (Hawkins et al. 2017; Wight et al. 2016), by addressing the specific developmental phases required for working with locally embedded innovation. It also responds to increase 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.

DECLARATIONS

Ethics approval and consent to participate: Ethical approval was obtained from Cardiff University School of Medicine Research Ethics Committee. Informed consent was obtained from all participants.

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

	Phase 4		**Phase 5**		***Participants who took part in both Phase 4 and 5***	
	Group 1	**Group 2**	**Group 1**	**Group 2**	***Group 1***	***Group 2***
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*	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[1]	3	1	3	1	*2*	-
Teaching staff	1	1	1	2	*1*	-
Form tutor	1	1	-	-	*2*	*2*
Leadership role[2]	1	3	2	2	-	-
School governor	-	1	-	-	-	-
Admin staff	-	-	1	-	-	-

*Year 13 no longer at school in July 2016

[1]Support staff members work in the support centre

[2]Leadership staff members include heads of year, heads of faculty

Table 2: Setting, context and implementation features, as per CICI framework (Pfadenhauer et al. 2017), of evaluations of restorative approaches in schools

Reference, type of paper	Setting[a]	Context[b]	Implementation				
			Theory[c]	Process[d]	Strategy[e]	Agents[f]	Outcomes[g]
Bittel (2005) National evaluation report	28 schools: 19 restorative approaches & 9 control, mixed urban and rural locations and mixed in England and Wales, UK	• *Political:* National commitment to addressing bullying and anti-social behaviour. • *Ethical*: Britain values the idea of citizenship - included in PSHE, part of the educational curriculum.	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) Randomised controlled pilot trial	8 schools with "satisfactory" of "good" performance as determined by the schools regulatory body (Ofstead), in London and south east England, UK	• *Political:* WHO recognition of bullying and significant impact on adolescent health. 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.	Markham and Aveyard's Theory of Human Functioning	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) McClusky et al (2008) 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.	• *Political:* Scotland has distinctive social history and educational priorities that draw on humanistic perspectives and sociological understandings of schooling and academic attainment. Most local authorities practice restorative justice to complement Children's Hearing system. Policy context well aligned with restorative principles – including new initiative in 2002: Better Behaviour, Better Learning • *Ethical:* Recognition that restorative practice is fair and	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.

		just e.g. approaches advocated					
Skinns et al (2009) Evaluation report	6 Mixed comprehensive schools (700-1200 pupils) in South Bristol, UK	• *Epidemiological:* 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".	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) Natural experiment	4 secondary schools with equivalence academic attainment records in Hong Kong.	• *Epidemiological: I*ncrease in bullying at school in Hong Kong • *Ethical:* 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: Case study school intervention logic model

Inputs	Whole school restorative activities	Immediate outcomes	Medium-term outcomes	Long term outcomes
Initiation funding Staff training in restorative approach Policy and systems alignment Benchmarking	**Individual-level** *Student-staff:* Restorative conversations; Student needs-led approach to learning *Student –student:* Peer mentoring *Staff-staff:* Peer mentoring ***Group level*** *Classroom*: Circle time; Rotational seating plans *Staff:* Circle time structure for meetings and policy development **Organisational level** • Distributive leadership • 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. **Community level** • Engagement with families • Engagement with local community	Intra-personal skill development – empathy, accountability Integration of values with action. Responsive, supportive, respectful relationships between: • Student-staff • Student-student • Staff-staff Enhanced confidence, self-efficacy and sense of achievement in learning among students. Language of school reflects restorative principles Improved communication between school and community.	Trustworthy, responsive, supportive relationships between: • Student-staff • Student-student • Staff-staff Student engagement in learning and pride in success. School connectedness Positive school and community relationships – enhanced school reputation. Improved family relationships.	Primary outcome: improved student metal health and wellbeing (physical, emotional, social). Improved staff metal health and wellbeing: reduction in staff absence due to illness. Increase in student attendance. Reductions in student suspension & permanent exclusion. Reduction in referrals to youth justice for students. Reduction in bullying (but also more reports of inappropriate behaviour). School culture – supportive, welcoming, trustworthy, safe and secure – promotes integrated learning academic attainment School oversubscription
	Dynamic and emergent system level influences			
	Re-enforce and promote cultural shift *School level* • 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 *Policy and political level* • Contextual drivers that value restorative approach, e.g. the Donaldson review	**Undermine or threaten cultural shift** *School level* • Staff changes – challenge with continuity • Sub-culture of staff resistance – challenge with consistency *Policy and political level* • 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, as per CICI framework, and interactions with the whole school restorative intervention in case study school

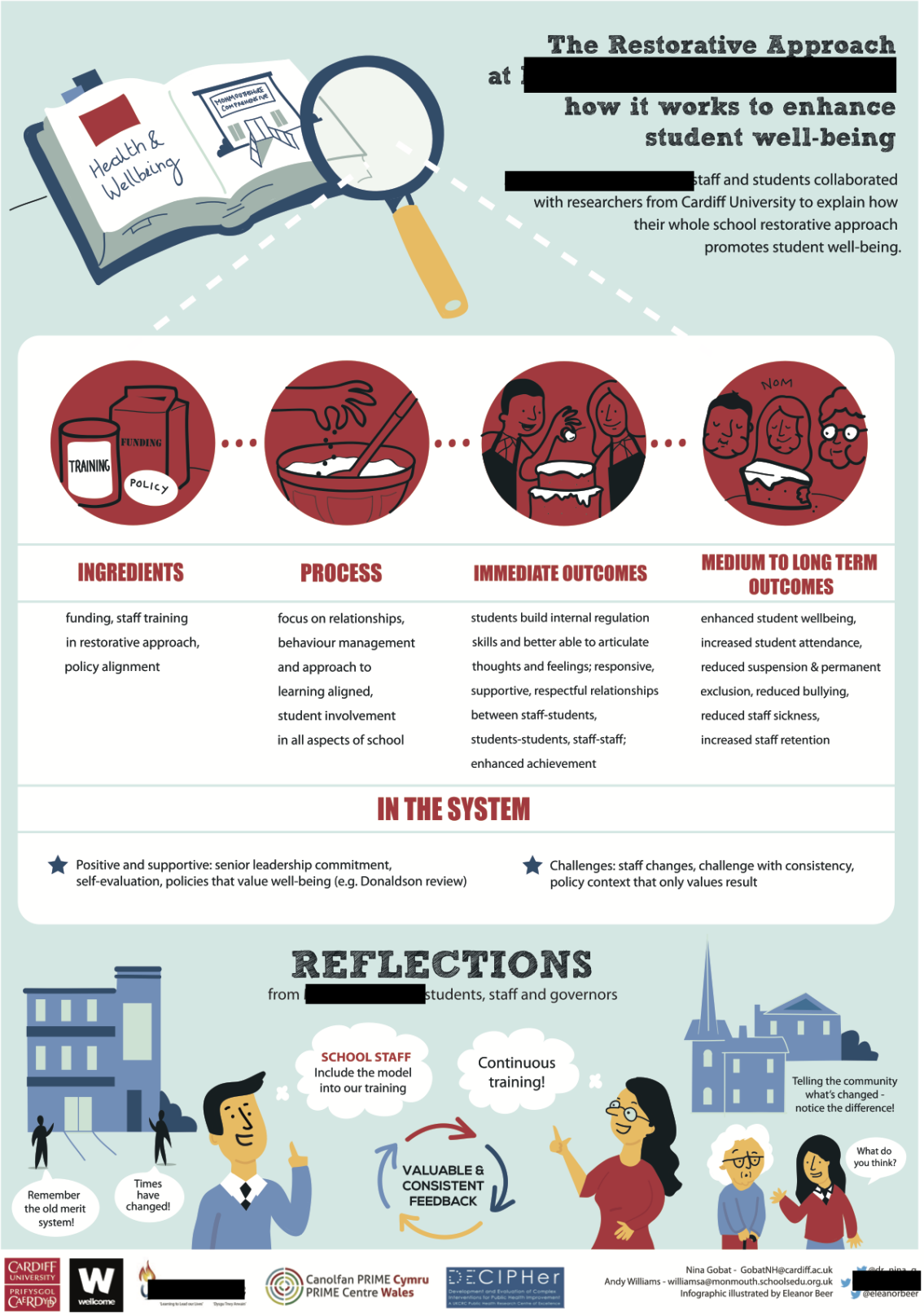
Setting[a]	Context[b]	Implementation				
		Theory[c]	Process[d]	Strategy[e]	Agents[f]	Outcomes[g]
Mixed comprehensive, secondary school (1700 students) in Monmouthshire, Wales. Approx. one quarter of students live in England. Lower than the national average in terms of social deprivation. *Interactions* Perception among external stakeholders that restorative practice can work in the school because relatively low social deprivation, with less antisocial behaviour. Also some assumption of greater cohesion in family and community groups.	*Contextual features* • International: OECD countries compare academic attainment of school students using the Programme for International Student Assessment (PISA) • 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. *Interactions* • Embedding of restorative practice as core part of pedagogy well aligned with curriculum review and with new legislative context, but competing pressures regarding academic attainment and school regulatory body targets create opposing tensions and demands. • Structures to sustain the intervention require reflexive practice and adaptability, and these mechanisms for, part of the intervention (on-going monitoring, review and training)	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. Theory used to guide and frame experience of implementation over time. Senior leadership use terminology to explain process.	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.	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 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	Government funding, school staff, governors, students, parents, multi-agency workers	Intervention is fully embedded in the school.

[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

Figure 1: Procedure for conducting the pragmatic formative process evaluation for intervention development and evaluation

1. Identification of innovative local practice
2. Scoping review to identify need; antecedent and emergent contextual characteristics; theory of change; 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 2: Visual minutes of the whole school restorative approach logic model and stakeholder reflections.



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