Feasibility study plan: Multi-site evaluation of practices

The Behavioural Insights Team

Project title	Multi-site evaluation of practices: Hospital navigators
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Study plan version history

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1.0 [*original*]	6 August 2021	
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Intervention

Overview of hospital navigator programmes

'Hospital violence navigator' ('navigator') interventions use 'teachable moments' of hospital attendance for violent injury to engage people at risk of further involvement in violence. The nature of support is tailored to the individual, and practice varies between delivery organisations, but fundamentally, it is a trauma-informed, community-based approach to support individuals to avoid future involvement in violence. Organisational variation notwithstanding, a navigator:

- recruits the patient as an intervention client,
- undertakes a brief motivational interview with the client and
- arranges for a follow-up contact post-discharge.
- in the community, provides pastoral and social support to the client and;
- signposts towards relevant support services where necessary.

The Thames Valley hospital navigator programme

The Thames Valley Violence Reduction Unit (VRU) have commissioned voluntary sector organisations to deliver navigator interventions in five hospitals. Navigators form a support service that is independent of healthcare and criminal justice services for those who have been victims of violence. The programme in Thames Valley is volunteer-led, and will be conducted across five hospitals ('sites'), each of which will be partnered with a delivery partner. Delivery partners (DPs) are responsible for recruiting, training and organising volunteers to attend navigator shifts at the hospital.

The hospitals, delivery partners and initial estimates of eligible populations (including under-18s as YEF's population of interest) are summarised in Table 1 below. Note that these figures are for violence-related injuries but *do not include self-harm*, which would also be in scope.[1]

[1] Using the WHO definition of violence.

Table 1: Navigator hospitals, DPs and eligible population estimates

Hospital (Hospital trust)	Navigator delivery partner	Violence-related *attendances* per year (under 18s)	Violence-related *admissions* per year (under 18s)	Estimated one-year reattendance (under 18s)
1. Milton Keynes Hospital (Milton Keynes University Hospital)	YMCA	2,660 (452)	133 (23)	160 (27)
2. The Horton, Banbury, Oxon (Oxford University Hospitals)	Connection Support	1,400 (238)	70 (12)	84 (14)
3. The Royal Berkshire Hospital (Berkshire including West Berkshire NHS Trust)	Starting Point	1,540 (262)	77 (13)	92 (16)
4. The Stoke Mandeville Hospital (Buckinghamshire NHS Trust)	7Roadlight	2,380 (404)	119 (20)	143 (24)
5. Wexham Park Hospital (Frimley Health NHS Foundation Trust)	Aik Saath - Together as One	5,460 (928)	273 (46)	328 (56)
Total		**13,440 (2,284)**	**673 (114)**	**807 (137)**

Table note: Calculations based on 10yrs of A&E attendance data (n=53,536) at a large urban hospital (one-year reattendance for violent injury among children (<18yrs) was 6%; proportion of attendees <18 years was 17%) and ONS data on sharp-object related admissions for assault at hospitals in Thames Valley area.

As of early August, the DPs have all progressed in planning and delivering the programme, but the rate of progress and start-up challenges have varied across sites. Three of the DPs have a project coordinator, two are currently recruiting one (with responsibilities being held by stand-ins in the interim)[2]. Similarly, three sites are further along in volunteer recruitment and training. Two delivery partners have begun delivery in hospitals. We will monitor the progress of each DP and any implications for evaluation (see *Risks* section). Given that all sites are in the early stages of delivery, the support that will be provided during the feasibility stage to develop a theory of change will be iterative and involve refinements as delivery progresses, as DPs adapt their model in response to contextual factors at each site, and as practices to randomise and evaluate are identified.

[2] One delivery partner has had to start a new recruitment process after the departure of the previous project coordinator, and delays in delivery are expected relative to other sites.

Prior evidence and rationale for intervention

Interventions similar in setting (emergency departments, or EDs), delivery model ('navigators'), support offered (signposting and mentoring), and based on the same psychological behaviour change gateway (teachable moments) exist. But variation in interventions, outcomes and effects means there are gaps in understanding whether such programmes are effective, particularly for young people.

Evidence for navigators

The evidence base for hospital-based interventions in the UK is limited in spite of their adoption by hospitals across multiple localities (including Glasgow, Edinburgh and London) and public health advocates. UK analyses to date are primarily descriptions of service uptake with an adult population and a 2020 report noted no empirical data had been gathered (to date) for violence-related outcomes generated by such interventions (Wortley and Hagell, 2020).[3] Process data from Scotland and England reported that 60-75% of contacted patients engage with navigators (Goodall et al., 2017; NPC Associates, 2017).

The experience of injury from violence may present a 'teachable moment' in a person's life, during which their amenability to health-based intervention is elevated (Putle et al., 2014; McBride et al, 2003). That said, definitions and effectiveness of teachable moments for youth violence prevention in EDs vary, and most work in EDs relates to drug/alcohol prevention (Wortley and Hagell, 2020). Again, this project would help to better understand teachable moments as a window for behavioural change.

Mentoring schemes share many common elements with navigator schemes, and there is evidence they may prevent repeat victimisation, but this depends on the timing, approach and mentor-mentee relationship (Tolan et al., 2013). Mentoring schemes focusing on peer relations have been found to increase youth delinquency (Gottfredson, 1987; McCord, 2003), and some studies note that prevention programmes for young people were not as effective as 'care as usual' (De Vries et al., 2018), or were ineffective (Axford et al., 2021). Framing navigators as mentors needs further research, as the nature of the relationship is not clear-cut, and depends on levels of engagement. Again, this is a unique opportunity to understand that component of navigator programmes in multiple locations.

[3] There is general evidence on the effectiveness of hospital based violence prevention initiatives (HBVPI), but there are methodological limitations in that body of work (see Purtle et al, 2015; Snider and Lee, 2015; Floyd et al. (2021)). Economic evaluations suggest these programs could produce substantial cost savings for health care and criminal justice systems (Sharp et al., 2014).

Understanding mechanisms using behavioural science

Successful navigation likely depends on several factors related to the navigator: their background/credibility; how and when they are introduced to the client; conversational manner; how they frame discussions of injuries; and how they present available support. Insights from behavioural science and research from similar contexts can help increase the likelihood that navigators build/maintain rapport. For example, intense experiences are remembered better ('peak-end' rule; Redelmeier & Kahneman, 1996), which may be one mechanism for building/maintaining rapport post-incident.

Evaluating practices

For sites where trials are possible, our proposed methodology following the feasibility stage mirrors Vil et al. (2021), which randomised variations of practice elements within EDs.[4] Practice evaluation is more reflexive than evaluating a manualised intervention. *What* should happen and *how* may not be clearly set out. Emphasis is on *what* is done, *when*, by *whom*, under *what* circumstances/context, particularly with reference to theories of change (Weiss, 1997), unintended harms (Bonnell et al., 2013), and allowing 'sense-making' by frontline staff and researchers (Reynolds et al., 2014). This knowledge, combined with the intervention (and its context) pushes us towards an approach sensitive to several factors:

- Evaluation of practice requires a mix of informal and formal methods.
- Stakeholders need to be aware of evaluation early on and embed evaluation into practice through reflective surveys/interviews/observations focused on measuring progress (Lyons & McQuillin, 2021).
- Youth-crime prevention uses a degree of flexibility/sensitivity to situations. Tools such as a theory of change/logic model help to elicit core/peripheral components, as well as an understanding of *how* putative changes arise and determining variation/adaptation across different contexts (Haynes et al, 2015).
- Using a framework to assess implementation, such as the Consolidated Framework for Implementation Research (CFIR)[5] can help ensure there is a balance of site context and comparable indicators across sites.
- When measuring practice impact, there are trade-offs regarding what is observable/measurable, and *whether measurable in evaluation timeframes.* Triangulating multiple data sources (quantitative/qualitative); using administrative/behavioural outcomes; and recording dosage, reach and mechanisms of change can all improve the validity/reliability of findings (Salkind, 2010).

[4] Vil et al (2021) refer to methodological limitations, notably that RCTs in this field test hospital interventions that vary from site-to-site, limiting our ability to determine treatment effects. As such, increased homogeneity of intervention and our proposed multi-site design would add significantly to knowledge of 'what works'.

[5] https://cfirguide.org/

Therefore, while there is enthusiastic adoption of hospital-based navigation interventions and a theoretical foundation for why they may be effective, there is limited evidence on their efficacy. There is also a need to develop approaches to evaluate practice-based interventions such as hospital navigator programmes. This research is an opportunity to contribute to filling these gaps, and the feasibility stage will help to refine our proposal for taking up this opportunity.

Research objectives

The feasibility stage has three primary objectives:

1. **Theory of change:** Develop a theory of change describing the hospital navigator programme's intended activities and pathways to target outcomes, within and across sites.
2. **Implementation:** Examine implementation relative to the theory of change within and across sites, and support refinements based on any gaps identified or opportunities to apply behavioural insights.
3. **Evaluation feasibility:** Assess the feasibility of evaluating the impact of i) variations in practices used in the hospital navigator programme, and ii) the overall programme.

Objective 1: Develop a theory of change within and across sites

Rationale

A theory of change is often the first step in intervention development/evaluation as it sets out steps in the change process and provides the basis for explaining 'how' change will come about through action(s) (De Silva et a., 2014). The theory of change for the Thames Valley navigator programme cannot be inferred from existing literature, and there are several factors to consider in how the intervention is framed for clients.[6] The theory of change developed together with the VRU and DPs will serve as the foundation for examining

[6] The suitability and consequences of targeting victims of violence as suitable candidates for violence interventions needs to be understood because it could play an important role in how the nature of the intervention is communicated, how rapport is established and, directly or indirectly, how responsibility for being a victim is attributed. In the hospital-based brief interventions or motivational interviewing interventions that have demonstrated efficacy and/or effectiveness, the intervention mechanism has been that an individual's health behaviour (e.g. alcohol consumption) has led directly to their hospitalisation, i.e. they caused the harm to themselves. In a hospital-based violence intervention, in provocative language regarded by some as 'victim blaming', the patient's behaviour could be seen to have 'precipitated' their injury. Given, also, that these other brief interventions were, almost exclusively, evaluated with an adult population, extrapolation of the components of effective behaviour change to an adolescent population is not advisable.

implementation, identifying possible refinements to programme design and delivery, and designing the impact evaluation.

Objective 2: Examine implementation relative to the theory of change and recommend refinements

Rationale

Based on the theoretical model of how the intervention is intended to be delivered captured in the theory of change, we will assess implementation in order to identify deviations from the theory of change and challenges in programme delivery. The lessons generated will be addressed through recommendations on possible programme refinements to better adhere to the theory of change, or revisions to the theory of change to reflect the realities of implementation.

The research activities will examine multiple dimensions of programme implementation, which may include:

1. *Fidelity/adherence*: To what extent do implementers adhere to the intended delivery model?
2. *Dosage*: How much of the intended intervention has been delivered?
3. *Quality*: How well are the different components of the intervention being delivered?
4. *Responsiveness*: To what extent do targeted young people take up and engage with the intervention?
5. *Adaptation*: Are changes needed to accommodate context and population need?

Objective 3: Assess the feasibility of evaluating the impact of i) variations in practice and ii) the overall programme

Rationale

The feasibility assessment will consider the potential to evaluate (i) both variations in practice (i.e. do differences in how the navigator programme is delivered between navigators, shifts or recipients affect outcomes?) and (ii) the overall programme (i.e. does the navigator programme as a whole affect outcomes?). The assessment will be guided by the "success criteria" outlined in this feasibility study plan (see next section) and will shape the recommendation on whether and how to proceed with the evaluation in the next phase of the project.

For i) variations in practice, the feasibility assessment is likely to result in a decision between practices, rather than a binary 'go/no-go'. For example, some practices are likely to be easier to randomise, control delivery and measure outcomes for than others. For each navigator practice shortlisted, we will formulate a recommendation on whether to move forward with a multi-site trial, and justify the recommendation based on findings from the assessment. We will also aim to pilot any relevant evaluation-specific activities (e.g. data collection, randomisation).

We will also assess the feasibility of proceeding with a quasi-experimental design (QED) for evaluating ii) the overall navigator programme. This process will largely be driven by the available data and the applicability of different QEDs, which will be examined as part of the assessment against the "success criteria" below.

Success criteria

Recommendations on the approach for the evaluation phase of the project will be based on the criteria described below for each feasibility phase objective. This section also outlines the information that will be used to assess the programme against each of the success criteria, and how this information will be used.

Objective 1: Develop a theory of change within and across sites

Criteria 1.1 - Site-level theory of change*: a theory of change can be articulated for each site.*
A theory of change can be articulated for each site based on the VRU and DP's shared vision of the programme, the activities implemented, the outcomes targeted, and the mechanisms envisioned to influence these outcomes. There should be a pathway between navigator action(s) and the stated outcomes that is supported by a priori evidence of behaviour change.

Assessment against criteria: this criteria will be met if for each site, a theory of change can be agreed upon between the DP, hospital representatives, the VRU and BIT.

Criteria 1.2 - Programme-level theory of change*: a coherent programme-level (cross-site) theory of change can be established.*
A coherent overall (cross-site) theory of change can be established based on shared features and vision for the programme, including a common target outcome for the programme across sites (e.g., re-attendance at an emergency department within 12 months).

Assessment against criteria: this criteria will be met if a programme-level theory of change can be agreed upon between the VRU and BIT.

Objective 2: Examine implementation relative to the theory of change and support refinements

Criteria 2.1 - Fidelity & adaptation: *the programme is implemented as envisioned in the site-level theory of change, or the theory of change can be adapted to reflect adjustments in delivery.*
The delivery of the programme at each site adheres to the intended model described in the theory of change, and is adapted based on specific context and adjustment needs identified.

Assessment against criteria: this will be assessed using monitoring data available and qualitative data gathered during site observations, interviews and discussions with navigators, DPs and hospital staff. We will identify critical assumptions relative to activities and outputs that are necessary to achieving target outcomes through the pathways envisioned in the theory of change, and assess whether these assumptions fully, partially or do not hold. This criteria will be met if all critical assumptions fully or partially hold.

Criteria 2.2 - Responsiveness: *take up is sufficient to enable testing and refinement of implementation.*
There is a sufficient number of young people meeting the target criteria admitted at the hospital sites and/or referred to the programme based on the current recruitment strategy, and a sufficient number among them who take up the services offered as part of the programme, where sufficient is defined as enough to test and refine implementation.

Assessment against criteria: this will be assessed using programme data on the number of referrals received, and the number of young people sign-posted to services and engaged (i.e., approached to enroll in the navigator programme). The exact threshold will be set in consultation with the VRU and DPs based on their perceptions of the number necessary to fine tune the programme eligibility criteria, the referral process, and approach to engage young people.

Criteria 2.3 - Dosage & quality*: dosage and quality of delivery activities are sufficient to expect a potential impact on target outcomes.*
The services offered and taken up by programme participants are sufficient in terms of quantity and quality to expect a potential impact on target outcomes.

Assessment against criteria: this will be assessed using monitoring data available on services taken up, and qualitative data gathered during site observations and discussions with DP, hospital staff and navigators. We will also consult the literature to compare observed delivery with that of similar interventions. Dosage and quality thresholds for each activity identified as critical will be defined based on the insights generated, and we will assess delivery for each critical activity as fully, partially or not meeting the threshold. This criteria will be met if the delivery of all critical activities fully or partially meets the quality and dosage thresholds.

Objective 3: Assess the feasibility of evaluating the impact of i) variations in practice and ii) the overall programme

Criteria 3.1 - Data collection*: there are processes in place to collect, store and share reliable data for at least one relevant and feasible outcome measure.*
There are processes in place to collect, store and share reliable data related to outcome and other indicators of interest for the evaluation. We anticipate this data will fall into three categories:

a. **Navigator programme monitoring data**: the VRUs Service Level Agreements (SLAs) already ask DPs to collect monitoring data on (a) navigators (including recruitment, vetting, training, and shift assignment) and on (b) young people engaged in the programme (including referrals received, sign-posting to services, and young people's engagement with programme services). Further relevant data could be related to the take up and continued engagement by young people of services they were referred to by navigators and are provided by external partners. In addition to monitoring and supporting implementation, the collection of this data can provide relevant process indicators for the evaluation related to reach, participation, completion, or dropout.
b. **Administrative data**: we are aiming to measure the impact of the navigators programme primarily on real-world outcomes. These could be accessed through (i) hospital data (e.g., violence-related hospital attendances, admissions and reattendance) and/or (ii) police records and other datasets that the VRU has access to (e.g., appearing in police records as perpetrators, as victims or witnesses to violence or crime, or as missing persons).
c. **Bespoke data collection**: data for additional indicators relevant to the evaluation may be collected through mechanisms designed specifically for the evaluation in collaboration with DPs.

Assessment against criteria: for the evaluation to be considered feasible with respect to data, there should be at least one outcome from across the three sources considered (programme monitoring data, administrative datasets, bespoke data collection) that measures or proxies

a key outcome in the theory of change, and could theoretically be impacted by the navigator programme in the time allowed for data collection. For the variations in practice evaluation, it must be possible to collect this data for navigator recipients and match it to the practice variation they received. For the overall programme evaluation, the data must be available for both navigator recipients and a defined control group (to be defined).

Criteria 3.2 - Practices*: at least one practice is identified that can feasibly be varied within each delivery site and for which an effect on the target outcome(s) can be theorised.*
Among the possible navigator practices that could be implemented and varied at each site, at least one practice can feasibly be randomised to enable an evaluation. A theoretical case can be made that this practice could have an impact on the outcome measure(s) selected for the programme.

Assessment against criteria: this criteria will be met if among the shortlist of practices to vary, at least one is considered feasible to randomise by the DPs, VRU, and BIT, and a theoretical case can be made that this practice could have an impact on selected outcome measures relative to the "core" intervention. The randomisation of this practice will be tested at sites to ensure feasibility.

Criteria 3.3 - Comparison group*: data is available and accessible, or can be collected, on young people (or other units of analysis) that could provide a comparison group for a QED.*
Data that can be used to form a valid comparison group exists and is accessible, or can be collected, thus enabling a possible evaluation of the impact of the overall programme through a QED. This might be focused on individual-level data, or could relate to different analysis units.

Assessment against criteria: this criteria will be met if the VRU has provided confirmation that it can provide (or BIT has otherwise secured) access to a database containing relevant specified variables for the evaluation of the overall programme. Specifically, we will examine whether the requirements for a QED are met in terms of:

- Comparison group: there exists data on non-participants who can serve as a valid comparison group, as assessed by their similarity with programme participants and the absence of factors systematically influencing outcomes for one group but not the other.
- Data availability: outcome indicator data post-intervention and pre-intervention young person profile data are available, for both programme participants and the comparison group.

Criteria 3.4 - Sample size*: there is a sufficiently large potential sample of programme participants to provide some evidence of promise of the practices evaluated (i.e., direction and magnitude of the effect).*

An important objective of this project is to test the feasibility of the methods proposed to evaluate variations in practice across multiple delivery sites. This involves understanding the type of sample size that may be required to detect a statistically significant effect of i) specific practices and ii) the overall programme on the outcome measures selected, given other plausible assumptions for parameters affecting statistical power. Power calculations outlining these considerations will thus be provided. However, meeting the required sample size will not be a strict criterion for evaluation feasibility, and if it is not met, we would analyse the direction and magnitude of any effect observed to gauge the promise of impact of the interventions evaluated.

Assessment against criteria: the estimated number of participants required to detect an impact on the selected outcome measure(s) will be reported to inform plans for future evaluations of similar interventions. However, meeting this number will not be a strict criterion for evaluation feasibility, and if it is not met, we would analyse the direction and magnitude of any effect observed to gauge the promise of impact of the interventions evaluated.

The estimated sample size required will be determined based on power calculations conducted using assumptions for other parameters informed by insights from feasibility stage activities. These parameters will include the level of randomisation, the baseline value and standard deviation for the outcome measure selected, a range for the expected effect size of each intervention evaluated, the minimum detectable effect size for the proposed evaluation, and thresholds used for power and level of significance. The assumptions for each parameter will be specified in the power calculations that will be included in the outputs for the feasibility stage (see *Outputs* section).

Methods

To achieve each of the feasibility stage objectives, we will implement the activities described below.

Objective 1: Develop a theory of change within and across sites

Theory of change workshops: we will conduct workshops for each site with the delivery partner and member of the NHS team supporting the programme to jointly develop a theory of change for the programme as it is envisioned to be implemented at each site.[7] During these workshops, we will lead a discussion to define the key components of the theory of change for each site, including the target groups, programme goals and intended outcomes, activities, and mechanisms and intermediate outcomes through which these activities are envisaged to influence target outcomes. The content of this discussion will be captured in a template providing a visual model of the programme. We will also describe how the theory of change will be used during the rest of the feasibility stage, and for the evaluation. Following the workshop, we will update the output and share it with workshop participants for feedback to ensure alignment, and facilitate revisions as implementation progresses and potential adjustments are introduced. As delivery is only beginning at some sites, we can work with DPs as they develop approaches to capture how they decide what to include/drop (and why). To further build our understanding of the programme, we will attend navigator training where possible[8].

Overall theory of change development: we will develop a programme-level (cross site) theory of change based on the site-level theories of change. We will discuss this theory of change with the VRU and incorporate feedback. We will also share this theory of change with delivery partners to encourage consistency across sites.

Objective 2: Examine implementation relative to the theory of change and support refinements

Workshop on applying behavioural insights to programme design and delivery: building on the shared understanding of the programme theory of change developed through workshops and follow-up communications, we will lead a workshop to introduce delivery partners to behavioural insights and identify possible applications to programme delivery at each site. This workshop will introduce participants to BIT's signature methods and tools (such as the

[7] For most sites, programme delivery will not have started at the point of conducting the workshop.

[8] We have attended one virtual training to date.

EAST framework) for improving service delivery. Depending on interest and capacity, we may provide coaching to delivery partners who wish to take forward specific programme refinement ideas to implement from the workshop; these refinements would be reflected in revised versions of the site-level or programme-level theory of change. We will also use this workshop to identify possible behaviourally informed practices that could be tested as variations in practice in the evaluation stage.

Interviews with navigators: we will conduct interviews with navigators to understand the fidelity, dosage and quality of implementation relative to the theory of change, understand responsiveness to the programme, and identify similarities and differences in delivery approach and challenges across delivery sites.

We plan to conduct interviews with 6-8 hospital navigators. The exact sampling criteria will be defined after completing the theory of change workshops, but we will aim to interview at least one navigator per site and capture a range of experience levels (navigators new to the role, those that are more established, and those with and without prior experience of similar roles). The interviews will be roughly 30 minutes long and will be semi-structured. The interviews with navigators will primarily focus on how navigators conduct their role and their interactions with young people. The specific topics covered will be: the target audience (who is being referred to them); interactions with young people (nature of the conversation, types of signposting); how they understand the outcomes of the navigator programme; and any challenges they are facing, and how those challenges might mediate outcomes. These conversations will identify points of alignment and diversion with the theory of change, as well as similarities and differences of approach across the delivery partners.

On-site observations and interviews with hospital staff: to further understand implementation, refine the theory of change for each site, and identify possible improvements to delivery, we will conduct observations at sites and speak with hospital staff. Observations will be conducted at 3-5 of the sites, depending on feasibility of arranging visits and delivery progress. On-site observations are complicated by the fact that observing interactions between navigators and young people is likely to impact the discussion and, given the vulnerability of the young people involved, also carries significant ethical risk. For this reason, the observations will focus primarily on the environment around the navigator and the referral process. Questions investigated could include: how do the nurses identify eligible young people? How are navigators introduced to young people? At what stage in their hospital visit, and at what locations, do navigators and young people interact? A pro forma will be developed based on the theory of change and evaluation objectives. In lieu of observing the interactions between the navigators and young people, we will instead conduct short interviews (20 minutes) with navigators immediately after an interaction. Whilst this

relies on self-reporting, the recency of the interaction and the fact that questions will focus on a single interaction (rather than the navigator's overall experience) should reduce some of the recall and interpretation biases that might occur through the main interviews. For both the observations and debrief interviews, we will not ask for or record any identifiable data about the young person involved in the interaction.

Additionally, we will conduct short interviews with NHS staff, particularly those involved in referring young people to the navigators. We will aim to interview one staff member per site. The interview will take around 20 minutes and will be semi-structured. Ideally, these will be conducted whilst on-site for the observations, but we may arrange follow-up calls if necessary. These interviews will primarily focus on: how the staff identify eligible young people and how they introduce them to the programme; NHS staff's perceptions of how the navigator programme is received by young people; and their understanding of the navigator role.

Review of available programme monitoring data: to complement insights from these interviews and observations, we will review available programme data to quantitatively track navigator training and recruitment, programme take up (number of young people referred, sign-posted and engaged), and dosage (number of services taken up by young people).

Objective 3: Assess the feasibility of evaluating the impact of i) variations in practice and ii) the overall programme

Evaluation workshop: we will lead a session introducing delivery partners to evaluation concepts and methods, how they are designed and executed, what insights they can provide, and what programme and data conditions they require. This will help to build DP understanding of how we will decide on an evaluation approach, and what may be required of them to facilitate an evaluation.

Identification of practice variation ideas and randomisation options: we will first create a shortlist of practices or interventions that could be trialled across the delivery sites, and corresponding options for randomising these practices within sites. The shortlist of practices will be generated from ideas elicited in the workshop on applying behavioural insights, relevant literature, and drawing upon BIT's internal expertise developing light-touch interventions. We will then assess each idea on two main criteria: (a) the feasibility of implementing the practice as a randomised trial in each delivery site, and (b) the theoretical basis for hypothesising a potential impact of the practice relative to core components of the programme. In selecting recommended practices for evaluation, we will consult relevant

existing literature and frameworks for identifying core components in complex, practice-based interventions such as the navigator programme (Van Melle et al., 2019).

Based on the service delivery plan (navigators offering 1 day p/w as volunteers), we plan to explore randomising practice during a shift. Depending on shift patterns, we may end up with week-by-week randomisation (e.g., Floyd et al., 2020). Randomising by day/shift has the advantage of maximising the sample (navigators X weeks). We have thus far identified the shift management software Rota Central that the VRU is considering introducing at each site as a potential mechanism for randomising practices by shift. We envisage trials are likely to cover practices relating to: (i) navigator recruitment, and training and communication (e.g., reminders); (ii) navigator interactions with young people in hospitals and tools used to support interactions; and (iii) referrals, follow-up contact, and support. We will work with the VRU and DPs to operationalise the mechanisms necessary to implement the randomisation (e.g., tailoring design and use of Rota Central software).

Support to establish data collection processes: we will work with the VRU, DPs and sites to determine (i) what indicators are most relevant for the evaluation of specific practices and the overall programme, and (ii) what indicators can feasibly be accessessed or collected. The selection of (i) relevant outcome and implementation indicators will be informed by the theories of change developed, and discussions with the VRU and DPs on which outcomes *they* believe are most appropriate for the navigator scheme. The selection of (ii) feasible indicators will be determined by the availability and accessibility of existing data, and the feasibility and ease of collecting additional data. We will take steps to assess the feasibility of obtaining each category of data described in the success criteria:

a. **Navigator programme monitoring data**: the VRU currently plans to introduce a data system (to replace the current manual processes) that will be used by navigators to collect, store and share data across sites and with the VRU. Processes to add data from hospital records and from organisations to which navigators refer young people into this data system (e.g., follow up calls by navigators to organisations) have yet to be defined by the VRU. Together with the planned shift management software, this data system would provide the main source of programme monitoring data. The use of a common data management tool enabling the collection, storage and sharing of programme data by all delivery sites instead of individual and/or manual tools is an essential step to facilitate both implementation and the evaluation. However, the introduction of this tool across five sites is also complex and could pose risk of delays in accessing relevant data for research activities. We will thus closely track the roll-out of this platform, and support the design of data collection forms and processes to

ensure relevant and high-quality data is collected, including by applying behavioural science principles where relevant.

b. **Administrative data**: the VRU has access to police records and other datasets containing data on relevant outcomes of interest, which it could share with BIT for the purposes of the evaluation[9]. The VRU will also seek to obtain hospital administrative data to enable programme monitoring, and could share this data as well. We will work with the VRU and DPs to determine the feasibility of linking programme monitoring data on participants with these administrative datasets by setting up the appropriate mechanisms to allow data to be shared with the VRU and used for research purposes.
c. **Bespoke data collection**: depending on the feasibility of obtaining all relevant data for the evaluation through the previous two categories, we may design additional mechanisms to collect data on remaining indicators of interest, while still aiming to minimise the burden placed on navigators and hospital staff.

Exploration of possible administrative datasets that could be used to identify a comparison group for a QED: in addition to linking programme data on participants with administrative datasets, we will explore the possibility of using these datasets to identify a comparison group for a QED. For instance, we have discussed with the VRU the possibility of creating a matched control group consisting of young people with similar histories (as it relates to variables appearing in police records) and demographic characteristics.

[9] The VRU have invested in data sharing across the partnership as part of a cutting-edge data integration project. This includes feeds from Thames Valley Police, along with referral and case data from Local Authority records (see Appendix). The VRU have a dedicated data lead and are building monitoring and evaluation capabilities across the programmes they are implementing via e.g. dashboards. The central VRU team intends to make monitoring and evaluation data collection digital, to ensure consistency, reduce error, and provide real-time monitoring.

Methods overview

Activity	Method / format	Participants / data sources	Analysis method	Criteria
Objective 1: Theory of change				
Theory of change workshops	Five online workshops with each DP/site moderated by BIT	DP representatives from each site; NHS representative from corresponding hospital	The information gathered will be captured in a theory of change template used across all sites, which will be refined through additional conversations and findings from subsequent activities.	1.1
Overall theory of change development	Desk work building on theory of change workshops	Consultation with VRU	The information produced will be captured in an adapted theory of change template, which may be refined through additional conversations and findings from subsequent activities.	1.2
Objective 2: Implementation				
Workshop on applying behavioural insights	Online workshop with DP representatives from each site, led by BIT	DP representatives from each site and VRU project lead	Ideas on programme design and delivery improvements informed by applications of behavioural frameworks introduced during the workshop will be documented and shared with DPs and the VRU, and may be incorporated in revisions to the theory of change and/or ideas of practices to evaluate.	2.1; 1.1

Interviews with navigators	Phone interviews (30 minutes) with sample of hospital navigators recruited through project coordinators	6-8 hospital navigators from across all sites. Navigators not covered in the observations will be prioritised, as well as capturing diversity in the experience of navigators (within the programme, and with other mentoring-based roles).	A consistent interview protocol will be used across all interviews, covering the target audience (who is being referred to them); interactions with young people (nature of the conversation, types of signposting); how they understand the outcomes of the navigator programme; and any challenges they are facing, and how those challenges might mediate outcomes. Findings will be summarised and used to annotate and modify the theory of change.	2.1; 2.3
Activity	**Method / format**	**Participants / data sources**	**Analysis method**	**Criteria**
Objective 2: Implementation (continued)				
On-site observations and interviews with hospital staff	In-person observations (2 hours) and short interviews (20 minutes) with navigators and hospital staff (to be complemented by phone interviews if necessary)	3-5 sites observed based on implementation status and feasibility of arranging visits. Short interviews with the navigators on duty during the observation, and with NHS staff involved in referring young people.	The observations will focus primarily on the environment around the navigator and the referral process, with notes recorded in a pro forma for each observation that is informed by the theory of change and evaluation objectives. We will speak to navigators immediately after the interaction to understand the interaction itself, reducing some of the recall and interpretation biases that might occur through the main interviews. Interviews with NHS staff will primarily focus on: how the staff identify eligible young people and how they introduce them to the programme; NHS staff perceptions of how the navigator programme is received by young people; and their understanding of the navigator role.	2.1; 2.3

Review of available programme data	Analysis of all programme data and data collection tools provided by the VRU	Data shared by the VRU based on information provided by each DP, including on navigator training and recruitment, programme take up (number of young people referred, sign-posted and engaged), and case stories from navigators.	Descriptive statistics will be produced and reviewed for all quantitative indicators, including on variation over time and across sites. For qualitative case stories, the data will be reviewed and used to identify challenges or trends that should be considered in refinements to programme delivery or the proposed evaluation approach.	2.2; 2.3; 3.4
Activity	**Method / format**	**Participants / data sources**	**Analysis method**	**Criteria**
Objective 3: Evaluation feasibility				
Evaluation workshop	Online workshop with DP representatives from each site, led by BIT	DP representatives from each site and VRU project lead	Reflections from DP representatives pertinent to the feasibility of different evaluation approaches (particularly related to randomisation, outcome data collection, and sample size) will be documented and considered in the evaluation feasibility assessment.	3.1; 3.2; 3.4

Identification of practice variation ideas and randomisation options	Online workshop with DP representatives from each site, led by BIT, with desk work from BIT prior and after	*For workshop*: DP representatives from each site and VRU project lead *For desk work*: discussion with VRU, DPs, and providers of data management software used at sites that could be utilised for randomisation.	The practices considered (both those initially explored and those shortlisted) will be documented in a list and assessed against relevant criteria (including the feasibility of randomising the practice, and the theoretical basis for expecting an impact on outcomes of interest).	3.2
Support to establish data collection processes	Desk work (including review of insights generated by previous activities); consultation with VRU and DPs	Discussion with VRU, DPs, hospital staff, and providers of data management software used at sites for data collection.	A list of relevant indicators will be drafted (informed by the theory of change) and categorised by their source and data collection process, and the feasibility of collecting reliable data for each indicator will be assessed to arrive at a recommended set of indicators to use for the evaluation.	3.1
Exploration of administrative datasets for QED	Consultation with VRU and review of any datasets provided	Consultation with VRU on datasets available and their possible uses	Relevant and accessible datasets will be documented in a list, along with their possible uses for the evaluation (including variables that could be used in a QED).	3.3

Outputs

The main outputs from the feasibility stage will be:

- *Objective 1*: Co-designed **theories of change** (programme- and site-level).
- *Objective 2*: Case studies that summarise delivery context, partners, starting points for delivery, and implementation activities.
- *Objective 3*: **Evaluation feasibility assessment and study plan** for specific practices and the overall programme based on success criteria outlined in this document, and recommendations for sites that are not ready for an evaluation (if any). This will also include:
    - Description of the *feasibility of different evaluation approaches considered*, and a justification of the approach recommended.
    - *Data monitoring* systems set up/piloted (including outcome data collection).
    - *Pilot evaluation implementation plan.*
    - *Updated estimate of the budget requirements for Phase 2*, based on our recommendations for evaluation activities.

Ethics

The proposed activities for the feasibility stage can be considered as service evaluation under NHS Health Research Authority guidelines[10,11]. As such, they should not require approval from the National Research and Ethics Advisors' Panel (NREAP), but require registration with the R&D departments of local NHS Trusts. We are in contact with the VRU and the NHS Trust at each site to schedule meetings with their R&D departments, and have identified NHS staff representatives at each site that can serve as the primary contact for the service evaluation. This may include accessing data, supporting the application process, and assisting in ensuring there are proper arrangements to conduct the research.

Evaluation activities (post feasibility stage) are likely to require NREAP approval. We have looked into ethics requirements, and will revisit them as the proposed evaluation approach and its ethical implications are more precisely defined. We will begin applications to allow sufficient time for review before the projected launch of evaluation activities.

Data protection

BIT conducts all research with a privacy by design approach to protect and maintain the privacy and security of research participants' and research subjects' data. BIT has implemented appropriate measures to ensure secure storage and handling of Personal Data, including obtaining a Cyber Essentials Plus certification and developing a comprehensive Data Handling Protocol. We are registered with the UK ICO under the terms of the Data Protection Act 2018 and have an appointed Data Protection Officer.

Based on discussions to date with the VRU and our legal team, we expect the VRU to be the data controller for all data collected and/or held by the VRU and sites, and BIT to act as a data processor for the VRU in regards to this data. In this case, we would establish a data sharing agreement with the VRU, and work with them where relevant to ensure the data privacy notices used for data collection reflect the agreed upon data governance and uses. If BIT were to be the data controller instead, we would intend to rely on 'legitimate interests' as our lawful basis for processing personal data[12].

[10] See tool http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf.

[11] Per these guidelines, the proposed activities for the feasibility stage would be considered service evaluation in that: i) They do not involve randomising individuals into different groups; ii) they do not involve changing the treatment individuals receive; iii) the overall aim of this phase is to understand what the standard service involves; iv) there will only be minor changes to the delivery of the service, if any.

[12] We feel this is appropriate, as the processing of this data is a legitimate interest in line with Article 6(1)(f) in the GDPR. A data privacy notice for the project would be made publicly available on BIT's website. All data would be stored on GDPR-compliant encrypted servers with access restricted to the study team.

For any additional data collection conducted by BIT (e.g., interviews with navigators and hospital staff), we expect BIT to be the data controller. We intend to rely on 'legitimate interests' as our lawful basis for processing personal data. Individuals interviewed will have the right to be informed about the collection and use of their personal data. This is a key transparency requirement under data protection legislation. We will therefore provide individuals with information including: what personal data we are collecting, the lawful basis for processing their personal data, our purposes for processing their personal data, our retention periods for that personal data, and who it will be shared with. This information will be conveyed through a data privacy notice, given to all participants at the time of data collection.

Our team is also experienced in working with delivery partners to ensure data collection for evaluation is lawful and ethical. We would work closely with the VRU to identify the data requirements for the research, establish a data sharing agreement, and agree on data transfer processes. We have a policy to minimise the use of personal data where possible and would seek to anonymise data where we are able. From experience, it is beneficial if delivery partners feel confident and are accurate in discussing the research and data sharing arrangements with participants. We will work with the VRU and DPs to ensure they understand the planned research and how data will be collected and used, and can provide an FAQ sheet to support consistent information sharing as needed.

Personnel

Delivery team

Team member	Role	Responsibilities
Kelly Reed	Communities & Partnerships – Hospital Navigator Project lead	Strategic coordination of the hospital navigator programme with each delivery partner and hospital site
Paul Gretsy	Communities & Partnerships - Strand Lead	Troubleshooting high level problems within programme delivery Facilitating contacts with regional partners, if required
Stan Gilmour	Thames Valley VRU Director	
Lewis Prescott-Mayling	Thames Valley DCI Violence Reduction Unit	Key contact for discussions on administrative datasets accessible to VRU
Connection Support	Delivery partner - The Horton, Banbury, Oxon (Oxford University Hospitals)	Responsible for navigator programme delivery at respective hospital site
YMCA Milton Keynes	Delivery partner - Milton Keynes University Hospital	
Starting Point	Delivery partner - The Royal Berkshire Hospital	
7Roadlight	Delivery partner - Stoke Mandeville Hospital	
Aik Saath – Together as One	Delivery partner - Wexham Park Hospital (Slough, Berkshire East)	

Evaluation team

Team member	Role	Responsibilities
Dr. Alex Sutherland	Principal Investigator	Overall strategic direction, management of strategic relationships. Ultimate responsibility for project delivery and quality.
Lucy Makinson	Project manager & delivery point of contact	Day-to-day project management and point of contact for YEF, with an emphasis on delivery of interventions / BI.
Clément Bisserbe	Research quality assurance	Management of evaluation requirements and oversight of research activities.
Bridie Murphy	Project staff (delivery) & behavioural insights	Point of contact for frontline delivery staff, fieldwork and delivery-partner liaison.
Lilli Wagstaff	Research advisor	Quantitative researcher supporting statistical elements.
Kim Bohling	Evaluation advisor & quality Assurance	Evaluation specific knowledge / expertise and quality assurance at key steps in the project.
Professor Iain Brennan	Expert advisor; University of Hull	Provide insights and guidance for the team based on previous experience in VRUs and navigation programmes.
TBC	Phase 1 field researcher	On-site qualitative fieldworker for Phase 1 - will be based in TV but employed by BIT.

Risks

Risk	Impact	Likelihood	Mitigation
DPs are not receptive to formative evaluation / and/or will not cooperate with evaluation activities.	High	Low	We will work with partners to broker a good relationship and be clear about the requirements up front (which we have already started doing). If we identify a risk that one or more DPs is not ready for evaluation, we will assess the feasibility of continuing the pilot using PICO (population, intervention, comparison, outcomes) principles, and identify opportunities to adjust our approach (e.g. including it as a control site in a natural experiment). We would also scope recruiting a replacement organisation with the VRU.
Sites (or participants within sites) will not engage with evaluation activities.	Medium	Medium	Some amount of attrition is to be expected in all evaluations. We have several strategies that aim to minimise attrition, which include: ● ensuring that evaluation activities are designed to be low-impact in terms of burden or time, and incentivising activities where appropriate; ● informing sites with sufficient notice about any planned activities with appropriate information about how useful the evidence created by the study will be; and ● where needed, utilising the relationships the VRU and DPs have built with volunteers and NHS colleagues to facilitate access/cooperation.
There are many components to the evaluation that require tight coordination. This could result in deadlines being missed or activities being delivered with poor quality.	Medium	Low	Our project management plan involves collaboration with DPs and the VRU to set out a realistic project timeline. The timeline will clearly set out any time points that will require careful coordination and include time buffers to the extent that is feasible. Regular check-ins will help to identify early on any risks to the timeline and allow for proactive problem-solving.

Administrative data is not fit for purpose.	Medium	Medium	The VRU partnership mitigates this risk to some extent, as does their ongoing relationship with trusts. Nevertheless, the administrative data review planned during the feasibility stage will help directly address this issue. We will work with the VRU to ensure that M&E systems are designed to collect relevant and good quality data. In the event that administrative data are not fit for purpose, we will consider other possible sources of data (programme data collected by hospital navigators, bespoke data collection led by BIT) and discuss these alternative approaches with YEF.
Staff turnover & project drift (*Note: this risk applies to BIT, VRU and DP staff*)	Medium	Medium	We will have a clear project plan and project management arrangements. We will ensure that any staff handovers overlap and have clear handover documents and briefings into the project. We will liaise with YEF/VRU/DPs about handovers.
Delays in delivery at some sites limits time available to refine delivery before the start of the evaluation phase.	Medium	Medium	We will monitor the progress of delivery for each DP and any implications for evaluation. If delivery progresses at different pace across sites, we will work in a staggered fashion to develop theories of change and conduct interviews, and work with DPs to update their theory of change as they adapt delivery to their context and lessons learned. We will take into account delivery progress in identifying practices to test and randomisation mechanisms, and test randomisation mechanisms to ensure their feasibility. We will regularly discuss the status of delivery with the VRU and YEF to identify and address implications for the evaluation.
Delays in setting up and rolling out new data management softwares planned by the VRU for navigator shift management and data collection limits time available for establishing data collection and sharing processes before the start of the evaluation phase.	Medium	Medium	While the introduction of a new common data management tool across 5 delivery partners can be complex, enabling the collection, storage and sharing of programme data by all delivery sites instead of individual and/or manual tools is an essential step to support both implementation and the evaluation. We will closely track the roll-out of these tools, and support the design of data collection forms and processes to ensure relevant and high-quality data is collected, including by applying behavioural science principles where relevant. We will also support the VRU to design processes for integrating data from hospital records and other service providers involved in the navigator programme into their data systems. We will work with the VRU to ensure data protection considerations are taken into account to allow for the sharing of this data with BIT by the VRU once it is available.

High refusal rates from patients	Medium	Medium	This would be a finding in the first instance, but the project is explicitly looking to test out ways of engaging patients so we would work closely with sites to understand what the barriers to take up are and design solutions to reduce friction/improve engagement.
Covid-19 restrictions disrupt delivery of the programme and evaluation.	High	Medium	If the programme is paused completely, the evaluation will have to be delayed and we would ask for a no-cost extension. If Covid-19 restrictions mean that researchers cannot conduct face-to-face activities, these activities will either: ● be modified to be virtual and is easy to do for interviews; or ● be rescheduled (this may involve the re-planning of some site observations).

Timeline

Dates	Activity	Staff responsible/ leading
Objective 1: Theory of change		
Jul.-Aug. 2021	Theory of change workshops	Lucy Makinson (BIT)
Aug. 2021	Overall theory of change development	Lucy Makinson & Clément Bisserbe (BIT)
By 30 Sep. 2021	***Output:*** *Co-designed theories of change (programme- and site-level)*	
Objective 2: Implementation		
Aug. 2021	Workshop on applying behavioural insights	Lucy Makinson (BIT)
Aug.-Sep. 2021	Interviews with navigators	Lucy Makinson (BIT)
Sep.-Oct. 2021	On-site observations & interviews with hospital staff	Lucy Makinson (BIT)
Jul.-Nov.2021	Review of available programme data	Lilli Wagstaff (BIT)
Objective 3: Evaluation feasibility		
Aug. 2021	Evaluation workshop	Clément Bisserbe (BIT)
Aug.-Sep. 2021	Identification of practice variation ideas and randomisation options	Lucy Makinson & Clément Bisserbe (BIT)
Aug.Nov. 2021	Support to establish data collection processes	Clément Bisserbe (BIT)

Aug.Nov. 2021	Exploration of administrative datasets for QED	Clément Bisserbe (BIT)
By 17 Dec. 2021	***Outputs:*** ● *Case studies for each site* ● *Evaluation feasibility assessment and study plan*	

Appendix: References

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