Perinatal Trauma and Loss Support Bundles: An Evaluation Framework

Health Innovation Wessex Insight team support to FLY Mama

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1. Introduction

The Health Innovation Wessex Insight team was commissioned to co-design an evaluation framework and logic model to support a real world evaluation of six support bundles offered by FLY Mama. This short report describes the evaluation framework and how it can be operationalised for use.

2. Background to FLY Mama bundles

The FLY Mama bundles are provided via an online platform and support women and birthing people during their childbearing years. The bundles support pregnancy, the postpartum period, and experiences of perinatal trauma and loss. A trauma-informed online platform provides accessible and professional guidance through several support bundles to meet the needs of each individual. The bundles consist of live classes, a library of video resources, and a private online community.

Across the bundles the team use a holistic five pillared approach, focused on education, movement, coaching, energy, and connection.

A partnership between FLY Mama and Forget Me Not Children's Hospice in West Yorkshire has been established to trial the use of the six bundles (Table 1).

Table 1: Six support bundles

	Bundles	**Description**
1	Stillbirth and Neonatal Death Support Bundle	This bundle supports physical and emotional healing following a stillbirth or neonatal death. It contains educational videos on how stress and trauma impacts on the somatic (physical) and nervous systems, and teaches regulation techniques. It contains women's health physiotherapy talks and trauma-informed yoga and pilates to help rebuild strength and reconnect to the body postnatally.
2	Rainbow Baby Support Bundle	This bundle supports pregnancy and birth after loss as well as when the baby arrives. Educational videos teach about the impact of stress on the somatic and nervous systems; regulation techniques help manage any anxiety and worry throughout pregnancy and postpartum period.
3	Pregnancy and Baby Loss (0-23 weeks) Support Bundle	This bundle supports physical and emotional healing following pregnancy and baby loss. It contains educational videos on the impact of stress and trauma on the body with practical tools and techniques to help reduce stress and aid relaxation and sleep quality. It contains women's health physiotherapy talks and trauma

		informed yoga and pilates to help reconnect to the body, improve sleep and restore physical strength.
4	Termination for Medical Reasons Support Bundle	This bundle supports physical and emotional healing following a termination for medical reasons (TFMR). Educational videos explain the impact of stress on the somatic and nervous systems and teach regulation techniques. The bundle also contains women's health education talks about how pelvic and hormonal health may be impacted by pregnancy and birth. The movement pillar includes trauma-informed yoga and pilates classes to help rebuild strength and reconnect to the body.
5	Life Limiting Diagnosis in Pregnancy Support Bundle	This bundle supports physicaland emotional health throughout pregnancy following the diagnosis of a baby's life limiting condition. It contains educational videos on the impact of stress and trauma on the body with practical tools and techniques to help reduce stress and aid relaxation and sleep quality. The bundle contains women's health physiotherapy talks and trauma informed yoga and pilates to help stay physically strong and reduce tension.
6	Life Limiting Diagnosis in Postpartum Period Support Bundle	This bundle supports physical and emotional healing after giving birth and receiving a baby's life limiting diagnosis. It contains educational videos on the impact of trauma on the somatic and nervous systems and teaches regulation techniques. The bundle contains women's health physiotherapy talks and trauma informed yoga and pilates to help rebuild strength and reconnect to the changing body following birth.

3. Developing an evaluation framework

The Insight team held a series of meetings in April and May 2024 with representatives of FLY Mama and Forget Me Not Children's Hospice, to determine the aims, activities, and intended outcomes of the bundles. The output of the meetings are described in the form of a logic model (Figure 1) and inform the methodological recommendations below.

The framework proposed below offers ideas for expanding an existing evaluation put in place by FLY Mama and the Forget Me Not Children's Hospice. We also raise some additional considerations for the FLY Mama team.

The existing evaluation is investigating these outcomes:

1. Pelvic floor health – via the Pelvic Floor Impact Questionnaire (Short Form PFIQ-7)

2. Depression, anxiety and stress – via the Depression, Anxiety and Stress Scale (DASS-21)
3. A bespoke participant survey, created by FLY Mama's evaluation partner, focuses on:
    a. Physical support and recovery
    b. Sleep quality
    c. Triggers and social capacity
    d. Self-esteem and body confidence.

The ongoing evaluation is using the outcomes above to assess all six bundles. There are no specific / separate outcome assessments for individual bundles.

4. Suggested expansions to the evaluation activities

At the logic model sessions, we discussed the importance of demonstrating impact in a range of ways to inform commissioners of women's health services about the evidence for this innovation. Impact can often be sought from the perspective of participants' views on the innovation, staff views on the innovation, and objective assessments of impacts on related health services.

With the above in mind, we have provided several suggestions to expand evaluation activities which support evidence generation that can inform commissioning decisions.

4.1. Evaluation design suggestions

The Insight team recommends the design continues its focus on all six bundles as a whole, rather than separate bespoke evaluations of each bundle. At present, there is a need to explore the potential impact of the bundles, rather than hypothesise and confirm that particular effects have been seen.

The Insight team recommends the overall design of the evaluation to be a concurrent triangulation mixed methods design. This broad design could involve established outcome measures, a qualitative investigation via participant interviews, and an assessment of participants' health services data to understand the effects of the bundles. Importantly, the process of triangulating / synthesising the findings from each evaluation element would provide the opportunity to expand / confirm / refute findings identified by other elements. For example, the qualitative interview findings could be used to explain the occurrence of change/no change in scores on the outcome measures and/or health services usage.

Several other methodological designs could be embedded within the broad mixed methods approach:

- An ‘on-entry to the bundle’ and after (repeated measures) design with the cohort of people using the bundles, with a focus on the outcome measures as the tools to see change once someone takes part and afterwards. Options to mitigate participant survey burden is discussed later in this report.
    - The throughput of people on the bundles with the Forget Me Not Children’s Hospice context is expected to be approximately 50 to 100 people, therefore it is recommended the whole cohort of participants be considered as one analytical group. This is to ensure any statistical tests of difference can be done, as they have minimum sample requirements – often approximately 50/60 per group in the analysis.
    - If large numbers of people take part in the bundles (e.g. 50 people per bundle), it would permit an assessment of each bundle (if this is of interest) to consider the differences in impact between bundles.
- A qualitative semi-structured interview design would permit an in-depth investigation of the experience of using the bundles. There is a need to explore with those who took part, after they have experienced all elements of their particular bundle – or combination of bundles – how they found the:
    - (i) online content (e.g. readability, relevance, and usefulness of content and video)
    - (ii) online delivery mechanisms (e.g. technical usability and timing of nudge emails)
    - (iii) fit with their existing life commitments.

It is recommended that a sample of 30 people are interviewed to ensure data saturation is obtained (i.e. starting to hear similar issues/themes so you know you’re capturing common issues).

- An ‘on-entry’ and after experimental design could consider retrospective and new health services usage, by a cohort of bundle participants, over at least six months. With the permission of participants and using their NHS number as an identifier, it may be possible to draw conclusions about the amount of previous service usage compared to service usage after the bundle/combination of bundles have been completed. The logistics of organising this are discussed later in this report.

4.2. Organisation of outcomes (and related outputs) into categories

The logic model sessions identified a need to categorise the current evaluation activities and add further evaluation options (see Table 2) to those categories. By describing the categories, it is possible to see where the current evaluation is focused and where new avenues of investigation exist.

Category: Satisfaction with mode of support

It was identified that this is an area of development; there are no detailed or standardised activities to assess participants' views about the online content, email nudge support systems, or modes of support (content/video). A benefit of examining this could be to compare 'completers' of bundles against 'partial completers' and 'non-completers' to see how their outcomes change/do not change. Several suggestions include:

- Harnessing the internal data captured by Kajabi (FLY Mama website host) and using the analytics to measure how participants engage with bundles, videos, content.
- Creating types of completion (e.g. completers, partial completers, non-completers) to use as a variable and compare outcomes (e.g. physical impact, emotional wellbeing etc).
- Specifying a level of minimum completion to ensure benefits can be taken away, e.g. 50% of course material must be viewed to have a chance of benefiting from the bundle. This would support how much email nudging to engage in and help describe to commissioners that even minimal completion of the bundle can have an impact.
- Measuring the concept of 'acceptability'. This can be defined as a multi-component concept[1] and we recommend using a standardised outcome measure to capture acceptability such as the Acceptability and Impact Measure (AIIM) [contact HIW for more details].
- Measuring participants' attitudes toward innovation, as this may influence how they engage and sustain their involvement in the bundle(s). We recommend using a standardised outcome measure to capture patients' attitudes toward innovation (PATIS) [contact HIW for more details].

Category: Physical impact

This category is covered fully by the existing evaluation and includes investigating pelvic floor health, physical support, sleep quality, and triggers leading to physical symptoms. HIW does not have any additional suggestions for this category.

Category: Emotional / wellbeing impact

The current evaluation is focused on symptoms of depression, anxiety and stress using the DASS-21 measure. The bespoke participant survey also focuses on self-esteem and body confidence.

[1] Sekhon, M., Cartwright, M. & Francis, J.J. (2017) Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Services Research, 17: 88.

Logic model meeting discussions highlighted:

- Consider replacing DASS-21 with more validated and recognisable measures of depression and anxiety. Namely, the nine-question Patient Health Questionnaire (PHQ-9) for depression and the seven-question Generalised Anxiety Disorder (GAD-7) measure. Both are widely used in primary and secondary care and their findings help clinical decision-making. Detecting a clinically meaningful change in both measures would be powerful evidence of the value of the bundles.
- Consider the concept of grief and how it would be applicable to all six bundles. Several measures of the symptoms of grief have been identified. These include the Traumatic Grief Inventory, Grief Response Scale, and Impact of Event Scale. There is also the Perinatal Grief Scale - Short Form, which still has 33 questions but could be used or adapted due to its relevance. The 26-question Perinatal Bereavement Scale (PBS) is also relevant and worth considering for use after participants' involvement with the bundles. Due to the sensitive nature of the topic, it may be appropriate to discuss the questions on a call face-to-face rather than ask participants to complete any grief measures themselves.

Category: Social engagement impact

The current evaluation's bespoke participant survey includes questions about social capacity. To further enhance these, it is suggested that impacts on work (e.g. return to work, or job-seeking) are considered a potential impact of using the bundles. With that in mind, the Work and Social Adjustment Scale is a well-known short measure (five questions) that could be used 'on-entry' and after participants' involvement with the bundles.

Category: Health services impact

An area yet to be explored is impact on health services. The logic model discussions highlighted an interest in this type of impact but also had concerns about how to organise this element. Several areas of interest are described in the logic model, including seeking to understand if reductions in service activity occur in bereavement services, maternity appointments, and mental health services.

Importantly, for a cohort of approximately 50 participants, understanding impact on health services at the individual level requires preparatory activities such as:

- Identifying which relevant metrics (e.g. number of bereavement services accessed, or number of medications prescribed for depression) are appropriate and connect conceptually to the outcomes in the logic model. This will involve speaking to the relevant data / analytics team or person at a hospital / practice to understand what is measured and accessible.
- Contacting hospital / practice information governance staff for advice on the process to access existing data. This will likely involve a Data Protection

Impact Assessment (DPIA) and development of a Data Sharing Agreement (DSA) between the organisations sharing data. In the context of this evaluation framework and according to the General Data Protection Regulation (GDPR), the hospitals / practices involved would be the Data Controller and FLY Mama (and any evaluation partner used) would be the Data Processor.

- Contacting service leads to inform them of the intention to use data held by them.
- Developing a specific consent form for participants to sign, indicating they are happy for their medical information to be searched for usage of health services, and for their NHS number to be used to link the data together.
- Developing a policy to secure, keep, and later destroy any identifiable data held by FLY Mama. This would involve contacting the services to inform them of the destruction of the data.

There are many possible avenues for studying impact on health services and these should be explored with the relevant services and an evaluation partner. The 'evaluability' of the plan should be carefully scrutinised.

In terms of study design, a retrospective and post-bundle completion assessment of health services usage may only be relevant for certain situations. For example, it may only be required or possible to look at use of bereavement services after the bundle completion. In this situation, a comparator position (sometimes called a counterfactual position) can be used to know what usually happens during business-as-usual. The comparator position can be compared to what happened for an individual, and this may result in 'avoided' activity.

A health economic study could be designed to complement the above and would require specialist health economic skillsets. The use of the NHS payment scheme and/or assessment of staff time would provide a way to cost avoided activity.

Table 2: Suggested new outcomes and methods of data capture

Outcome	Method	Notes
High acceptability of bundle(s) experienced	One-off completion of the Acceptability and Impact of Innovation Measure (AIIM)	This short measure has been developed by Health Innovation Wessex. It provides a standard assessment of acceptability based on current research literature. In this context, it would be used to ask about each bundle experienced. Contact HIW for more details.
Improved attitudes toward online support platforms	Patient Attitudes Toward Innovation Survey (PATIS)	This short measure has been developed by Health Innovation Wessex. It provides a standard assessment of patients' attitudes toward a specific innovation and is based on research literature. In this context, it would be used to determine if attitudes influenced whether participants accepted the bundle(s). Contact HIW for more details.
Reduced symptoms of depression	PHQ-9	This widely used measure is recommended for use. A copy of the measure is provided.
Reduced symptoms of anxiety	GAD-7	This widely used measure is recommended for use. A copy of the measure is provided.
Reduced symptoms of grief	-Traumatic Grief Inventory -Grief Response Scale -Impact of Event Scale -Perinatal Grief Scale Short Form -Perinatal Bereavement Scale	Several measures were identified, including perinatal measures of grief symptoms. The FLY Mama team will be best placed to determine which measure is most appropriate and links to their bundle content / five pillars of support. Copies of the measures are included.
Improved capacity to work / obtain employment	Work & Social Adjustment Scale	This widely used measure is recommended for use. A copy of the measure is provided.

Figure 1: Logic model (also provided separately in PowerPoint)

Logic model for FLY Mama

Aim: To understand the value and impact of six support bundles to support the physical and emotional healing and wellbeing for women and birthing people who have experienced perinatal trauma or loss.

INPUTS	ACTIVITIES	OUTPUTS	OUTCOMES	IMPACTS**

• PERINATAL TRAUMA AND LOSS SUPPORT
• FLY Mama staff
• Online website support from developers
• Clinical expertise: five pillars of health are woven through all the Support Bundles:
1. Education
2. Movement
3. Coaching
4. Energy
5. Connection
	PERINATAL TRAUMA AND LOSS SUPPORT
	Online support bundles
	1. Stillbirth and Neonatal Death Support Bundle
	2. Rainbow Baby Support Bundle
	3. Early Pregnancy and Baby Loss Support Bundle
	4. Termination for Medical Reasons Support Bundle
	5. Life Limiting Diagnosis in Pregnancy Support Bundle
	6. Life Limiting Diagnosis in Postpartum Period Support Bundle
		SATISFACTION WITH MODE OF SUPPORT
		• Website content analysis (of functions, content, and timing)
		• At least 50% of service users completing the bundle activities
		• Acceptability and Impact Measure (AIIM)
		• Patient Attitudes Toward Innovation Survey (PATIS)
		PHYSICAL IMPACT
		• Participant survey: physical support, sleep quality, triggers
		• Pelvic Floor Impact Questionnaire (PFIQ-7)
		EMOTIONAL/WELLBEING IMPACT
		• DASS-21 (Depression & Anxiety & Stress) OR PHQ-9 (Depression) and GAD-7 (Anxiety)
		• Participant survey: Self-esteem, body confidence
		• Traumatic Grief Inventory / Grief Response Scale / Impact of Event Scale
		SOCIAL ENGAGMENT IMPACT
		• Participant survey: Social capacity
		• Work & Social Adjustment Scale
		HEALTH SERVICES IMPACT*
		• Reduced number of appointments to bereavement services
		• Reduced number of additional maternity appointments
		• Reduced number of mental health-related hospital admissions
		• Reduced number of medications prescribed for depression or anxiety
		• Reduced number of GP appointments
		*Further work is needed with relevant health services to identify specific metrics/variables they collect and link to these categories.
			SATISFACTION WITH MODE OF SUPPORT
			• High acceptability / satisfaction with website module
			  • Content
			  • Delivery methods
			  • Module communications
			• High acceptability toward bundle experienced
			• Improved attitudes toward online support platforms
			• Good fit with life commitments
			PHYSICAL IMPACT
			• Improved physical support and recovery
			• Improved sleep quality
			• Improvement management of triggers
			• Reduced pelvic floor issues
			EMOTIONAL/WELLBEING IMPACT
			• Reduced symptoms of depression
			• Reduced symptoms of anxiety
			• Reduced symptoms of stress
			• Improved self-esteem and body confidence
			• Reduced symptoms of grief
			SOCIAL ENGAGMENT IMPACT
			• Improved social capacity
			• Improved capacity to work / obtain employment
			HEALTH SERVICES IMPACT
			• Avoided use of bereavement services
			• Avoided additional maternity appointments
			• Avoided mental health-related hospital admissions
			• Avoided use of medication
			• Avoided GP appointments
				** Please note an assessment of long-term impacts would need a two or three-year evaluation.

5. Considerations for undertaking the evaluation

5.1. Evaluation burden for FLY Mama

The use of a mixed method multi-focused evalution, and enhanced use of outcome measures in this report could be considered burdensome, but it would only be experienced whilst the bundles are being evaluated. It is true that an assessment of Kajabi analytics, participant interviews, and outcome measure deployment and analysis would be additional work for FLY Mama. However, this would only need to be done over a finite period to develop the evidence base for future discussions with commissioners. Importantly, finding a balance between participant burden and acquiring enough evidence to convince comissioners is a decision to be taken carefully and in consultation with potential commissioners.

Importantly, this evaluation framework cannot cover every possible option for evidence generation and the possible challenges that may arise. It is recommended that FLY Mama continue to partner with a research and/or real world evaluation provider. These providers offer advice, guidance and experience of setting up evaluations in the NHS, and often provide access to the key contacts needed to rapidly set up and undertake an evaluation.

It is recommended the evaluation provider is generally familiar with using outcome measures such as those in Figure 1. Each measure will have its own manual for scoring/summing the data and interpreting the findings. Some of the measures may have guidance in the research literature on what a clinically meaningful change would be. This should be sought and used where possible to develop conclusion statements.

5.2. Timeframe for the real world evaluation

Due to the timeframe required to use the content within the bundles, it is recommended an evaluation be planned over a minimum of six months and preferably 12 months. This would allow multiple people to experience the bundles and would ensure the evaluation is based on a robust number of participants (between 50 and 100 people). The minimum evaluation timeframe would also allow multiple bundles/bundle combinations to occur and thus allow the evaluation to assess the effects of multiple bundles on an individual/groups.

The timing and sensitivity of the administration of the post-intervention outcome measures should be carefully planned. To manage the possibility of assessing an individual embarking on multiple bundles, it is recommended this possibility is explored before starting the first bundle. If it is known that an individual intends to complete multiple bundles, they can be grouped (for the purposes of the evaluation) as a ‘two intervention completer’ or ‘three intervention completer’ and the post-intervention measures can be completed after they complete their final bundle.

5.3. Ethical review

Due to the evaluation involving sensitive topics, it is highly recommended that the evaluation provider approach an appropriate organisation or regulatory body to complete an ethical review of the full evaluation plan. This may be the NHS Health Research Authority or a local NHS trust research department. An ethics review will likely focus on elements including the appropriateness of the planned methods of data collection, the participant consent process, how people will experience the evaluation activities, and how data will be stored and used.

It is possible that evaluation activities, e.g. asking questions about mental health symptoms, may provoke uncomfortable feelings. Comprehensive plans should be made (e.g. a flowchart of actions) to support and manage participants' reactions whilst undertaking evaluation activities.

5.4. Information governance

It is recommended that information governance considerations are made as early as possible in the evaluation planning. If FLY Mama plans to share the monitoring data (e.g. number of sign-ups etc) with the evaluation provider, it is likely that a data sharing agreement will be needed between the relevant parties and that the evaluation partner is named in participant information/consent. This is to safeguard the information provided by participants.

5.5. Feedback burden for participants

It is important to be mindful of the burden on participants when using more outcome measures. Minimising the burden on participants should be carefully considered and balanced against the requirement to demonstrate sufficient and robust evidence of impact to inform commissioning decisions.

It is noted this is not an easy balance to achieve.

Suggestions to mitigate this challenge:

- All participants complete all outcome measures; however, these are completed over the telephone or face-to-face in a conversational style format, whereby answers can be recorded and it feels less like a formal research experience. Also, it is recommended the measures are completed in two to three separate sessions, within a day or two of each other, to minimise burden.
- Where possible, iincludedata collection as part of planned consultations to minimise time needed for both staff and participants.
- Select a cohort of participants to ask to complete part of the full battery of outcome measures. For example, participants 1-25 complete the physical and emotional measures but not the other measures. Participants 26-50

complete satisfaction with mode of support and social engagement measures.

- Obtaining follow-up completion of surveys/outcome measures can be difficult. Strategies will be needed to obtain the required data. For example, by updating bundle participants on the purpose and progress of the evaluation, perhaps by having a link to explain the evaluation on the FLY Mama website. By obtaining multiple ways to contact an individual as part of the consent process. By re-emphasising the importance of evaluating new innovations to promote learning and to develop a reputation for impact.
- If there are concerns about using all the suggested evaluation elements or outcome measures, it is suggested that a staged approach be undertaken. An early focus would be on exploring the value of the bundles with participants (i.e. the qualitiative element) and could happen before exploring impact on health services in a later evaluation.

5.6. Development of evaluation questions

Importantly, the evaluation questions must be related to the outcomes of interest (see Figure 1). Some example questions are provided. It is recommended the evaluation questions are carefully considered before starting the evaluation, to ensure they are addressing areas of interest for FLY Mama. Also, we recommend involving people with experience of trauma in the development of the questions and methods, to make sure evaluation questions target areas relevant to them and survey/interview questions are worded sensitively and appropriately.

If the evaluation questions radically change from the ones proposed below, care should be taken to check that the links between the new questions and the outputs and outcomes in the logic model still stand.

5.7. Possible evaluation questions

The questions below are based on the outcomes identified in the logic model.

1. What impact has [specify bundle and/or combination] had on participants' clinical symptoms of depression and anxiety [use DASS/PHQ/GAD/qualitative interviews]?
2. What impact has [specify bundle and/or combination] had on physical wellbeing [use bepoke participant survey, PFIQ, qualitative interviews]
3. What impact has [specify bundle and/or combination] had on symptoms of grief [use one of the grief measures and qualitative interviews]?
4. What impact has [specify bundle and/or combination] had on self-esteem and body confidence [use bespoke participant survey and qualitative interviews]?

5. What impact has [specify bundle and/or combination] had on social and work engagement [use WSAS and qualitative interviews]?
6. What is the impact of [specify bundle and/or combination] on usage of relevant health services on-enty and after completion of the bundle(s) [use hospital/primary care data]?
7. What is the level of participant acceptability of the content and delivery mechanisms of the online support bundles [use Kajabi website analytics, AIIM, PATIS, and qualitative interviews]?
8. Are there differences in the level of impact between different bundles and/or bundle combinations?
9. Are there differences in the level of acceptability between different bundles and/or bundle combinations?
10. What improvements could be made to each bundle [use qualitative interviews]?

Statement about publication:

Health Innovation Wessex is committed to supporting a learning health system and so the sharing of findings to aid spread and adoption is key to our purpose. As a default we will make all co-design outputs available on the Health Innovation Wessex website.

Should FLY Mama publish its findings from an evaluation that uses this framework, we request that the Insight team's support is credited: "This evaluation was delivered using an evaluation framework co-designed with the Health Innovation Wessex Insight team. For more information about Health Innovation Wessex, visit www.healthinnovationwessex.org.uk"

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