Watch Me Play Protocol
Tavistock and Portman NHS Foundation Trust

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Watch Me Play!

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Intervention Recipients	20 parents or carers of children aged 0-8 years
Evaluation Participants	20 parents or carers of children aged 0-8 years
Number of Sites	6 delivery sites.
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Summary

This document outlines the feasibility evaluation of Watch Me Play!

Background

Around one in six children in England were identified as having a mental health problem in July 2020, an increase from one in eight children in 2017. Early intervention to prevent or reduce the likelihood of mental health problems developing is important. Services however have experienced rising demand and are not always able to offer help when families need it. In 2019-20 only a quarter of children estimated to need help in England received it. Those who do get access to services often have to wait months or years. Barriers to accessing help are further exacerbated for certain groups e.g. children with developmental delay and those living in areas of high deprivation. This is despite such children being known to be at increased risk of developing mental health problems.

Strengthening parent-child interaction and relationships is known to protect children's mental health. Watch Me Play! (WMP) is an intervention for caregivers with their babies or young children that aims to enhance child development and caregiver-child relationships. WMP involves a parent watching the child play and talking to their child about their play for a period of up to 20 minutes (this is called one session). Some sessions will be facilitated by a trained practitioner who will join the parent in watching the child or baby either in-person or online (using secure video conferencing software), and talking to the child about their play, and provide prompts to the parent where necessary. It is recommended that services offer 5 facilitated sessions, following an introductory meeting, and parents do at least 10 independent sessions with their child over a 5-week period (i.e., 3 sessions a week, of which one is facilitated). Adherence is defined as having done 10 (of 15) sessions, including the 5 facilitated ones.

Watch Me Play! was first developed in a Local Authority service for children in care to promote mental health resilience for babies and children. It aims to do this by promoting individual attention and age-appropriate stimulation and by supporting the caregiver relationship and interaction with their child. Caregivers have reported improvements in their relationship with their baby or child and in children's play skills, speech and language development, and behaviour. We think these improvements may help to prevent future mental health problems. WMP is now offered as an early intervention in a wide range of services across the UK. Since the Covid-19 pandemic, it has been offered remotely via video-link as well as in face to face sessions and home visits.

What will we do?

Although WMP shows promise and it is already used in some services, we do not yet know whether it is effective. To determine if WMP improves well-being in families, we would ultimately want to conduct a test called a Randomised Control Trial (RCT). However, before we do this, we want to understand how parents engage with WMP by doing this smaller study (a feasibility study). In this study, twenty parents will be recruited from early years and children services and offered WMP. Online delivery of WMP offers the potential of making it more easily accessible when face-to-face sessions are not possible or preferred. WMP therefore has the potential to provide a flexible model for practitioners supporting families either face-to-face or online. This research will explore whether families prefer online or in-

person sessions, or a combination of both. Families of babies and children (age 0 to 8) referred to early years' services across the UK will be invited to participate in the study.

What will the outcomes be?

We will learn more about the experiences of families receiving WMP and also about families' experiences of participation in the research study itself. We will investigate whether parents like WMP and engage with it, what factors help or get in the way of doing WMP, whether it is possible to evaluate WMP and what participants think about the study and WMP. We will also investigate how WMP works as an intervention from the perspective of families, practitioners and services. We will investigate what other treatment is offered as usual practice in services, and how much WMP costs to deliver. We will share our findings widely including with the parents, foster carers, clinicians, service managers and social workers who have advised on design of this study.

The work will be completed by April 2024. Key milestones are to have recruited participants by the end of November 2023, to have completed intervention delivery by the end of December 2023, to have completed follow-up data collection by the end of January 2024, and the final report by the end of April 2024.

Background and problem statement

Half of mental health problems are established by the age of 14 years and 75% by 24 years (Public Health England, 2019). Early intervention and prevention of mental ill health is therefore vitally important. However, increased demand over recent years has meant that access to child mental health services is often restricted to those in severest need. In 2019-20, only a quarter of children estimated to need help received it (Children's Commissioner, 2021) and difficulties accessing treatment remained a key concern in 2021 (BBC, 2021b)(BBC, 2021a). Those not offered help include children at higher risk of developing problems later and those with problems that do not meet service thresholds (Crenna-Jennings & Hutchinson, 2020). Important opportunities for prevention and treatment are therefore missed and resource-stretched services and practitioners are left frustrated at not being able to intervene at an optimal time (Colizzi et al., 2020).

Children in care are known to be at high risk of developing mental health problems in childhood and adolescence (National Youth Advocacy Service, 2019) (York & Jones, 2017) (Care Leaver Covenant, 2018). WMP was originally developed in the context of a local authority mental health service for children in care to offer an intervention to babies and children who would otherwise be offered little. It is an early intervention designed to support caregiver attunement and attention to the child in order to promote social-emotional well-being and thereby mental health resilience. The first manual of WMP was published in 2019, followed by a revised and expanded version in 2020. Since its publication, demand for the intervention has surged with services wanting to introduce it and practitioners asking for training. Practitioners interested in WMP come from a range of health, education and social care services, as WMP is an intervention that can support different families in different contexts without modifications. We conducted a survey in 2021 of WMP take up; services told us they were offering WMP to families referred for parent-child relationship difficulties (67% of referrals), families with suspected infant mental health problems (67%), parent mental health problems (58%) and child developmental delay (50%). During COVID-19

lockdowns many services supported their clients or patients remotely, WMP was delivered online or in combination of online and face to face sessions in 2020 and 2021.

WMP therefore likely addresses/may have the potential to address the need for a low intensity, scalable, preventative intervention, inclusive of a broad age range (0 to 8 years) that can be offered by practitioners in NHS, Local Authority and Voluntary Sector settings. It has the potential to address key challenges for children's mental health identified in the 2021 Children's Commissioner's report of both increasing access to intervention for children and broadening the 'system of support' on offer across a range of services (Children's Commissioner, 2021).

This study directly addresses priority 4 of the top ten priorities for children's mental health identified by the James Lind Alliance i.e. 'What are the most effective early interventions or early intervention strategies for supporting children and young people to improve mental resilience?' (McPin Foundation, 2018). The key importance of early intervention in improving children's lifelong mental health and the need to develop widespread service and practitioner capacity within the UK in order to do this is further highlighted in the recently published 2021 DHSC Early Years Health and Development Review Report: 'The Best Start for Life: A Vision for the 1,001 Critical Days' (Department of Health and Social Care, 2021). In addition, the 5 Year Forward View for Mental Health emphasises the need for 'action to intervene early and build resilience as well as improving access to high-quality evidence-based treatment and services'. Maximising opportunities for prevention and improving access are also noted as priorities in the Framework for Mental Health Research (Department of Health and Social Care, 2017) and in the Mental Health Research Goals 2020-2030 (Academy of Medical Sciences, 2020).

There has been rising demand for WMP during the pandemic; over 250 practitioners were trained in 2020-21 and the manual has been translated into several languages (including Chinese, Dutch, Greek, Italian, Japanese, Norwegian, Russian and Ukrainian). WMP is designed to complement or precede other interventions e.g., video-feedback and parent training programmes. As it is less resource-intensive to deliver, WMP may enable services to increase access and address barriers to engagement that can limit the reach of more intensive approaches. WMP has been found to be particularly of benefit in circumstances where there may be additional barriers to accessing mental health support e.g. children in the care system, remote rural areas, areas of high deprivation, ethnic minority communities. Children with a social worker may experience particular risk factors which may be addressed with WMP (Table 1). The broad age range (0-8 years) includes the possibility of early intervention in infancy when relationships and developmental trajectories may be most amenable to change. It is therefore essential that the evidence-base for WMP is developed to enable services to offer the right support to families. The first step in this process will be to formally assess the feasibility and acceptability of WMP for families referred to early years and children's services, either currently experiencing mental health problems or at significant risk of developing mental health problems in later life. Results of the present study will indicate whether it is feasible and appropriate to conduct a full-scale effectiveness evaluation (RCT).

Implications of the intervention for children with a social worker:	Risk factors that may be addressed with the intervention include:
The WMP programme was first developed with children in care and is now more widely used. Feedback from foster carers, adoptive parents, social workers and independent reviewing officers suggested that it could be helpful in the following situations: - For children entering care and aged between four months and eight years - For children with complex psychosocial and attachment difficulties and who may need more intensive subsequent psychological intervention: WMP support can help to indicate the type of further support or more specialised assessment that might be needed - For caregivers needing further support: WMP support can help to indicate the type of further support or more specialised assessment that might be needed - For children in transition or for whom a move to a special guardians, a new foster home, an adoptive family or return to parents is planned. WMP support would be provided to the child with the current caregiver and the new caregivers would be trained and supported to continue the approach when the child was placed with them. - For children in supervised contact with family members, with the support of trained contact supervisors. WMP is also used to support families receiving Early Help, Children In Need and children experiencing attachment, bonding or other psychosocial difficulties prior to possible social care involvement.	- Long delays in treatment or support for infants and young children presenting with early signs of attachment, regulation, conduct, behaviour or emotional difficulties, but not meeting thresholds or criteria for referral to Parent-Infant or CAMH services. - Inadvertent neglect of children's emotional and developmental needs resulting from difficulties in forming sensitive and attuned relationships early in life, or avoidant patterns of attachment that result in a child's needs continuing to be unrecognised and therefore unattended too. - The ongoing impact of unattuned interactions between child and caregiver, sometimes for caregivers who have psychosocial or mental health difficulties or who experienced deprivations in childhood themselves - Risks to children's well-being and relationships resulting from abrupt transitions with insufficient integration between current and new caregivers - For children in care, risks to their well-being and placement stability resulting from repeated experiences of unattuned interactions with family members during supervised contact.

Table 1. Risk factors and implications for WMP for children with a social worker

Intervention and logic model

Watch Me Play! can be done from the first weeks of a baby's life up to the age of five, six or seven years depending on the kind of play they enjoy and are ready for. WMP involves a parent watching the child play freely, making their own choices, and talking to their child about their play for a period of up to 20 minutes (this is called one session). The parent prepares by switching off the TV, phone and screens and putting out a small selection of non-electronic toys. he parent watches their child as they play, only joining in if the child invites them to do so, allowing the child to lead the play, as long as this is safe. The parent follows the child's play and describes what the child is doing. WMP is very similar with very young children (babies) who cannot yet interact with toys: the parent notices and follows the baby's signals, mirrors facial expressions, movements and sounds, and talks to the baby, imitating the baby's expressions or sounds as if having a conversation. This can give an idea of what the baby is interested in. The parent does not engage in other activities, giving instead their full attention to the child or baby during the up to 20-minute session. The parent does not direct play. Baby and child-led play helps parents to tune into their child throughout their development. In helping the child to play freely, parents are giving space for their child's imagination and skills for learning. The parent is encouraged to record their reflections in a diary at the end.

Some sessions will be facilitated by a trained practitioner who will join the parent in watching the child or baby, either in-person or online (using secure video conferencing software), and talking to the child about their play, and providing prompts to the parent where necessary. Towards the end of the session, the trained practitioner will talk with the parent about the child's play: what they saw, what was new, or not new, what the child enjoys; and about the parent's experience: what they noticed, enjoyed, or found difficult. A facilitated session lasts up to one hour. A session that is not facilitated may last up to 20 minutes. It is recommended that services offer 5 facilitated sessions, following an introductory meeting, and parents do at least 10 independent sessions with their child over a 5-week period (i.e., 3 sessions a week, of which one is facilitated). Adherence is defined as having done 10 (of 15) sessions, including the 5 facilitated ones. We will be monitoring frequency of session to see what works for families. Since WMP's publication in 2020, it has been offered online as well as in face-to-face sessions (because of social distancing restrictions), with practitioners supporting parents through Zoom or Teams during the facilitated sessions. In this study, WMP will be primarily delivered online but where the parent or the WMP practitioner feel that some in-person contact is important, services may offer in-person sessions (e.g., the introductory meeting and/or one facilitated session). Online delivery offers the potential of making WMP more easily accessible for families with digital technology. Many services have returned to face-to-face sessions but we want to see how WMP could provide a flexible model for practitioners supporting families either face-to-face or online. Online just means that the therapist is engaging with the parent via Zooms or Teams. This research will explore whether families prefer online or in-person sessions, or a combination of both. We will monitor the format of facilitated sessions across all participating sites.

WMP materials and training of practitioners: A parent and therapist WMP manual and leaflets in Traditional Chinese, English, Dutch, Italian, Japanese, Norwegian, Russian, Ukrainian and Greek are available for free download from the webpage: https://tavistockandportman.nhs.uk/watch-me-play (Wakelyn & Katz, 2020). Any healthcare, social care or early years professional with two or more years' experience of work with children and families can be trained in the approach. Training is a 1-day workshop

introduction followed by group supervision delivered by Dr Jenifer Wakelyn. The manual is a resource which will help parents to support their child's development through play, and covers:

1. What is Watch Me Play!
2. How to do Watch Me Play! – Quick View
    a. Preparing
    b. Baby and Child-led play
    c. Watching your child play
    d. Talking with your baby or child about their play
    e. Talking with another adult about the child's play
3. Toys and materials for play
4. A Watch Me Play! Diary
5. Why Play Matters

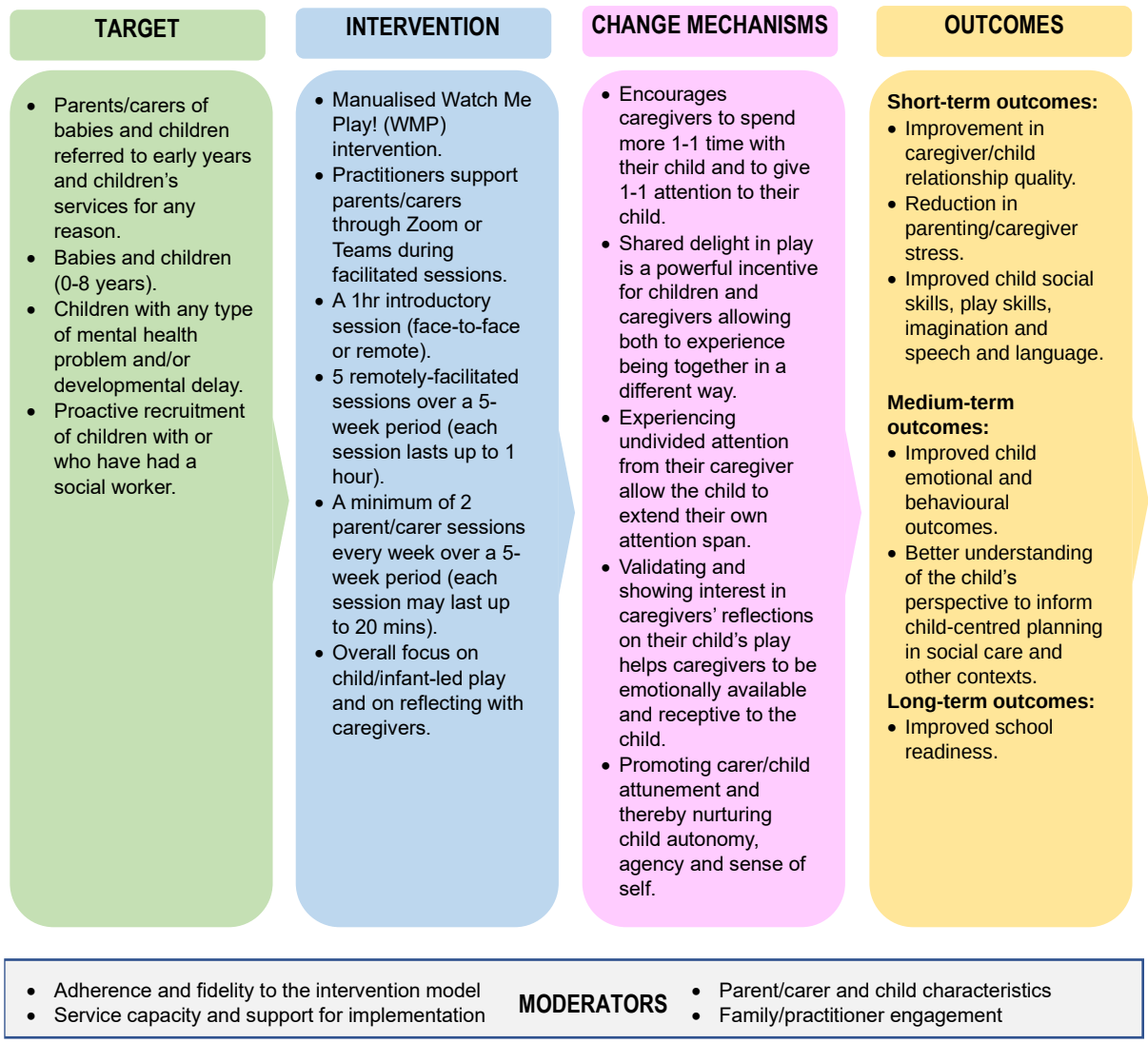
Two shorter leaflets are also available for parents and a 4-minute video explaining the approach will be available from June 2023.

Fidelity of delivery:

Fidelity will be assured and monitored through small supervision groups for the duration of the intervention period. Four group supervision meetings will take place during the 5-week intervention period. During supervision, WMP practitioners meet with the WMP supervisor in small groups and take it in turns to discuss their case drawing on written notes of a recent session. An additional option of a monthly drop-in supervision will be available to discuss issues arising. As part of regular practice, practitioners complete a 5-item WMP checklist (Appendix 1) after each session with caregiver(s). A random sample of 25% of the checklists will be rated to determine whether fidelity has been achieved: each of the 5 items is rated as 'achieved' (2), 'partially achieved' (1) and 'not yet achieved' (0) and 'explored with caregiver?' (Yes = 1, No = 0). For a session to be completed with acceptable fidelity, a score of 10 or more out of 15 is expected.

Adherence is defined as having completed 10 (of 15) sessions, including the 5 facilitated ones. The study will provide descriptive statistics on adherence.

Figure 1. Watch Me Play! Logic Model



Research questions

The study aims to address the following research questions.

The primary objective is to assess the feasibility of delivering WMP for babies and children (age 0 to 8 years) referred to early years and children's services in the UK. To achieve the primary objective, the following will be assessed:

1. Evidence of feasibility –
    a. What is the **feasibility** of **recruiting** families, recruitment rates, adherence to the intervention and retaining families for 3 months?
    b. What is the **feasibility** of recruiting and training suitable intervention providers and facilitators to **deliver** the WMP **intervention**?

c. Can WMP be delivered according to **fidelity** and what are the barriers to, and facilitators of, **implementation** and variation across context (online and face-to-face)?
d. Are study processes **acceptable** to delivery organisations, delivery staff and parents/carers?
e. Is the WMP intervention **acceptable** and what are the barriers and facilitators to delivery organisations, delivery staff, parents/carers to inform a future trial?
f. What are the potential harms of the intervention?

2. Evidence of promise –
    a. What is the intervention receipt and hypothesised **mechanisms of action**? This information will then be used to refine the intervention **logic model**.

3. Readiness for trial –
    a. What is **treatment as usual** (TAU) as delivered by participating services; how is WMP delivered in relation to TAU and does it interact with TAU; what is the most appropriate comparator for a definitive trial?
    b. What is the most appropriate **primary outcome** for a future efficacy/effectiveness trial?

4. Cost -
    a. What are the intervention **costs** and the feasibility of collecting health economic data in a future definitive effectiveness trial?

Outcomes

Research question	Indicator	Method
What is the feasibility of recruiting families, recruitment rates, adherence to the intervention and retaining families for 3 months What is the feasibility of recruiting and	Recruitment	Qualitative data from interviews with staff and parent/carers on barriers and facilitators of recruitment to the study. Descriptive statistics of number of parents who have or had (in the previous 24 months, or prior to this) contact with a Social Worker and have been invited to participate, and the number who agree to participate.

training suitable intervention providers and facilitators to deliver the WMP intervention?	Retention	Descriptive statistics on the number of participants who remain in the study at 3 months.
	Adherence to the intervention	Quantitative data to describe the degree to which parents/carers engage with the intervention (descriptive statistics on the number of sessions (total and facilitated) offered and completed, % of participants who completed 10/15 sessions, including all 5 facilitated sessions).
Can WMP be delivered according to fidelity and what are the barriers and facilitators of implementation and variation across context (online and face-to-face)?	Fidelity of WMP programme delivery	A random sample of 25% of the checklists will be rated to determine whether fidelity has been achieved: each of the 5 items is rated as achieved (2), partially achieved (1) and not yet achieved (0). For a session to be completed with acceptable fidelity, it is expected that a score of 10 or more out of 15 items will be 'achieved.
Are study processes acceptable to delivery organisations, delivery staff and parents/carers.	Assessment of the barriers and facilitators to implementation.	Qualitative data from interviews with delivery staff and managers on the acceptability and feasibility of offering online WMP, including the barriers and facilitators of delivering WMP; qualitative data on whether implementation differed across different types of services; quantitative data from the standardised WMP checklist that practitioners complete after each session with caregiver(s) to describe fidelity of implementation.

Is the WMP intervention acceptable and what are the barriers and facilitators to delivery organisations, delivery staff, parents/carers to inform a future trial.	Acceptability of WMP to parents, WMP practitioners and service managers.	Qualitative data from the process evaluation interviews.
What are the potential harms of the intervention?	Adverse event reports	Adverse events will be monitored and reported quantitatively.
Evidence of promise What is the intervention receipt and hypothesised mechanisms of action?	Intervention Mechanisms	Qualitative data from interviews with parent/carers and delivery staff on how they experienced the process of WMP and perceived impacts.
Readiness for trial What is treatment as usual (TAU) as delivered by participating services; how is WMP delivered in relation to TAU and does it interact with TAU; what is the most appropriate comparator for a definitive trial?	Treatment as usual (TAU) description.	Descriptive data from early years and family services on the named interventions (manualised intervention packages) they offer to families of 0-8 year old children referred for support over the past 12 months. Qualitative data from the process evaluation interviews with staff to describe how WMP interacts with or is delivered in relation to TAU, so as to define the most appropriate comparator for a definitive trial.

What is the most appropriate primary outcome for a future efficacy/effectiveness trial?	Acceptability and feasibility of data collection procedures.	Qualitative data from interviews with parents on the experience of taking part in the study.
	Outcomes measures:	Percentage completion of all questionnaire measures, including the health economic measures (as described under 'Cost Evaluation' below.
Cost Intervention costs and the feasibility of collecting health economic data in a future definitive effectiveness trial.	Intervention costs	Descriptive cost data of WMP delivery across study sites.

Methods

Sample selection and recruitment

The study will be carried out in sites spread across the UK serving a mix of populations. We formed a Parent Carer Advisory group including key stakeholder groups who advised on all research material. We included compensation for research time participation to mitigate any negative financial impact from taking part in the research. Our target sites were selected to represent remote/rural and urban areas. Prior to study commencement, we surveyed potential sites regarding their referral population and identified that potential sites accepted referrals for a range of reasons (in addition to referrals because of concerns about the mother-child relationship, e.g., concerns about maternal mental health, concerns about child development). Potential sites included significant numbers of children in contact with a social worker and children with a developmental delay. The study will monitor recruitment in relation to ethnicity, parent education, developmental delay status, and child contact with social worker (currently or in the past).

Eleven sites have expressed an interest in participating (CAMHS, child development teams, foster care services, mental health services for children in care). Interested sites have at least one staff member trained to deliver WMP (but vary in the extent to which they already offer WMP to parents). Some interested sites have no members of staff trained on WMP. We will offer to train up to three members of staff in WMP so that each service has at least three staff trained. We will aim to recruit some sites with no prior exposure to WMP so we can investigate the feasibility of rolling out training.

20 families will be recruited. As this is a feasibility trial which was agreed, we did not perform a formal sample size calculation, but agreed that 20 families would provide adequate feasibility data to inform the design of a larger future randomised trial.

Participants are eligible for the study if they meet all of the following inclusion criteria and none of the exclusion criteria apply.

Inclusion criteria

Parents/carers: Consenting parents or carers of children aged 0 to 8 years-old who have a referral to or have been accepted by an early years/children's service.
Parent/carer able to complete outcome measures in English (with support if required).
Children with any type of mental health problem, and/or developmental delay will not be excluded from taking part provided all eligibility criteria are met.
Staff: Staff involved in the delivery of the WMP intervention.

Exclusion criteria

Parents/carers: Parents/carers currently receiving or planning to receive WMP not within the context of this study in the next 6 months.
Staff: Staff not able to deliver the WMP intervention.

Participants will be identified by services as potentially eligible: we will ask sites to identify referrals/cases within the right age range and in particular those with a social worker now or in the past 24 months. Participating services will email parents/carers a brief information leaflet (briefing sheet) about the study. Parents interested in taking part or knowing more will either go straight to the screening/consent questionnaire via a link code on the briefing sheet, or contact the research team via contact details on the briefing sheet. The researcher will discuss the study in more detail with the participants. The screening/consent questionnaire will contain the full participant information sheet. Those who provide informed consent will be screened for eligibility. We will proactively target children with or who have had a social worker for recruitment, noting barriers and facilitators to recruitment where they exist. Recruitment will be monitored to ensure diversity in relation to ethnicity, low SES, poor literacy and under-served populations, as per NIHR INCLUDE and INCLUDE ethnicity guidance. We will encourage BME participation in consultation with the Centre for BME health (https://centreforbmehealth.org.uk/). In the context of this study we monitor recruitment of under-served populations in relation to:

- Ethnicity
- Parent disability
- Parent unemployment
- Child disability and developmental disability status
- Child contact with social worker (current and in the past).

Data collection

In summary, feasibility data will be captured through:

Data collection method	Sample size	Collection timeline
Online survey	20 parents/carers	Screening, baseline and 3 month follow-up
Qualitative interview	Up to 14 Parents/Carers and practitioners	Post intervention

Assessments

Measurement of parent/child outcomes (baseline and post-intervention): Parent and child outcomes will be measured at baseline and post intervention. Child outcomes (mental health, socialisation, and communication) will be measured at baseline and post-intervention follow up. All outcomes, except for parent-child interaction, will be measured through parent report (questionnaires to be completed via a survey link). Parent-child interaction during free play will be video recorded (for 20 minutes) by researchers remotely during baseline only for a smaller number of randomly selected participants, from those who have consented to be contacted (up to n=8). Additional information will be collected at baseline only on presence of child's developmental delay and on the child's status as in contact with social worker.

Follow-up

In the event that participants' follow up appointments are missed at the proposed time points, the research team will contact the participant by telephone to rearrange the appointment as soon as possible. Follow up assessments for all participants will be conducted 3 months from baseline with a +/- 2-week window.

Process evaluation

The process evaluation will examine (i) recruitment and reach; (ii)retention (iii) engagement and adherence; (iv); intervention implementation; (v) intervention acceptability, barriers and facilitators of participation. We will use MRC guidance (Moore et al., 2015) as a framework to describe implementation processes, examine intervention mechanisms, and consider how the intervention interacts with existing delivery systems across different contexts (e.g. urban/rural areas). A mixed methods approach will be used. Quantitative methods will assess recruitment rates/patterns and intervention fidelity/adherence. Qualitative interviews with participants and delivery staff, including trainers, will examine implementation processes, intervention mechanisms and the role of contextual factors.

Qualitative data collection

Interviews will be conducted virtually or by telephone. A topic guide has been developed using a scoping literature review and input from the research team and PPI advisory panel. Qualitative interviews with parents will explore their experience of receiving the intervention, including perceived benefits and mechanisms. These data will enable us to explore the extent to which key intervention mechanisms appear to be working as intended, variation across context (e.g., delivery sites, professional role of delivery staff, family characteristics such as child's age), and any unintended mechanisms or barriers to participation. We will also explore attitudes towards inclusion of randomisation in a future trial design. These data will be used to refine assumptions underlying proposed intervention mechanisms and theory of change and inform final selection of outcomes for a future effectiveness trial.

Semi-structured interviews will also be conducted virtually or by telephone with staff members who have delivered the intervention. We may also invite to interview other staff members, e.g. managers in the organisations who have been involved but not delivered the intervention. A topic guide has been developed using a scoping literature review and input from the research team.

Qualitative interviews with staff will explore engagement with WMP, and factors affecting adherence. We will invite members of delivery staff: trained WMP practitioners and managers/individuals responsible for implementation coordination (6-8 sites, 1 per site, n=6-8) to participate in interviews to explore their experience of delivering WMP, and influences on implementation fidelity. These interviews will also explore the systems and structures needed for future implementation of WMP at scale across a range of early years and children's services. Interviews with parents, delivery staff and trainers/managers will explore provision of existing services (usual practice) and distinctiveness of WMP from other interventions. This will aid interpretation of quantitative data collected on service utilisation.

We will ask staff to reflect on their feelings about taking part in the intervention, any barriers and facilitators to participation and any way in which the intervention or the surrounding administration could be improved. A key aspect of this is to find out from the staff members whether the experience of the intervention online has been a success in comparison to their experiences (if any) of delivering the intervention in person.

The topic guides for parents/carers and staff will include overarching topics we would like to cover, but will be flexible and allow the interview to be guided by the interviewee in terms of order and wording, and allow the interviewee to initiate and develop topics that have not been pre-empted by researchers and PPI advisory panel.

Our data collection and analysis plan details the role of researchers including their background and prior experience. Researcher field notes recorded following each interview will allow for personal and interpersonal reflection, and consider how the researchers unique perspective, relationship with the interviewee and power dynamics influence the research. We will use NVivo data management software to maintain an audit of analysis and qualitative decision log recording decision made to ensure methodological reflexivity.

We will be pragmatic in sample size. The number of interviews will be based on preliminary analysis/interviewer field notes indicating whether the data collected sufficiently answer the research questions. Our proposed sample size for interviews with parents is up to14 and for staff is 6-8. We will conduct up to three parent/carer interviews and one staff interview per participating site, thus giving greater breadth of practice variation. We will monitor the breadth and depth of data, whether interview participants are representative of the study population, and practical aspects of recruitment (attempts to invite participants, numbers declined, and withdrawn). We will continually review our sampling decisions and keep detailed notes on our sampling strategy to maintain transparency. Data collection will be iterative, allowing preliminary analysis to guide the subsequent sampling decision and selection of further interviewees. We will purposefully sample interviewees with maximum variation across location.

Analysis

Primary analysis:

The primary outcomes are to determine the feasibility of future research. This is a mixed methods approach, including qualitative interviews. The quantitative measures contributing to the primary feasibility outcomes will be:

1. Recruitment feasibility: The number of families invited to take part, and the number and percentage who attend at least one WMP session
2. Retention: The number and percentage of families who remain on the study at 3 months.
3. Adherence:
    a. Number of online WMP sessions initiated for each family, separated by total sessions and facilitated sessions.
    b. Number of online WMP sessions completed for each family, separated by total sessions and facilitated sessions.
    c. The number and percentage of families who completed 10/15 sessions including all 5 facilitated sessions.

4. Fidelity of programme delivery: Quantitative data from the standardised WMP checklist will be descriptively summarised with tabulations and graphics. Practitioners will complete a short WMP checklist after each session with caregiver(s). A random sample of 25% of the checklists will be rated according to fidelity criteria to determine whether acceptable fidelity has been achieved.
5. Acceptability for families:
    a. The number of questionnaires (EQ5D, health economics and service use) completed by families at each visit.
    b. Number of remote videos captured by families completing this element, and number of over 5 minutes duration.
6. Acceptability for staff: Number and percentage of delivery staff who report that the intervention is acceptable to deliver.

Outcome measures related to the clinical, Quality of Life and health economics are:

1. Cost of WMP: Total costs attributed to WMP from study sites
2. Identification of potential outcomes and assessments for a future trial:
    a. Descriptive tabulations of baseline demographic information, and social worker status at baseline.
    b. Descriptive tabulations and graphics showing responses to the Parent/child and health economic measures listed in Table 1.
    c. Number and percentage of children with reported developmental delay at baseline.
    d. Number and percentage of families reporting overall improvement in relationship with their child at 3 months compared to baseline.
    e. Number and percentage of families who attribute improvement to the WMP intervention.
    f. Number and percentage of children in the program with existing mental health problems at baseline, number and percentage of children with sustained, improved and worsened mental health problems at 3 months, as reported by the families and by the practitioners.

Descriptive analysis will summarise data for all patients and will include tabulations of categorical data, with the median and interquartile ranges of quantitative measures (such as questionnaire scales). Where percentages are calculated, these will be presented with 95% confidence intervals. Demographic, medical history and baseline data will be summarised, then the interventional sessions will be summarised for each session. The 3-month timepoint will be the follow-up timepoint for determining outcomes for a larger future trial.
There are no formal statistical tests required for this analysis.

Qualitative analysis

Interview transcripts will be analysed using thematic analysis (Braun & Clarke, 2022). After familiarisation of data, we will generate preliminary codes to label data of interest based on the research objectives.. We will retrieve coded data to generate themes and produce summaries of interviewees' talk on each theme, for each individual participant, and visually arranging in a table to build an overall picture of the whole data set. This will allow for comparison across parents/carers, staff and sites to identify variation and similarities in the final stage of interpretation of data. The next stage will involve the research team using the summaries to examine the quality and boundaries of themes identified.. From this we will finalise a thematic map refining the specifics of each theme to capture key concepts and

produce an analytic commentary and interpretation of the data set as a whole and connect with the original research objectives. The qualitative software package, NVivo (2015) will be used to manage the data. A proportion of transcripts will be double-coded until consensus is reached (likely to be 10%).

We will use the qualitative data to explore from the perspectives of parents/carers and staff. We will use the data to identify barriers and facilitators (practical, management, organisational) to implementing virtual or hybrid WMP in other sites which do not routinely use a virtual delivery.

Cost evaluation

The health economic component will assess the costs of delivering remotely facilitated WMP and report a cost per child of delivering WMP, including training cost and time spent on different components of the intervention.

The feasibility of collecting service use data and Health Related Quality of Life (HRQoL) information will also be evaluated for use in a future cost-effectiveness analysis. Service use will be collected using a modified version of the Child and Adolescent Service Use Schedule (CA-SUS). We will collect information on the use of Primary and Community Care, Parental groups, Urgent and Emergency Care, Hospital attendances and support from a social worker. In addition, a question on parent service use will be used to evaluate if a future trial should include a parent specific Client Service Receipt Inventory (CSRI). We will report information on levels of service use and completeness to assess the feasibility of using the questionnaire and whether any changes should be made for a future study. We will report the mean total cost of service use per child.

We will collect the self-reported EQ-5D-5L from parents/carers. The EQ-5D-5L is a generic HRQoL measure used to calculate Quality Adjusted Life Years (QALYs), which account for both quality and quantity of life lived. QALYs are the National Institute for health and Care Excellence's (NICE) recommended outcome for use in healthcare resource allocation decision making (National Institute for Health and Care Excellence, 2022). QALYs will be calculated using utility values derived from the UK value set for the EQ-5D-5L. We will report completeness, mean utility at each timepoint and QALYs over the course of the study. This will help us assess the sensitivity of the measure to changes in HRQoL following WMP and the acceptability of the measure in this participant group to inform a future trial.

Ethics

This protocol has approval from a Research Ethics Committee (REC) that is legally "recognised" by the United Kingdom Ethics Committee Authority for review and approval. This study protocol will be submitted through the relevant permission system for global governance review dependant on the location of the lead site. The study will also seek Health Research Authority (HRA) Approval for the study protocol and all the study materials such as the Participant Information Sheet and Consent Form prior to the start of the study

Approval will be obtained from the host care organisation who will consider local governance requirements and site feasibility. The Research Governance approval of the host care organisation must be obtained before recruitment of participants within that host care

organisation.

Informed consent

Informed consent will be obtained for all participants prior to the participant undergoing procedures that are specifically for the purposes of the study. Informed consent for the whole study will be recorded as an e-consent (via Qualtrics). All potential participants will be provided with an information sheet when they first contact the researcher, or download it from the initial screening/consent questionnaire; they will be offered an opportunity to discuss the study and ask questions and there will be sufficient time after the initial invitation to participate before being asked to provide consent. Parents/carers will be notified that they can withdraw consent at any time during the trial period. For children in foster care, agreement to participate will also be sought from the child's social worker.

Separate informed consent will also be taken for participation in the qualitative interviews and in the video recordings of free play. For qualitative data and analysis, the parent/carer's verbal informed consent must be obtained by the research team at CTR, Cardiff University, prior to undertaking any qualitative interviews using the study consent form script. Separate optional selection boxes on the study e-consent form allow the participant to consent (or not) to being contacted by the researcher in the future for the interview and/or video recording to arrange the interview/video meeting. If these boxes are selected, the researcher will be given participant contact details to arrange these at the appropriate time (for video recording this is before the intervention and for interview this is after the intervention). At this point, the participant could decide not to take part in the interview or video recording.

We will comply with Welsh language requirements and the Patient Information Sheet (PIS), Consent Form and any other required participant documentation will be available in Welsh. However, all documentation used for data collection (i.e. outcome measures) will remain in English as they are designed and validated in English. Please note, only when informed consent has been obtained from the participant will any data collection take place, including screening data collection.

Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the study.

If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from:

1. Withdrawal from intervention
2. Partial withdrawal from further data collection (e.g. questionnaires, interviews)
3. Complete withdrawal from further data collection
4. Withdrawal of consent to all of the above

The withdrawal of participant consent shall not affect the study activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal. Furthermore, it is important to collect safety data ongoing at the time of withdrawal,

especially if the participant withdraws because of a safety event. There is specific guidance on this contained in the PIS but briefly:

A participant may withdraw or be withdrawn from study intervention for the following reasons:

- Withdrawal of consent for intervention by the parent/carer
- Any alteration in the child's condition which justifies the discontinuation of the intervention in the PIs opinion.
- Non-compliance

In all instances participants who consent and subsequently withdraw should complete a withdrawal form or the withdrawal form should be completed on the participant's behalf by the researcher/site intervention staff based on information provided by the participant. This withdrawal form should be sent to the study team. Any queries relating to potential withdrawal of a participant should be forwarded to the study manager.

Ethical consideration	Mitigation
Psychological distress related to the data collection: As participants will be invited to provide information about mental health, it is likely they might experience mild psychological discomfort associated with reflecting on their own mental health and the mental health of their child while filling in the relevant questionnaires	Participants will always have the option not to answer any questions they are asked. However, should participants feel upset or distressed at any point, we advise they contact the team looking after them in the agency who referred them. They would be able to discuss this with them and signpost them to further support if needed.
The protection of participants' personal information:	Minimisation of risk by design: Services will identify potentially eligible parents and provide study information via mailouts or directly in consultation. The study team will collect aggregated anonymous data only from each site on the number of families they emailed or gave the study brief. No personal information will be transferred from sites to the study team. Participants will be provided with clear information on the mechanisms associated with the protection of their personal information in the Participant Information Sheet. Data minimisation: We only collect data required for the purposes of the study (e.g., we do not collect granular data or genders other than male/female/other). We minimise the repetition of collecting personal identifying information during online surveys.

	Interviews will be transcribed by an external service provider for transcription. All interviews will be sent securely. Once transcribed, transcripts will be anonymised with pseudonyms or codes replacing participant information or direct references used to other individuals, places, service names etc. Personal identifying data downloaded from Qualtrics (names, email addresses, telephone numbers) will be kept in a password-protected database separate from the other study data. Study databases will be pseudonymised, i.e., participants will be allocated a code.
Limits to participants' right to confidentiality:	Data collection involves interviews with participants. In the event of disclosure of an issue that has safeguarding implications (adult safeguarding or child safeguarding), the researcher will raise the issue with their line manager immediately following the disclosure and no later than 24 hours after the disclosure. All members of the research team collecting data from participants directly will receive training on Good Clinical Practice, Data Protection and Safeguarding.

Data protection

The data we collect will be used solely to address our research questions and will be pseudonymised and held under a Participant Identification Number (PID). During consent processes, participants will be informed of their right not to take part or to withdraw at any time. The CTR, Cardiff University will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Direct quotes may be published from qualitative interviews: to protect participants' identity we will use pseudonyms or codes (e.g. parent 1).

Data will be stored confidentially on secure password protected severs and accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR). Personal information will be collected, kept and stored securely in compliance with UK GDPR. The research team and staff at participating sites are trained in GDPR compliance. The Data Controller is Tavistock & Portman NHS Foundation Trust. The data custodian for this study is the CI, Dr Eilis Kennedy.

A Data Protection Impact Assessment (DPIA) has been completed as part of an overall trial risk assessment.

Personnel

Project Team
The project team consists of the Chief Investigators and team at Centre for Trials Research (CTR):

Chief Investigator	Eilis Kennedy	Tavistock and Portman NHS Foundation Trust
Chief Investigator	Vaso Totsika	University College London
Study Administrator:	Kelly Lewis	Cardiff University, Centre for Trials Research
Study Managers & qualitative researchers:	Kim Smallman Josie Henley	Cardiff University, Centre for Trials Research
Data Manager:	Marielle Sansom	Cardiff University, Centre for Trials Research
Quantitative data analyst:	Sean Johnson	Cardiff University, Centre for Trials Research
Senior Trial Manager:	Liz Randell	Cardiff University, Centre for Trials Research
Senior Statistician:	Angela Casbard	Cardiff University, Centre for Trials Research
Qualitative lead:	Jeremy Segrott	Cardiff University, Centre for Trials Research
Principal Research Fellow, Trials	Rachel McNamara	Cardiff University, Centre for Trials Research
PPI lead	Kathy McKay	Tavistock and Portman NHS Foundation Trust
Intervention lead	Jenifer Wakelyn	Tavistock and Portman NHS Foundation Trust
Social Care lead	David Wilkins	Centre for Trials Research
Health Economics	Marie Le Novere	University College London

Risks

This section outlines the anticipated risks that may arise and steps that will be taken to mitigate against these.

Risk	Mitigation
Low engagement of LA staff and families	The study is designed to minimise burden on the local authority and participants. Engagement in the intervention forms part of the trial feasibility evaluation.
Intervention not delivered as intended	All intervention delivery staff will have received relevant training as specified by the intervention providers (Tavistock and Portman NHS Foundation Trust). Issue with delivery will be addressed in supervision. Fidelity of delivery will be addressed as part of the feasibility evaluation.
Recruitment and attrition of families	Families will be followed up by the research team. Recruitment and attrition will be explored as a feasibility outcome of interest.

Timeline

This timeline is indicative only, as it is dependent on final project delivery timescales

Phase	Timing	Lead
Study set-up: • Contracts • Forming PPI group • Develop evaluation pack & study materials • Develop study protocol • Services survey • Ethics approval • Design/validate database	Months 1-8	Vaso Totsika and Eilis Kennedy

Data Collections and Analysis: • Recruit/screen participants • Baseline assessment • Intervention period • Post-intervention follow-up • Data entry/cleaning • Qualitative interviews • Qualitative analysis • Statistical Analysis • Health Economics analysis	Months 6-20	Vaso Totsika and Eilis Kennedy
Dissemination and Output: • Reporting/dissemination	Months 19 and 20	Vaso Totsika and Eilis Kennedy

Appendices

WMP Checklist for Practitioners

WMP checklist for practitioners

Practitioner name: …
Session date: …
Parent and child initials: …
Age of child: …

1. Preparation:

Guiding parents or carers to select up to 6 age-appropriate toys; asking parents or carers to put away electronic and battery toys, screens, phones away and turn TV off; sitting with parents or carers on or near the floor; encouraging parents or carers to help the child to prepare for the end of the play session.

Achieved **2** Partially achieved **1** Not yet achieved **0**
Explored with caregiver? Yes **1** No **0**

2. Baby or child-led play:

Supporting the parent or carer to allow the baby or child to take the lead and play freely, and to join in if invited to by the child, but still following the child's lead; encouraging and guiding the parent to avoid teaching, correcting, directing or tidying up during the WMP time.

Achieved **2** Partially achieved **1** Not yet achieved **0**
Explored with caregiver? Yes **1** No **0**

3. Watching the baby or child play:

Supporting the parent or carer to give their undivided attention to whatever their baby or child chooses to do, encouraging the parent or carer to watch their baby or child and see how they respond, giving the baby or child time to respond and find their own way in play

Achieved **2** Partially achieved **1** Not yet achieved **0**
Explored with caregiver? Yes **1** No **0**

4. Talking with the baby or child about their play:

Describing what the baby or child does and encouraging the parent or carer to do the same; with a baby, echoing their sounds and vocalisations and encouraging the parent or carer to do the same; guiding and encouraging the parent to talk with their baby or child about their play using simple language or sounds

Achieved **2** Partially achieved **1** Not yet achieved **0**
Explored with caregiver? Yes **1** No **0**

5. Talking with another adult about the child's play:

Talking with the parent or carer the child's play in the last play session - what they noticed, any changes or lack of change, and reflecting on how it feels to be with their child while they are playing; sharing their own observations about moments of connectedness, developments and difficulties, linking with the parent or carer's goals, if these have been agreed; problem-solving with parents or carers about what is difficult for them in WMP and what could help

Achieved **2** Partially achieved **1** Not yet achieved **0**
Explored with caregiver? Yes **1** No **0**

Was this session online or in-person?

Date case last discussed in supervision/work discussion:

Comments /observations:

Fidelity Score for this session:

If the Fidelity Score is less than 10a, please re-read the WMP Short Guide, Manual for Parents and Further Information.

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