

Watch Me Play!: A pilot study of a remotely delivered mental health intervention for children age 0-8 years

Submission date 09/03/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

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. Barriers to accessing help are further exacerbated for certain groups e.g. children with a social worker, 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) 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 primarily been offered remotely via video link. Although WMP shows promise and it is already used in some services, it is not yet known whether it is effective. To determine if WMP improves well-being in families, researchers need to conduct a test (a randomized control trial - RCT). This study will determine if it is possible to conduct this test by doing a smaller study that seeks to understand how parents engage with WMP (a pilot feasibility study).

Who can participate?

Families of babies and children (age 0 to 8 years) referred to early years' services across the UK

What does the study involve?

WMP involves a parent/carer watching the child play and talking to their child about their play

(or for babies, observing and following signals) for up to 20 minutes per session. Some sessions are facilitated by a trained practitioner who provides prompts where necessary, gives feedback and discusses the child's play with the caregiver. Services will offer five facilitated sessions and parents/carers will be asked to do at least 10 additional sessions on their own with their child in a 5-week period.

The researchers will learn more about the experiences of families receiving WMP and also about families' experiences of participation in the research study itself. They 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. They will also investigate how WMP works as an intervention from the perspective of families, practitioners and services. The researchers will investigate what other treatment is offered as usual practice in services, and how much WMP costs to deliver. They will share their findings widely including with the parents, foster carers, clinicians, service managers and social workers who have advised on design of this study.

What are the possible benefits and risks of participating?

Many caregivers have found that Watch Me Play! has helped the development of children including their social and communication skills, attention, learning, language and memory. Feedback has also suggested that it can improve the caregiver-child relationship. It is not expected that this research will cause distress. However, the questionnaires will ask carers to reflect on their experiences, their child's abilities and difficulties, and their relationship with their child. Therefore, there is some potential for this to touch on sensitive subjects. We don't anticipate any negative effects for the children taking part in the study.

Where is the study run from?

Cardiff University (UK)

When is the study starting and how long is it expected to run for?

June 2022 to April 2024

Who is funding the study?

What Works for Children's Social Care (UK)

Who is the main contact?

Dr Claire Nollett, watchmeplay@cardiff.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

322873

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 322873, CPMS 55265

Study information

Scientific Title

Watch Me Play!: A pilot feasibility study of a remotely delivered Intervention to promote mental health resilience for children (age 0-8 years) across UK early years and children's services

Acronym

Watch Me Play!

Study objectives

Feasibility study of Watch Me Play (WMP). WMP 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. Although WMP shows promise and is already used in some services, we do not yet know whether it is effective. Before completing an effectiveness randomized controlled trial, we are completing a feasibility study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/03/2023, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048276; berkshireb.rec@hra.nhs.uk), ref: 23/SC/0045

Study design

Pilot feasibility study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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

Interventions

WMP involves a parent/carer watching the child play and talking to their child about their play (or for babies, observing and following signals) for up to 20 minutes per session. Some sessions are facilitated by a trained practitioner who provides prompts where necessary, gives feedback

and discusses the child's play with the caregiver. Services will offer five facilitated sessions and parents/carers will be asked to do at least 10 additional sessions on their own with their child in a 5-week period.

Intervention Type

Behavioural

Primary outcome(s)

1. Recruitment: Qualitative data from staff and parents/carers on barriers and facilitators of recruitment to the study. Descriptive statistics of the 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. Collected at screening and following baseline.
2. Retention: Descriptive statistics on the number of participants who remain in the study at 3 months.
3. 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 five facilitated sessions). Collected at post-intervention (3 months).
4. 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 five 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 out of 15 items will be 'achieved. Measured at post-intervention (3 months).
5. Assessment of the barriers and facilitators to implementation: qualitative data from 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. Collected at post-intervention (3 months).
6. Acceptability of WMP to parents, WMP practitioners and service managers: qualitative data from the process evaluation interviews at post-intervention (3 months)
7. 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. Collected at post-intervention (3 months).
8. Acceptability and feasibility of data collection procedures: Qualitative data from parents on the experience of taking part in the study collected at post-intervention (3 months)

Key secondary outcome(s)

1. Percentage completion of all questionnaire measures, including the health economic measures of EQ-5D and service use at baseline and 3-month follow-up:
 - 1.1. Child mental health measured using the Child Behavior Checklist (CBCL)
 - 1.2. Child mental health measured using the Strengths and Difficulties Questionnaire (SDQ)
 - 1.3. Child socialisation and communication measured using the Vineland Adaptive Behavior Scale
- 3
- 1.4. Parenting stress measured using the Parent Stress Index-Short Form
- 1.5. Parenting competence measured using the Being a Parent scale
- 1.6. Parent-child relationship quality measured using the Mothers' Object Relations Scale-Short

Form (MORS-SF) and MORS (Child) for 0-3 years, the Parent-Child Relationship Scale for 3+ years, and the frequency of parent-child activities (Parent-Child Activity Index)

1.7. Parent-child interaction assessed using a 20-minute videotaped free-play interaction between the parent/caregiver and the child (n = 8 baseline participants)

1.8. Parent/carer health-related quality of life measured using EQ-5D-5L

1.9. Service use for child measured using a modified version of the Child and Adolescent Service Use Schedule (CA-SUS)

2. Intervention costs: Descriptive cost data of WMP delivery across study sites at baseline and follow-up (3 months)

Completion date

30/04/2024

Eligibility

Key inclusion criteria

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

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

0 years

Upper age limit

8 years

Sex

All

Key exclusion criteria

Parents/carers currently receiving or planning to receive WMP not within the context of this study in the next 6 months

Date of first enrolment

31/05/2023

Date of final enrolment

30/11/2023

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Cardiff University

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Sponsor information

Organisation

The Tavistock and Portman NHS Foundation Trust

ROR

<https://ror.org/04fx4cs28>

Funder(s)

Funder type

Research organisation

Funder Name

What Works for Children's Social Care

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/04/2024	05/04/2024	Yes	No

[Funder report results](#)
[HRA research summary](#)

01/11/2024

27/01/2025

No

No

26/07/2023

No

No