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Is the infant massage intervention “Shantala Babymassage Individueel” effective for vulnerable families in early life?

Submission date 15/03/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 29/03/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/09/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Individual Shantala Infant Massage is a promising intervention that is already offered as preventive standard care by some Preventive Child Healthcare (PCH) organizations. It targets vulnerable families and it aims to enhance sensitive parenting and to reduce stress of the parent. The Individual Shantala Infant Massage intervention consists of three home visits with a fixed structure. Parents receive instructions on infant massage and parenting support. The intervention is carried out by a certified nurse of the PCH organization. The aim of this study to investigate the effectiveness of “Individual Shantala Infant Massage”, including an effect and process evaluation.

Who can participate?
The study is carried out in the setting of the PCH. In a (quasi-experimental) non-randomized controlled trial, an intervention group of infant-parent dyads who receive the intervention as part of the care offered by their PCH organization, will be compared with a control group of infant-parent dyads whose PCH organization does not offer this intervention. All dyads are included through the PCH organizations. The target number for inclusion is 150 infant-parent dyads per arm, 300 in total. However, this number includes margins for 30% non-response. 105 infant-parent dyads with complete data per arm (210 in total) are sufficient for data analysis.

What does the study involve?
The primary scientific outcomes are the measures where promising effects have previously been found in international research. We expect that the preventive intervention will reduce maternal stress and increase maternal sensitivity, and that it will have a positive influence on the development and growth of the infant. There are three measurement moments: T0: pre-test at inclusion (child age between six weeks and three months), T1: post-test (after completion of the intervention, or ± four weeks after T0), and T2: follow-up (child age five-six months). Participants are asked to fill out questionnaires at T0, T1 and T2. At T2, a tuft of hair will be cut from the mother in order to measure levels of the stress hormone cortisol. Data on infant growth and development will be obtained from the PCH files. In the intervention group, additional data will be collected for the process evaluation: parents will answer evaluation questions at T1, the

infant massage teachers will keep logbooks of the process of intervention sessions and focus groups or interviews will be done with a number of parents and professionals.

What are the possible benefits and risks of participating?
The intervention that is investigated, is already offered as part of standard care by some PCH organizations. In case the hypothesized effects are found, the infant-mother dyads in the intervention group can benefit, as well as later vulnerable mothers and infants participating in the infant massage intervention after the study has finished. There are no risks of participating. The study is not expected to have negative outcomes for the infants, even if it should not retrieve the hypothesized effect. All measures are non-invasive and the burden on participants is limited to a minimum.

Where is the study run from?
The study is run from TNO (the Netherlands Organisation for applied scientific research), Dept. of Child Health, in collaboration with the Radboudumc (Dept. of Cognitive Neuroscience) and the participating PCH organizations.

When is the study starting and how long is it expected to run for?
March 2020 to June 2024

Who is funding the study?
The study is funded by ZonMw, (Prevention program; Effectiveness Studies 2019-2022). ZonMw project number: 555002011 (the Netherlands)

Who is the main contact?
Dr Mariska Klein Velderman, mariska.kleinvelderman@tno.nl

Study website
https://www.zonmw.nl/nl/onderzoek-resultaten/preventie/programmas/project-detail/effectiviteitsonderzoek/the-effectiveness-of-the-infant-massage-intervention-shantala-babymassage-individueel-for-vulnerab/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Mariska Klein Velderman

ORCID ID
http://orcid.org/0000-0002-5799-7812

Contact details
Sylviusweg 71
Leiden
Netherlands
2333 BE
+31 888 666153
mariska.kleinvelderman@tno.nl

Type(s)
Public

Contact name
Dr Dafna Windhorst

ORCID ID
http://orcid.org/0000-0003-4755-9808

Contact details
Sylviusweg 71
Leiden
Netherlands
2333 BE
+316-29647252
dafna.windhorst@tno.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZonMw 555002011, TNO 060.39065, Radboudumc (PaNaMa) 112073

Study information

Scientific Title
The effectiveness of the Infant Massage Intervention “Shantala Babymassage Individueel” for vulnerable families in early life

Study objectives
The main hypothesis of this study is that the intervention Shantala Infant Massage Individual, offered as part of standard care by some Preventive Child Healthcare (PCH) organizations to parents with a young baby who have a risk of low sensitive parenting behavior, will lead to:
1. A more sensitive parent-child interaction
2. Lower reported and physiological stress of the parent,
3. Improved child growth and development.
in the intervention group, compared to a control group where this intervention is not (yet) part of standard care.

A secondary hypothesis is that the intervention will lead to a decrease of parental concerns (e.g. about crying, feeding and sleeping behavior of the baby) and increased parenting confidence.

Furthermore, we will try to answer the following research questions:
• Which subgroups may profit the most / least from the intervention (exploratory)?
• How do intermediary (professionals) and end users (parents) evaluate the intervention, including preconditions for further implementation? (evaluation of the intervention process)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/06/2021, TNO Institutional Review Board (TNO-IRB, Healthy Living Schipholweg 77-89, 2316 ZL Leiden, P.O. Box 3005, 2301 DA Leiden, The Netherlands; +31 (0)88 866 90 00; toetsing_mensgebondenonderzoek@tno.nl), ref: 2021-054
2. On 07/04/2021, The Research Ethics Committee of the Radboud University Medical Centre in Nijmegen (CMO regio Arnhem-Nijmegen) judged the study not to be subject to the Medical Research Involving Human Subjects Act (Radboudumc, Huispost 348 Commissie Mensgebonden Onderzoek, Postbus 9101, 6500 HB Nijmegen, The Netherlands; +31(0)24 3613154; commissiemensgebondenonderzoek@radboudumc.nl), ref: File number 2021-8221

Study design
Multicenter quasi-experimental interventional non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
This is an evaluation study of an intervention used in Preventive Child Healthcare in the Netherlands to enhance sensitive parenting and to reduce stress in parents at risk of low sensitive parenting behavior.

Interventions
Current interventions as of 03/02/2023:
The intervention Individual Shantala Infant Massage is offered as part of standard care by some Preventive Child Healthcare (PCH) organizations in the Netherlands. The target group concerns parents who have a risk of low-sensitive parenting behavior with a baby from six weeks to nine months old. Examples of vulnerable families are; families with low socio-economic status (SES), family systems under pressure, maternal stress and/or excessive infant crying. The intervention aims at enhancing sensitive parenting and reducing the stress of the parents.

The intervention is carried out by a certified nurse, who received extensive certified training. The intervention consists of a total of three weekly home visits of one hour. During each session, the parent learns how to massage the infant, while the nurse demonstrates this on a doll. Furthermore, topics such as holding the infant, signals of the baby, body language, and crying behavior are discussed and parents can ask questions. The intervention focuses on the sensitive responses of the mother to the emotional, physical and mental state/needs of her infant.

A more detailed description of the Individual Shantala Infant Massage intervention is provided on the website of the Dutch registry of health interventions (RIVM, Loket Gezond Leven): https://www.loketgezondleven.nl/interventies-zoeken#/InterventionDetails/1402295

This study is a non-randomized controlled trial, carried out in the daily practice of PCH. An intervention group consisting of PCH already offering Individual Shantala Infant Massage is compared with a control group of PCH where infant massage is not (yet) part of standard care provision. The target number of participants to be included is 150 per group (300 in total). However, this number includes margins for non-response. The complete data of 105 participants per arm, 210 in total, are sufficient to perform the data analysis.

Previous interventions:
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Intervention Type
Behavioural

Primary outcome measure
Time points:
T0 = Age baby between six weeks and (about) three months. (Prior to the intervention for the intervention group)

T1 = Approximately four weeks after T0. (After the intervention ends for the intervention group)
T2 = age baby five months

1. Physiological maternal stress is measured via hair cortisol. Hair samples are collected at T2.
2. Experienced maternal stress is measured using the Perceived stress scale (PSS-10, Cohen 1983) and the Postpartum Specific Anxiety Scale-Real Short Form (PSAS-RSF, Davies et al., 2021) at T0, T1, and T2.
3. Maternal sensitivity / mother-infant interaction (responsiveness, feelings about newborn, and cry perception): is measured using the Non-responsiveness scale of the Maternal Responsiveness Scale (MRQ, Leerkes & Qu, 2017), the Mother to Infant Bonding Scale (MIBS, Taylor, 2005) and the Cry Perception scale (Lester et al. 1992) at T0, T1, and T2.
4. Growth of the baby: data on length and weight assessed at multiple timepoints from birth to six months as part of standard care, are retrieved from PCH files after T2.
5. Development of the baby: Van Wiechen study scores (Jacobusse et al., 2008) assessed as part of standard PCH care at multiple timepoints, from birth to six months, are retrieved from PCH files after T2.

Secondary outcome measures
Time points:
T0 = Age baby between six weeks and (about) three months. (Prior to the intervention for the intervention group)
T1 = Approximately four weeks after T0. (After the intervention ends for the intervention group)
T2 = age baby five months

1. Parenting confidence of the parent is measured using the Karitane Parenting Confidence Scale KPCS (Crcnec et al., 2008) at T0, T1 and T2
2. Information on (parental concerns with regard to) crying, feeding, sleeping and related outcomes measured using Likert scales at T0, T1 and T2.
3. To evaluate the process of the intervention, data is collected in several ways:
3.1 An evaluation questionnaire is filled out by participants in the intervention group at T1
3.2 Semi-structured logbooks are completed by professionals after each intervention session
3.3 (Focus group) interviews with participants and professionals at the end of the study

Overall study start date
01/03/2020

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Parents or primary caregivers of a baby with an age up to (about) 3 months at the time of enrollment.
2. Included via one of the participating Preventive Child Healthcare organizations/locations
3. Participating in Individual Shantala Infant Massage intervention, offered by the PCH organization (intervention group only)

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
We aim to include 300 participants, 150 per arm. However: this number includes margins for 30% non-response. Complete data of 105 participants per arm, 210 in total, are sufficient to perform the data analysis. *additional information: Based on effect sizes as found in previous research, a medium effect size (d=0.50) is included as the basis for the power and sample size calculation. With a Cohen's d effect size of 0.50, 84 participants per research arm are needed for a power of 0.9. This is based on an ANOVA analysis between two groups of equal size. Because it is not possible to randomly assign participants or clusters, it is necessary to correct for possible differences between the groups e.g. by adding covariates or applying propensity score weighting (Johnsson et al., 2018). This reduces the effective sample size, because participants in one arm who are not very similar to participants in the other arm, make a small contribution to the analysis. An effective sample size reduction of 20% is taken into account as a result of possible group differences. To achieve a power of 0.9, and taking 20% loss into account, 105 participants per arm must be sampled. In addition, there may be non-response (missing of measurements / questionnaires, dropout from the study). Taking into account a non-response of 30%, we aim to recruit a total of 150 participants per group; 300 participants in total.

Total final enrolment
185

Key exclusion criteria
Current participant exclusion criteria as of 03/02/2023:
Unable to complete questionnaires in Dutch or English (alone or with help)

Previous participant exclusion criteria:
Unable to understand the Dutch language.

Date of first enrolment
01/08/2021

Date of final enrolment
10/07/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
CJG rijnmond
Westblaak 171

Rotterdam
Netherlands
3012 KJ

Study participating centre
Youth health care Kennemerland (Jeugdgezondheidszorg Kennemerland)
Kleermakerstraat 51 A
Velserbroek
Netherlands
1991 JL

Study participating centre
GGD Amsterdam
Nieuwe Achtergracht 100
Amsterdam
Netherlands
1018 WT

Sponsor information

Organisation
TNO (Netherlands Organization for Applied Scientific Research)

Sponsor details
Sylviusweg 71
Leiden
Netherlands
2333 BE
+31 888 666153
childhealthsecretary@tno.nl

Sponsor type
Research organisation

Website
https://www.tno.nl/nl/

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
Once the project has ended and reported, an archive or repository for (certified) long-term archiving of our data collection will be selected. The data will be stored for 10 years. Our project data will be accessible for further research and verification in line with the FAIR principles; a set of guiding principles in order to make data findable, accessible, interoperable and reusable. The data collection of this project will be findable for subsequent research by using the data repository for the publication of data (e.g. the Data Archives Networked Services, DANS or the Zenodo repository (https://zenodo.org). A formal, accessible, shared, and broadly applicable language for knowledge representation will be used for the metadata.

Pseudonymised individual data will be made available on request and after the researchers' approval (mariska.kleinvelderman@tno.nl). In the informed consent form, participants give permission for reuse of the data for studies focused on (the wellbeing of) parents and babies in the first six months. Before the data are shared, a set of terms of use will be drafted with the help of a legal advisor. For example, data will be made available on request, but may be restricted depending on whether the data has been published, purpose of usage and depending on handlings fee. A Data Transfer Agreement (DTA), specifying the aim and type of data sharing, will be signed by both parties. It will be ensured by the researchers that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them. The research process and the software used will be documented. Quality checks on the data will be performed to ensure that data are complete, correct and consistent.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/07/2023	12/07/2023	Yes	No