**Moemoeā Study Protocol**

1. **Title: A culturally relevant sleep and wellbeing intervention for New Zealand whānau (families) with pēpi (infants) aged 2-12 months: The Moemoeā study.**

**2. Study Investigators**

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1. **Rationale**

Getting enough good quality sleep is essential for children’s health and wellbeing (1). However, while children of all ethnicities have the right to the highest attainable standard of health (2), we know that inequities in sleep health exist in children in New Zealand (3, 4). While guidelines to promote good sleep health exist, we know that some of these messages do not fit the cultural preferences or lived realities of many whānau (5-7), who would appreciate messages that are more aligned with Māori and Pacific worldviews (5). Examples include restricting the use of electronic media before bed which is thought to delay the onset of sleep, but is viewed by whānau as a good way for the whole whānau to relax and connect prior to bed (8).

To date, few sleep interventions for children have been co-developed with indigenous groups (9). Furthermore, existing sleep interventions tend to be “package” interventions, with multiple components, based on the justified premise that behaviour change generally requires a multifaceted approach. However, what this means is that when randomised controlled trials of these package interventions are undertaken, all we are able to evaluate is the overall success (or not) of that intervention. What we are unable to do is to determine how each of the individual components within these interventions has performed. Given scarce healthcare resources, it is important to only include those components that are known to be effective (and safe). In recent years, an engineering-inspired approach called the “Multiphase Optimization Strategy” (MOST) has been increasingly used in health research to identify the “active ingredients” (effective components) in interventions. A MOST factorial trial is undertaken prior to an RCT to determine which components are effective, both singly, and in combination so that it is only these components that are included in an “optimized” intervention which is then tested in a randomised controlled trial (RCT) (10). Optimized interventions are theoretically more effective, efficient, scalable, and practical to implement exactly as they were designed or evaluated, than interventions which have not been optimised (10).

With this in mind, our Moemoeā study has been developed by a collaborative team of researchers who are working in partnership to create resources and tools for whānau that are centred in mātauranga Māori and promote improved sleep and wellbeing in infants and whānau (Phase 1). In this application (Phase 2), we wish to test these components in a 2 x 3 factorial trial – the “optimization” part of the full MOST process.

1. **Aims and objectives**

The three phases of the MOST approach, which are mirrored in the design of the Moemoeā study, are:

\*Phase 1 (Preparation – currently nearing completion)

\***Phase 2 (Optimization – the phase being described in this protocol)**

\*Phase 3 (Evaluation - to be undertaken once Optimization is complete)

**Aims:**

The aim of **Phase 1** was to develop culturally relevant tools and resources for whānau with pēpi aged 2-12 months.

The aim of **Phase 2** (this application) is to test these three components in a 2 x 3 factorial trial (representing 8 combinations) to determine which pou (and in which combinations) are most effective at improving sleep in pēpi aged 2-12 months and wellbeing in their whānau.

The aim of **Phase 3** will be to test the optimized online sleep toolkit in an appropriately powered randomised controlled trial (RCT).

**Objectives:**

**Primary objectives of Phase 2:**

1. to identify which pou (or combination of pou) are most effective at improving children’s sleep over a 6-month period
2. to identify which pou (or combination of pou) are most effective at improving caregiver wellbeing over a 6-month period

**Secondary objectives of Phase 2:**

1. to explore the mediating pathways to children’s sleep and caregiver wellbeing for each of the pou
2. to to explore differences in effectiveness by ethnicity

**4. Design and methods**

**4a. Participants & recruitment**

Participants will be recruited by Whānau Awhina Plunket (nationwide, n=300) and three Māori healthcare providers; National Hauora Coalition (based in Auckland, n=100), The Centre for Health (Tauranga, n=100), and Waihopai Rūnaka (Southland, n=100). Providers will identify whānau who may be interested in participating and provide them with our website URL ([www.Moemoeāsleep.co.nz](http://www.Moemoeāsleep.co.nz)) via a printed card, email, or social media link. On arrival at the website home page, participants will be directed to answer four screening questions to assess eligibility (are at least 16 years of age, caregiver to a pēpi aged 2-12 months, live in New Zealand, have access to the internet) and one question on ethnicity (for stratification purposes). Eligible participants will be able to provide written informed consent online before completing the baseline questionnaire. Participants will then be randomised into one of eight groups using computerised sequence generation (Stata 17.0), stratified by age group (2-6; 7-12 months) and Māori (and non-Māori) ethnicity. Random sized blocks with a minimum size of 16 will be used. Once randomised, participants will have access to relevant intervention materials for the duration of the 6-month intervention. All access will be provided online through our study website and associated phone app. Participants will be able to download the intervention resources to their devices so that they are able to be used at all times (including when network reception or internet data are not available).

**4b. Pou (intervention components)**

Our components have been developed in phase 1 after extensive whānau and expert interviews, which highlighted that whānau start their bedtime rituals from the evening meal. Connection is one of our underpinning aka matua (main research threads), which has led to these three components:

**Rongo time** was named after Rongo, the atua (god or deity) of peace. These tools focus on helping whānau make conscious, self-determined choices about ‘lifestyle behaviours’ (such as food, activity, rituals and whānau connection) which support them to live healthy lives. Healthy lifestyles will be framed from a culturally responsive, non-prescriptive, non-judgemental perspective and we hypothesize that this intervention will improve healthy behaviours among the whole whānau, resulting in better sleep for pēpi. We identified nine personae for Rongo of which four have been used to shape this component. In addition to Rongo the atua of peace, we have used Rongo Maraeroa who is the atua of the great expanse (typically the ocean). This persona gave us an opportunity to look at ways to incorporate outdoor activity for whānau. We composed a walking jingle and tatai which are short forms of karakia to help whānau connect to the spaces they will interact with. Rongo mā Tāne is the atua of cultivated food; this persona allowed us to incorporate ritual into food related activities. We have composed karakia and developed short videos and activities to increase the ritual around dinner and connection amongst whānau.

**Uru time** has been named for Uru-te-Ngangana, the red light which expands across and ignites the sky at dawn and dusk. This intervention focuses on providing whānau with online tools and resources to help settle pēpi to sleep. From a Te Ao Māori perspective, this pou can be viewed as providing whānau with tools and resources to help “transition” their pēpi from an awake state of being to the state of being asleep. From a more western paradigm, this is likely to be viewed as a “bedtime routine” which prepares children for sleep. As our research showed us that the main tools whānau use for sleep are water based such as a shower or bath, but also more laterally such as a walk along the beach, we developed waiata and oriori for bath time, for massaging baby, a lullaby for sleep and a sleep story. Other tools are purakau based, such as karakia (prayer), oriori (lullaby), kōrero (stories), and kai (food) before sleep.

The third pou is named **whānau support**.This intervention will help participating whānau to identify the multiple types of resources and support available to them, both online (at local, regional, and national levels) and physically within their local communities. For example, whānau may identify other whānau members as part of their support system, but if they identify they need access to cultural resources such as information on the Māori lunar calendar and how it relates to sleep and well-being, this can be provided. One of our Māori providers run workshops on this kaupapa for whānau and will support whānau to enrol in this workshop. We hypothesize that this intervention will improve whānau perceptions of being connected and supported in their communities, resulting in better abilities to support their pēpi’s sleep.

Regardless of group assignment, **all** participants in the trial will also receive access to a video about safe sleep for pēpi.

Figure 1: Conceptual model outlining how the intervention is hypothesized to work.



**4c. Factorial trial**

The MOST uses a factorial trial to assess the main effect of each intervention component, as well as the interactions between the different components. As the Moemoeā trial has three separate components, our optimization trial will be a 2 x 2 x 2 factorial trial. This means that participants will be randomised to one of eight groups as shown in Table 1. They represent every possible combination of the three intervention pou of Rongo time, Uru time, and Whānau support. Our optimization trial will recruit approximately 600 whānau, for a total of approximately 75 whānau randomised to each experimental group. However, these 8 groups will never be directly compared to each other. Instead, the main effects of, and interactions between, intervention components will be determined (see statistics section).

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| **Table 1. Factorial table of experimental groups in MOST optimization trial.** | | | |
| **Group** | **Rongo time** | **Uru time** | **Whānau support** |
| **1.** | Yes | Yes | Yes |
| **2.** | Yes | Yes | No |
| **3.** | Yes | No | Yes |
| **4.** | Yes | No | No |
| **5.** | No | Yes | Yes |
| **6.** | No | Yes | No |
| **7.** | No | No | Yes |
| **8.** | No | No | No |

**4d. Intervention details**

Table 2 (Appendix) presents a brief outline of what is contained within each of the six steps that contribute to each of the three pou (Rongo time, Uru time, Whānau support). Within the website and the phone app, each intervention is delivered in six ‘steps’. It is recommended that whānau complete one step per week when they first enrol in the study, and then continue to use the resources over the remaining study time period (6 months in total).

**4e. Measurements**

All data (except for child length and weight) will be collected by an online questionnaire administered at baseline and intervention completion (6 months post-baseline), with the exception of growth data which will be obtained from providers. All questions have been adapted from existing questionnaires or developed by the research team as described in more detail below. Adaptations generally focussed on making the questionnaires more strengths-based, rather than deficit-focused, while maintaining the “purpose” or intent of the question itself. The face and convergent validity of these questions has been ascertained as part of Phase 1 of this work (ethics app #21/028), which tested the questionnaire in approximately 1000 participants in late 2021.

**Primary outcome measures:**

1. A ‘**Perception of Infant Sleep Score (PoISS)**’ which measures how parents feel about the sleep of their pēpi. This score is calculated from 3 items in the online questionnaire that ask i) has the night-time sleep of *infant name* been a problem for you?, ii) how well do you think *infant name* has slept at night?, and iii) how satisfied have you felt about the way you settle *infant name* to sleep at night? 4-5 answer options are available for each question. The scores for each of the three items are combined as a mean to give a perception of sleep score ranging from 0 (good) to 1 (not good).
2. **Caregiver wellbeing**, which will be measured using a slightly modified version of the WHO5 Wellbeing questionnaire, which consists of 5 questions. Three of these questions had minor wording changes (e.g. ‘vigorous’ to ‘energetic’, ‘in good spirits’ to ‘in a good mood’ and ‘filled with things that interest me’ to ‘included things that interest me’) following consultation with Māori and Pasifika communities.

**Secondary outcome measures:**

1. **Connection** (the effectiveness of the Rongo component) will be measured using 3 questions that assess the frequency of using waiata (songs) and karakia (prayers) when with whānau (family) when preparing food, eating, and spending time outside in nature, and by 3 questions that assess connection to the pēpi (baby), whānau (family) and taiao (environment) using 4 or 5 point ordinal scales. These questions have been designed by the research team following phase 1.
2. **Settling** (the effectiveness of the Uru component) will be measured using 5 questions that assess whether there is a bedtime ritual, the frequency and length of any ritual, confidence in settling the infant, and enjoyment in the process using 4 or 5 point ordinal scales.
3. **Supported** (the effectiveness of the Whānau support component) will be measured using 4 questions about the level of support the mother (or other caregiver) feels they receive from whānau (family), health providers and in general, and how confident they feel in finding and using support using 4 or 5 point ordinal scales.
4. Participants will be asked to provide consent to us accessing their **pēpi’s growth data** from their Well Child Provider that was collected during the time they were involved in the intervention (6 months). If granted, providers have agreed to provide us with date, length, and weight data as relevant.
5. **Whānau wellbeing** will be measured using a single question from Te Kupenga (Statistics NZ survey) that asks participants to rate how well their whānau is doing nowadays on a visual analogue scale from extremely badly to extremely well.

**6. Statistics and power**

A sample size of 506 provides 80% power (to the alpha=0.05 level) to detect a difference in primary outcomes of 0.25 SD (⁓0.06 PoISS score; 1.1 WHO-5 score). With 15% drop-out this requires recruitment of 600 participants, which gives 75 randomised to each of the 8 groups and 63 completers in each group.

The statistical analysis of this factorial trial will involve the inclusion of interaction terms between the intervention components in a regression model for the primary outcome (using effect coding rather than dummy coding to reduce collinearity and maintain power). The effect sizes of the different combinations are compared to assess which combinations are most effective. These combinations are then compared against the optimisation criteria to determine which intervention package should then be tested for effectiveness in a two-arm parallel randomised controlled trial. The optimisation criteria are: optimal effectiveness for both sleep and wellbeing outcomes as well as demonstrated effectiveness for Māori.

Mediation will be explored using regression models that first assess how each component influenced the mediators in the conceptual model. There are questionnaires to assess each one of these constructs.

**7. Risks/safety considerations**

Moemoeā has been designed as a 100% online intervention which has both risks and benefits. We initially planned to create an intervention which could be delivered by Well Child providers in existing Well Child visits. However, there were some indications from providers that this would be difficult to do within existing appointment time-frames. Additionally, with the emergence of the Covid-19 pandemic and national lockdowns, we decided that an online intervention, which could proceed even under strict lockdown conditions, would be safer and more viable than an intervention delivered face-to-face. However, it does rely on families having internet access, adequate data to download tools and resources, and being confident to engage with an online intervention even if they would prefer information to be delivered face-to-face. Our study website will include a list of support people (both internal and external to the study) who participants can contact if they need face-to-face support with their child’s sleep or any other aspect of the study. We will also provide participants with opportunities to provide feedback about the online nature of the study and any associated advantages and disadvantages that they may have noticed and which can be taken into account when planning future interventions.

During the time period of the optimization trial, the tools and resources for each experimental group will only be available to those in that group, using an access code to the intervention section of our study website. All data will be collected online via baseline and follow-up questionnaires on our website. Careful consideration is being given to ensure that all intervention materials and all participant information and data is stored online in a secure way so that only participants and research staff can access it.

Our sleep tool-kit is centred in mātauranga Māori and aims to provide whānau with culturally responsive tools and resources to help their pēpi sleep better. Our aim is to provide information and advice in a non-prescriptive, non-judgemental manner. However, we recognise the possibility for psychological distress among both Māori and non-Māori participants who may feel shame, guilt, sadness or many other complex emotions when accessing some of this information, which may to date have been denied to them due to the ongoing effects of colonisation and the dominance of Western-centric knowledge and recommendations related to children’s sleep and other aspects of health. Within the online intervention, participants will be provided with the contact details of groups and individuals who they can reach out to for support, if required. This list will include our study staff as well as external groups and organisations, such as health and disability advocates, Māori health support, and the Otago University ethics committee.

**8. Māori consultation**

As described earlier, the aim of this phase of the Moemoeā project is to develop a culturally relevant, inclusive sleep intervention for whānau. To achieve this, we have created a collaborative team of Māori and non-Māori researchers who are committed to working in partnership throughout the project’s conception, development, optimization and evaluation.

Dr Justine Camp (Kāi Tahu, Kāti Momoe, Waitaha) is one of the Co-Principal Investigators and is responsible for ensuring the cultural relevance and integrity of this project. Additionally, we have two Māori research assistants, Talia Ellison (Kāi Tahu, Te Ātiawa, Ngāti Toa) and Takiwai Russell-Camp (Kāi Tahu, Kāti Momoe, Waitaha)*,* working on this project. Justine, Talia and Takiwai have all been involved in consultation with Māori cultural experts and Māori whānau which has informed Phase 1 and Phase 2 of this project (two earlier ethics applications, ‘Tools whānau using for settling pepi’ (reference number 20/106) and ‘Creation of a culturally relevant outcome measurement questionnaire for use in the Moemoeā study’ (reference number 21/028)) have outlined this work. Furthermore, they have sought out the mātauranga Māori required to develop each of the pou in our online sleep tool-kit, and created the tool-kit with input from Māori cultural experts and colleagues. They have also been working in partnership with the rest of the research team to create the MOST conceptual model for our study and ensure that knowledge and techniques from both te ao Māori and Western science are integrated into our study design.

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| **Table 2. Resources provided to participants in the Moemoeā study, by study pou (pillar)**1 | | | | |
| **Step** | **Pou: Rongo Time** | **Pou: Uru Time** | **Pou: Whānau Support** | **Safe Sleep** |
| 1 | **Kupu Rongo and Tātai Rongo:**  \*1x Kupu (pictorial dictionary) Rongo2  \*3x Tātai (short ritual chants to use when transitioning between different activities)3 | **Kupu Uru, Whakamāramatanga and Horoi**  \*1x Kupu (pictorial dictionary) Uru2  \*1x short video to explain to help whānau understand the composition of the resources in this pou  \*1x Waiata Horoi (song to use when bathing pēpi)3 | **Kupu Whānau and He waka eke noa (Part 1)**  \*1x Kupu (pictorial dictionary) Whānau2  \*1x writing activity encouraging whānau to consider how they are bound together and what strengths they have | 7-minute video provided to all in Week 1. No additional resources. |
| 2 | **Waiata Hikoi:**  \*1x Waiata Hikoi (song to sing when exploring natural environments)3 | **Mirimiri**  \*1x Waiata (song) to use when massaging pēpi3 | **He waka eke noa (Part 2)**  \*1x writing activity to encourage whānau to consider how they can use their strengths to support each other |
| 3 | **Maara Kai:**  \*3x videos: Tipu Kai, Haukake Kai and Tunu Kai (short videos to encourage whānau to cultivate, cook and share kai (food) together)  \*1x waiata (song to sing while doing these activities)3 | **Oriori**  \*1x oriori (lullaby) to soothe pēpi to sleep3 | **He waka eke noa (Part 2)**  \*Brief information to help whānau identify the various levels of support which they may be able to access if needed  \*1x interactive “drag and drop” online activity for whānau to create their own whānau (family) waka (canoe) |
| 4 | **Whānau Kai:**  \*2x short videos about making healthy kai (food) for pēpi (baby) and whānau (family) | **Karakia Moe**  \*1x karakia (ritual chant) to use to help pēpi transition from awake, to sleeping3 | **Wataka – Navigating Maramataka**  \*1x wātaka (calendar) which introduces whānau to maramataka Māori (environmental observations) and their links with how pēpi and whānau are feeling. |
| 5 | **Kiriata Kai and Kāri Kai**  \*3x 1-page infographics about introducing complementary foods to pēpi (baby)  \*4x short videos about introducing ritual to various aspects of food preparation | **Sleep Story**  \*1x 22 minute video to play while pēpi goes to sleep. | **Journal – Navigating Mana Atua**  \*1x journal which builds on Step 4 (Wataka) by encouraging whānau to understand rhythms and introduce ritual in their days. |
| 6 | **Self-Directed**  \*No new resources  \*Whānau are encouraged to use and reflect upon the resources from Steps 1-5, and to plan how to use them in the future | **Self-Directed**  \*No new resources  \*Whānau are encouraged to use and reflect upon the resources from Steps 1-5, and to plan how to use them in the future | **Self-Directed**  \*No new resources  \*Whānau are encouraged to use and reflect upon the resources from Steps 1-5, and to plan how to use them in the future |

1All provided online, in a website and an app, and able to be downloaded for frequent use.

2The Kupu Rongo pictorial dictionary contains 32 words while the Kupu Uru and Kupu Whānau pictorial dictionaries each contain 24 words.

3Provided in audio and written formats. The audio uses te reo Māori (Māori language); the written format is Māori with an English translation provided.