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**RESEARCH PROTOCOL**

HARTI HAUORA TAMARIKI

A Randomised Controlled Trial of an Opportunistic, Holistic and Family Centred Approach to Improving Outcomes for Hospitalised Children and their Families

Funded by the Health Research Council of New Zealand

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# Key Contacts and Committee Members

## Steering Committee Members

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## Operations Group members

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| --- |
| Dr Nina Scott |
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| Dr Bridgette Masters-Awatere |
| Dr Amy JonesDr Rebekah Graham |

## Advisory Group Members

The Advisory Group will comprise:

* **Midland Child Health Action Group representation and Paediatrics** – Dr David Graham, Clinical Unit Leader, Paediatrics, WDHB
* **Expert in Kaupapa Māori methodology and data sovereignty –** DrDonna Cormack, University of Otago
* **Māori whānau representative** – Regan Ruki
* **Māori whānau representative** – TBA
* **Māori clinical support** - Te Aro Moxon, registrar in paediatrics, WDHB
* **Kaitiaki** – Dale Marriott, Kaitiaki, Te Puna Oranga
* **Pou Herenga –** Hemi Curtis, kaumātua, Te Puna Oranga
* **Paediatric Nursing staff –** Betsy Smith, Clinical charge nurse (paediatrics), WDHB

# Summary

## Rationale for Research

We intend to improve access to holistic health and social services for tamariki Māori (Māori children) and their whānau (families) and all tamariki (children) admitted to a hospital and their whānau. In doing so, we are increasing recognition of the need for, and value of, Māori led culture change within the clinical realm. One of the intentions of Harti Hauora Tamariki (HHT) has been to change the way those who deliver health services see their role. We want providers and staff to be encouraged to recognise their responsibilities for improving Māori health and for addressing health inequities and to realise their potential as powerful agents for change. Our study is underpinned by the He Pikinga Waiora Implementation Framework - a theoretical and practical guide for developing and implementing interventions that has Māori self-determination at its core and elements that have demonstrated evidence of positive outcomes (Oetzel et al., 2017). The Midland Child Health Action Group represents a range of child health providers and is extremely supportive of HHT and will be a vehicle for implementing the tool in paediatric wards for hospitals throughout the Midland region. The need for Māori led holistic care that takes a whānau ora approach in addressing the determinants of health, health protective factors and health risk factors is not limited to child health alone. The innovative HHT tool provides a model for all providers of health services and we intend to develop a suite of HHT tools in the future.

## Aims

The aim of this research is to measure the impact of the Harti Hauora Tamariki tool: a comprehensive approach to assessing and addressing holistic health needs for hospitalised children and their whānau as derived from te Ao Māori. Specifically, this research will:

* Provide quantitative and qualitative evidence of the effectiveness of the Harti Hauora Tamariki tool as a whānau ora assessment and follow up instrument within inpatient care
* Determine the level of unmet need identified by the Harti Hauora Tamariki tool
* Assess the impact of Harti Hauora Tamariki on meeting needs and achieving improved outcomes for tamariki and whānau; and
* Provide a qualitative assessment of how HHT led to the observed quantitative outcomes and how satisfied patients and their whānau were with the intervention.

## Design and Method

The **quantitative** part of HHT is a **parallel-group** **randomised controlled superiority trial** with approximately 1100 Māori and non-Māori children aged 0-4 admitted to hospital under a paediatric medical team. The intervention consists of assessment and follow-up using the HHT tool. The control group will receive usual care only. The **primary endpoint** of readmission after discharge will be measured at 12 months from the date of discharge from hospital for both groups. We will also perform interim analyses for 30 days, 3 months and 6 months post discharge. **Secondary endpoints** are:

* Difference in satisfaction with hospital experience between the intervention and control groups.
* Difference in preventive services utilisation and access between the intervention and control groups.
* Difference in enrolment in, and utilisation of selected preventative (health and non-health) services between the intervention and control groups.
* Differences in the rate of referral to smoking cessation services for households with any members documented to be smokers.
* Differences in the rate of referral to Whare Ora (a housing intervention).
* Difference in the total cumulative length of hospital stay in the 12 months following the index discharge event.
* Difference in the frequency of readmission in the 12 months following the index discharge event.

The **qualitative** part of our study involves a **series of in-depth interviews** with 20 whānau (half among those who received a HHT assessment and half among those who did not). These interviews will be guided by Kaupapa Māori Theory and grounded in Kaupapa Māori practice. Emphasis will be on whānau perspectives of engagement with Harti and hospital staff, as well as their experiences of hospital care and how their needs, broad health and non-health, were assessed and addressed.

## Research Impact

The potential for the findings of this proposed research to be translated into Māori health gains is very high. We have already engaged with a wide range of key stakeholders who are enthusiastically awaiting the results of our research. The He Pikinga Waiora Implementation Framework guided the redevelopment of the tool and will guide the study to meet health issues that are prevalent for Māori. This means we will deliver the tool in a way which maximises Māori health gains. We are beginning work on the development of a virtual and gamified product with the aim of linking to clinical and other records, improving usability, effectiveness and quality. We plan to use the virtual product in many settings including a new service for the over 6000 people in, or visiting, the Waikato hospital daily. Tamariki Māori and their whānau have more to gain from the HHT tool than non-Māori children due to greater unmet health need. Hence the HHT tool is to be expected to contribute toward decreasing the unjust and pervasive inequities in health that exist between Māori and non-Māori New Zealanders, particularly for children.

## Trial Registration

The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR).

The registration number is: ACTRN12618001079235

# Key Definitions Used in the Protocol

Hospital acute admission: A patient with a length of stay greater than 3 hours ***and*** who is formally admitted to one of the Waikato Hospital’s acute paediatric medical wards ***and*** whose admission is coded as acute (i.e. not planned or elective) ***and*** whose admission was not for palliative care.[[1]](#footnote-1)

Hospital acute readmission: A study subject meeting the criteria of a hospital admission (paediatric and emergency department) ***and*** whose date/time of admission was at least 24 hours after any previous discharge ***and*** was not a transfer from another hospital or hospital service ***and*** whose admission was not for palliative or elective care.

Whānau For the purposes of this study, the term whānau extends beyond immediate family members living in the home, and includes both whakapapa (genealogy) and kaupapa-based (shared interests) family members as determined by the whānau.

Whānau ora An approach which is defined as placing whānau at the centre of service delivery, requiring the integration of health, education and social services.

# List of Abbreviations

DHB District Health Board

DSM Data Safety Monitoring Body

HDEC Health and Disability Ethics Committee

HHT Harti Hauora Tamariki

HHTt Harti Hauora Tamariki tool

# Background

### Health Services and the High Burden of Disease of Tamariki Māori

Hospitalisations for diseases of poverty (or those with a social gradient) are increasing for tamariki Māori (Māori children) in New Zealand (NZ) and are linked to a multitude of complex risk factors(1). Hospital staff like to think that they provide the best care, especially for children, and that the health sector will do what is required to ensure that tamariki can stay well and not have to return to hospital with another or the same preventable condition within a few weeks or months. Unfortunately, hospital and health sector staff do not yet have the tools to provide basic holistic and preventative health care, and large numbers of tamariki Māori are being hospitalised with preventable illnesses, then re-hospitalised with other preventable illnesses.

The Waikato District Health Board (DHB) region has approximately 29,000 tamariki Māori (Robson et al., 2015) - more than any other DHB region in NZ. Consistently, 40% of the birth cohort in the Waikato DHB are Māori, and more than a quarter of Waikato Māori live in the most deprived NZ Deprivation Index decile (Atkinson, Salmond, & Crampton, 2014). Two in five children in Māori households were in households with low (under $15K) equivalised household incomes in 2013 (Atkinson et al., 2014). The health need for tamariki Māori in the Waikato region is significant. Tamariki Māori accounted for 44% of hospital admissions for the 0-5 age range in the winter months of 2014. An important majority of these children (71%) were admitted due to a medical condition with a social gradient (diseases of poverty) such as acute bronchiolitis (43%), pneumonia (11%), asthma (6%) and acute upper respiratory tract infections (4%). A shocking 51% of tamariki Māori admitted with these diseases of poverty were re-hospitalised (at least once) within the next 6 months and at 12 months, for all causes of admission, the risk of readmission was 56% (More, 2016).

### Harti Hauora Tamariki tool development

As a response to tamariki Māori health need, and high hospital readmission rates in the Waikato, Te Puna Oranga (Māori Health Unit) at Waikato DHB led a co-design consultation process with Māori and non-Māori nurses, Kaitiaki (cultural support workers) and doctors who had worked, or were working in child health across the Waikato region (Eyles et al., 2016). This consultation process found that there was no consistent high-quality approach to assessing and addressing the complex factors (within health and non-health sectors) that cause poor health in children, hospitalisation, and readmission. This work concluded that holistic care was lacking for hospitalised tamariki and their whānau. The traditional hospital care model that focussed almost exclusively on the presenting illness was not able to address the broader cause of disease, and indeed wellbeing or whānau ora. Whānau ora describes the healthy families goal within New Zealand’s Māori Health Strategy, He Korowai Oranga, and the Whānau Ora government work programme. In this research, we use the term Whānau Ora to describe an approach which places whānau at the centre of service delivery, requiring the integration of health, education and social services. There is increasing recognition worldwide of the importance of non-health care needs (such as poverty, education, housing, social and cultural cohesion) in policies and programmes aimed at improving health outcomes (Baker et al., 2000; Krieger & Higgins, 2002; M. Marmot, Friel, Bell, Houweling, & Taylor, 2008; Seligman, Laraia, & Kushel, 2010; Wilkinson & Marmot, 2003). There is also developing understanding that the health care setting provides a unique opportunity to address both health and non-health care needs by:

* improving health equity;
* reducing recurrent readmission;
* improving the coordination and quality of health care; and
* more effectively supporting priority populations (Bachrach, Pfister, Wallis, & Lipson, 2014; Garg, Marino, & Vickani et al, 2012).

Waikato DHB staff expressed the need for a tool to enable the provision of holistic and preventative care to determine both health and non-health sector need, particularly for tamariki Māori and to support opportunities to address such need. The co-design consultation process led Te Puna Oranga and Waikids (the Child Health Service of the Waikato DHB) to develop the Harti Hauora Tamariki tool.

The Harti Hauora Tamariki tool (HHTt) is based on a Whānau Ora approach and weaves Kaupapa Māori methodology into the provision of hospital-based health care. Kaupapa Māori Theory within HHT recognises the need: to critique traditional approaches; to enact systems change; direct structural transformation; and address unequal power relationships to improve outcomes for Māori. Co-design is purported to be potentially more effective than traditional researcher/clinician designed approaches and to have a better fit for working with indigenous population, in part due to its iterative approach that allows for conceptual or tool re-developments and refining based on the social-cultural needs of partnership groups(Eyles et al., 2016). The HHT process aligns to Kaupapa Māori Theory through the prioritisation of indigenous development and aspirations, the use of tikanga and mātauranga in the development of the tool, and by our partnership approach with key Māori and system stakeholders across the spectrum of programme design, implementation, and evaluation. In line with the broader methodological approach, the inquiry takes an ecological system-focused approach (Bronfenbrenner, 1977) to the research question, whereby our interest is understanding the complex environment so that the focus is on supporting systems change and improvement, rather than remaining solely focused on ‘fixing’ the patients’ symptoms. Holistic, whānau-centred care approaches have long been integral to Māori conceptualisations of health and wellbeing (King & Turia, 2002). The Ministry of Health’s strategy (He Korowai Oranga) aims for a health system that will work in a way that acknowledges Māori health aspirations and the central role of whānau as a principal source of strength, support, security and identity (Ministry of Health, 2016). Westernised health systems are increasingly recognising family-centred practice as an important component in healthcare. Family-centred practice is characterised by a “partnership between parents and service providers, a focus on the family’s role in decision-making, and recognition that parents are the experts on their child” (Law et al., 2003) p.357). While the concepts of family-centred practice are firmly embedded throughout Aotearoa New Zealand’s education, health and social welfare sectors (Chenery, 2004), a disconnect has been identified between best practice and what in fact occurs (Alliston, 2007).

### Harti Hauora Tamariki tool content Version 1

Initially introduced in 2015, the Harti Hauora Tamariki tool consisted of a set of 16 questions and 1 assessment. The Tool (components described in Figure 1), was designed to be holistic and address the cumulative nature and impact of health inequities. The 2015 HHTt implementation plan included training and ward promotions and a local Māori artist helped develop a whānau Harti Hauora information booklet to give to all whānau plus resources for tamariki. Currently, the tool has been used for well over 2,000 paediatric admissions, and the HHT tool remained in use to September 2017.

### Harti Hauora Tamariki tool utilisation review

In 2015, a small review was undertaken comparing clinical notes of children admitted to hospital while the HHTt was in use with the notes of children admitted in the period prior to implementation of the tool, 53 children in total. This found a dramatic increase in documentation evidence in clinical notes of risk and health protective factors that were easily addressable by staff for hospitalised children and their whānau (Figure 1). Overall, those children who had received a HHT assessment had 90% documentation of need compared to only 17% documentation in the clinical notes of children who didn't get a HHT assessment. Only one HHT impact measure - oral health enrolment (OHE) – was examined during this review. A single child (5%) from the non-HHT group had documented evidence of OHE and this child was enrolled and had also been admitted for dental extraction under general anaesthetic. (Admission rate for dental extraction for tamariki Māori increased by 40% from 2000 to 2013 double that of non-Māori) (Simpson, Adams, Oben, Wicken, & Duncanson, 2015). In comparison, 90% of the HHTt children had documented evidence of OHE, 84% where identified as un-enrolled and all were subsequently enrolled during their hospital stay.



Figure 1. Comparison of documented evidence in clinical notes for hospitalised children of the risk assessment questions included in the HHTt for winter 2015 patients assessed with the HHTt vs winter 2014 patients when the HHTt was not available.

The 2015 HHTt review determined that the introduction of HHTt was feasible and could be translated into “business as usual”. The review also highlighted that HHT resulted in increases in documentation of need and identification of preventative care for hospitalised children and their whānau. Two primary gaps from the previous review have been addressed within the design of current study. Firstly, the review drew upon the notes of 7 Māori (and 24 non-Māori) children in the HHT assessment group, and 10 Māori (12 non-Māori) children in non-HHT group. Drawing from a larger group was identified as essential to determine statistical significance and to make confident claims regarding equitable outcomes for Māori. Secondly, the review focused only on documentation in clinical records and did not include a determination of the impact of HHT screening for tamariki and whānau, by assessing outcome measures.

There is now widespread interest from other services who want to use the HHTt, including other hospitals and DHB regions. Further, modifications of the HHTt have been proposed for use with Māori health providers, primary care, the Hamilton Children’s Team, Plunket and other Well Child/Tamariki Ora providers. Wider use of HHTt is predicated on evidence of its effectiveness and acceptability to be established by the current study.

### Harti Hauora Tamariki tool redevelopment

The HHTt has been redeveloped for the current study. The process of redevelopment included the Project Manager and/or study investigator meeting with subject matter experts (SME) for all areas of the current tool. Further to this, new subjects were added to the tool, including: vision and hearing, drug and alcohol use, support services, safety (accident prevention) as part of the housing assessment, child development and skin concerns (see [Appendix 2](#_Appendix_2._) for final version of the tool). The addition of these subjects arose out of discussion amongst the greater research team and feedback from WDHB medical staff and SME meetings.

At each SME meeting, feedback was sought on the screening question, the follow-up protocol, training needs for staff, whānau booklet content, barriers to ideal care and possible solutions, additional resources/brochures or information to provide to whānau and measureable outcomes or key performance indicators (KPI). From this feedback, the tool was revised and reviewed by steering committee members.

# Aim and Specific Objectives

The overarching aim of this study is to determine how effective HHT is at providing a whānau ora assessment, documenting levels of need, and achieving improved outcomes for the patients and whānau who receive the intervention. To do this it will apply a mixed methodology approach including a randomised controlled trial for quantitative evaluation, and qualitative whānau interviews to provide in-depth understanding of how it achieves (or fails to achieve) these objectives. The specific objectives are therefore the following:

* To provide a quantitative measure of the effectiveness of Harti Hauora Tamariki tool as a whānau ora assessment within inpatient care
* To determine the level of unmet need identified by the Harti Hauora Tamariki tool.
* To assess the impact of Harti Hauora Tamariki on meeting those needs and achieving improved outcomes for tamariki; and
* To provide a qualitative assessment of how HHT led to the observed quantitative outcomes and how satisfied patients and their whānau were with the intervention.

This study will therefore answer the following research questions:

* Does the use of the HHTt increase documentation of assessment of health and non-health needs compared with usual care?
* Does use of the HHTt result in a lower readmission risk for hospitalised children?
* Does the HHTt improve satisfaction with hospital experience compared with usual care?
* Does the HHTt increase access to and utilisation of preventative health services compared with usual care?
* How can the HHT process be improved to further meet needs for patients and whānau?
* What are the differences in experience of patients and whānau who received the HHTt versus those who did not?

# Randomised Controlled Study Design

## Overview of Design

The study will be a randomised controlled observer-blinded parallel groups single centre superiority trial of the impact of the HHTt compared with usual care on child and whānau health outcomes, as specified in the primary and secondary endpoints, with patients randomised to intervention and control groups at a ratio of 1:1. The intervention group will receive usual care plus assessment with the HHTt. The control group will receive usual care only. The primary endpoint is the proportion of patients readmitted to hospital within the twelve-month period following discharge from their initial admission.

Secondary endpoints are:

* the difference in a summary patient experience score;
* the differences in documentation of non-enrolment with a GP and/or the oral health service, and incomplete utilisation of immunisation and well child tamariki ora (WCTO) services
* the differences in achieved access and utilisation of the services listed in the previous bullet (tested if the former endpoint is statistically significant);
* the differences in the proportions of households that have documented resident smokers where any have been referred to smoking cessation services during the admission period;
* the differences in proportions of children’s households referred to the Whare Ora programme;
* the differences in the child’s total cumulative length of stay in hospital from acute admissions in the 12 months from the date of discharge
* the difference in the rate (frequency) of acute admission in the 12 months following the initial discharge event (estimated as a rate ratio).

## Patient Information and Informed Consent

The Harti research assistant will approach eligible patients and their whānau and explain the study in broad terms, stating the main aims of the study are to look at wellbeing for children and their whānau and look at the best ways to keep whānau well and healthy by improving hospital care. The whānau will be told what the study involves for patients (including matching the child’s NHI number against other databases and access/use of other health services), and ask for consent. They will explain to whānau that there are two groups they could be randomised to and the only difference between the groups is the number and type of questions that will be asked. The child’s parents / caregivers will be provided with a copy of the Patient Information Sheet ([Appendix 1](#_Appendix_1._Patient)) and offered ample time to ask questions and discuss participation with their whānau. For those agreeing to take part, the patient consent form ([Appendix 1](#_Appendix_1._Patient)) will be signed by the parent/caregiver before the child enters the study and before randomisation to intervention or control group. Patients will have the opportunity to withdraw from the trial at any time prior to the administration of the HHT but analysis will be on an intention-to-treat basis. Patients who do not consent to take part in the study will receive usual care.

HHT aims to address preventable risk factors for patients and whānau. Although it is expected there will be beneficial effects on HHT outcomes, it is acknowledged that some past interventions designed specifically to reduce readmission rate have either had no effect or have increased rates of acute readmission. If this occurs with HHT, the likelihood of its wider adoption in NZ will be significantly enhanced by the study results. Without such evidence, it is difficult to argue that scarce healthcare resources should be dedicated to this and not some other intervention for which evidence of efficacy already exists.

## Outcome Measures

Outcomes that will be assessed by this study include: hospital readmission risk, whānau satisfaction with hospital experience; documentation of holistic health needs, and measures of HHT impact on access to services.

### Primary Endpoint

The primary endpoint is the **relative risk of an acute hospital readmission in the 12 months following discharge** for intervention group patients compared with control group patients. The relative risk of readmission rather than readmission rate ratio was chosen as the primary endpoint because risk (probability of readmission within specified period) is easier to measure and just requires counting the first time a patient is readmitted. By only counting the first readmission we avoid patients with large numbers of readmissions having a disproportion impact on the endpoint measure. This also simplifies statistical analysis. However, we have included the hazard ratio of readmission as a secondary endpoint (see below). The definition of an acute hospital readmission is provided at the beginning of the document.

**Hypothesis 1:**

**Use of the Harti Hauora Tamariki screening assessment and follow up Tool will result in a 7% lower readmission risk at 12 months for children aged 0-4 admitted to hospital.**

We will measure ethnic-specific differences in the primary endpoint measures and differences according to primary diagnostic groupings and geographical area of residence. The study is powered to detect a 7% difference in overall 12-month readmission risk for Māori and non-Māori patients (combined).

To determine the superiority limit for the purposes of sample size calculations (see Statistical Considerations section below), it was considered that the Harti Hauora Tamariki Tool should deliver at least a 7% absolute decrease in overall readmission risk as this would be both clinically meaningful for patients and financially meaningful for the DHB. Furthermore, we have designed the study so that it has power to detect a 12% absolute decrease in the 12-month risk of readmission for the Māori subpopulation. It is not powered to detect differences between Māori and non-Māori or any other ethnic group.

###### *Additional pre-specified analyses of an exploratory nature, based on the primary endpoint*

These will include the following:

* The **hazard ratio** for (first) readmission in the intervention group compared with the control group. This compares time to the first readmission rather than just the fact of a readmission. As such, it can make use of varying lengths of follow-up time and may be more sensitive to the impact of the HHT intervention. However, the use of the hazard ratio relies on the proportional hazards assumption, which is that the relative hazard of readmission remains constant over time.
* The **relative risk** of any readmission within one month of discharge, and from one to six months from the index admission event. This will examine whether the observed effect of the intervention on readmission rates occurs with a short or medium time frame. These analyses are exploratory as the trial has not been powered to detect difference within these time frames (although it may have adequate power to do so).
* A simple **Kaplan-Meir analysis** to compare the ‘survival’ functions of intervention and control groups where survival in this case is taken to mean time following discharge without hospital readmission.

### Secondary Endpoints

There are seven quantitative secondary endpoints:

1. **The overall difference in satisfaction with hospital experience between the intervention and control groups.** This will be measured using the first seven questions from the Patient Satisfaction with Hospital Care (Mārama) survey (Appendix 3). In addition to the first seven Mārama questions, two questions have been added for the purposes of this research: one on the responsiveness to whānau needs, the other on whether a holistic approach was employed (see [Appendix 3](#_Appendix_3._) for details). The eighth open-ended Mārama question will also be asked and analysed within the qualitative component of the study. The responses will be scored on a 5-point Likert Scale ranging from Strongly Disagree to Strongly Agree (1 point for the former, 5 for the latter), so the total possible score range for someone answering all questions is from 9 to 45 which will be scaled to a range of 0-100 to accommodate cases where one or more questions is not responded to. The responses will be provided by the child’s primary care-giver.

**Hypothesis 2:**

**HHT result in a 5% higher satisfaction with hospital experience score than in the Usual Care group.**

1. **Difference in preventive services utilisation and access between the intervention and control groups.** This endpoint has two parts to it: **documentation** and **achievement**. For documentation, external sources will be used to determine whether at admission the child was (i) enrolled with a GP; (ii) enrolled with the oral health services; (iii) up to date with all immunizations; (iv) up to date with WCTO visits. Where ‘non-compliance’[[2]](#footnote-2) is documented with any of these services, the patient’s HHT record, or medical record for Usual Care (UC) patients will be examined post-discharge to determine whether that non-compliance was documented. The indicator that will be compared between the HHT and UC groups is the number of children with non-compliances in any of the four domains (GP enrolment, oral health enrolment, up-to-date immunisation, and up to date WCTO visits) in whom this has been fully documented in the HHT or patient record during the child’s admission, divided by the total number of children with non-compliance in any of these four domains.

**Hypothesis 3a**

**Compared to usual care, the HHT assessment will result in at least a 50% increase in the full documentation of non-enrolment with a GP, non-enrolment in oral health services, incomplete immunisation (for age) and incomplete WCTO participation.**

 For the **achievement** component of this endpoint, which is contingent on detecting a significant difference in the **compliance** component, HHT and UC groups will be compared on the proportion of children who at admission were non-compliant on any of the four domains, and who became fully compliant within 30 days of discharge from the hospital. Fully compliant is defined as all of the following; enrolment with a GP, enrolment in oral health services, complete on the compliance pathway for immunisation (for age) and complete WCTO participation.

**Hypothesis 3b**

**Compared to usual care, the HHT assessment will result in at least a 25% increase in full compliance with GP enrolment, oral health service enrolment, immunisation and WCTO participation.**

1. **Referral to smoking cessation services.** The proportion of households documented to have one or more smokers resident for which at least one referral was made during the hospitalisation period for cessation services. This will be calculated by sending a list of addresses to the smoking cessation provider of households documented to have at least one resident who smokes. The provider will then confirm if a referral had been received for that address during the admission/hospitalisation period.

***Hypothesis 4***

**Compared to the UC group, the HHT group will have at least a 25% higher complete smoking referral rate for households with a documented resident who smokes.**

1. **Referral to Whare Ora services.** The difference between HH and UC groups in the proportion of children for whom a Whare Ora referral was made within 30 days post-discharge. This will be calculated simply as the number of Whare Ora referrals in each group divided by the total number of study children in that group. Any child can be counted only once in the numerator.

**Hypothesis 5**

**The HHT group will have at least a 25% higher complete Whare Ora referral rate compared with the UC group**

1. **Cumulative hospital length of stay.** The differences between HHT and UC in median cumulative length of stay (LOS) in acute hospital admissions in the 12 months following discharge. Only coded events with lengths of stay of 3 hours or more will be included in the calculation. Length of stay will be calculated in hours from the time of admission to the time of discharge using the hospital time stamp records. Length of stay will be calculated using, where appropriate, the rules established in the Ministry of Health’s LOS indicator. These join events within the same DHB where there is a transfer between the two and the second event commences less than 24 hours after the end of the prior event. In these cases, if the initial admission is not acute then this and any length of stay in a joined subsequent hospitalisation, even if acute, will not be counted. Hospitalisations where none of the contributing stays is case-mix coded will also therefore be excluded, consistent with these rules. This endpoint will be calculated as the difference in median cumulative lengths of stay by individual (i.e. not summing for the group as a whole) and will include acute hospital stays at any hospital in Waikato DHB. Using medians and individual level data will avoid outlier cases with very long lengths of stay having undue influence on the result of the test.

 **Hypothesis 6**

***The HHT group will have a significantly lower median cumulative length of hospital stay in all acute admissions in the 12 months following discharge from the index admission event compared with the UC group***

1. **Frequency of readmission.** This endpoint will be calculated as the rate ratio of acute readmission in the 12 months following discharge from the index admission event. It differs from the primary endpoint in using all admissions in the numerator, and a person-time denominator which will exclude any days in which the patient is in hospital.

***Hypothesis 7***

***The readmission rate in the HHT group will be 25% less than the readmission rate in the UC group.***

Pre-testing will be undertaken to ensure that data can be accessed (e.g. GP enrolment and WCTO records) for all study endpoints.

## Sample Size and Statistical Considerations

### Sample size requirement

A total of 1100 subjects will be recruited to the study, of whom we expect 43% will be Māori (based on current figures and expected acceptability of the research protocol). This sample has been calculated to ensure that there is sufficient statistical power to detect a 7% absolute reduction in the 12-month readmission risk in the HHT group for all children as a collective/total (from an expected 28%) and a 12% absolute reduction in the 12-month acute readmission risk in Māori. Sample size calculations were based on a two-tailed 0.05 level of significance with 80% power. We are assuming that the acceptability of participation will be similar for Maori and Non-Māori.

We will measure differences between the intervention and control groups in the primary endpoint measures controlling for age, sex, ethnicity, primary diagnostic grouping and geographical area of residence. The study is powered to detect a 7% difference in overall readmission risk for Māori and non-Māori patients combined and a 12% difference between intervention and control groups for Māori alone. The study is not powered to test for heterogeneity of the impact of HHT between Māori and non-Māori.

### Other statistical and analysis considerations

Analysis will be performed on an intention to treat basis. That is, endpoints will be compared for the two groups as defined from the point of randomisation to intervention or control group. For the primary endpoint participants who are readmitted multiple times from each group will be included in the analysis only for the first (valid) occasion on which they are readmitted in the 12 months following the index admission.

The sample size calculation was worked out for a risk as that is simpler from an analytic point of view. If we counted each readmission, then we would be measuring a rate which needs a person-time denominator. There is a danger that the use of a rate will be biased by a few individuals with frequent readmissions however this is being calculated as a secondary endpoint.

Bivariate analyses comparing groups will test for statistical significance using the Chi Square test for differences in proportions. For the length of stay secondary endpoint where a difference in medians is to be tested, the Mann-Whitney U test will be used.

Although the randomised design is expected to yield balanced intervention and control groups in a study of this size, logistic regression analysis will be used for the primary and secondary endpoints to control for important confounding variables and to facilitate the assessment of interaction variables that increase or decrease the efficacy of the HHT. Statistical significance will be tested at the alpha level of 0.05. We will control for the false discovery rate in the secondary endpoints using the Benjamini-Hochberg method (Benjamini & Hochberg, 1995).

The study is not powered to detect ethnic differences in the impact of HHT (effect modification). However, we will nevertheless conduct exploratory tests for effect modification with ethnicity (Māori/non-Māori), gender (male/female excluding other), and deprivation (as a dichotomised variable) using the Breslow Day test for homogeneity of odds ratio, and standard maximum likelihood methods (likelihood ratio tests) based on binomial regression models. We will assume an additive interaction for these analyses and report the relative excess risk due to interaction (RERI) where this is significant.

## Subject Selection and Recruitment

### Inclusion Criteria

* All patients currently residing in the Waikato DHB region
* Aged 0-4 years
* Acute medical admissions to a paediatric ward at Waikato Hospital

### Exclusion Criteria

* Patients who have already entered the study
* Patients who are not eligible for publicly funded healthcare in New Zealand
* Arranged or wait list admissions to paediatric wards at Waikato Hospital
* Patients who are not a current resident in Waikato DHB at the time of admission
* Patients with severe illness deemed by their medical team likely to die within 6 months of admission. This will be advised by the charge nurse who will provide a daily list of patients not to approach.

### Rationale for Selection Criteria

The 0-4 age group is a focus of this research study for multiple reasons. Important health need and ill health burden occurs during this time period, with the 0-4 age group a significant policy and health service target for the reduction of Ambulatory Sensitive Hospitalisations (ASH) in New Zealand currently. In addition (and in relation to this burden), important universal preventative care is provided in this period (including immunisation and the Well Child/Tamariki Ora programme). Further, this age group provides the greatest opportunity for critical and cost-effective early intervention across the health, education and social sectors. Focused investment on the early years is known to be crucial to reducing health inequities across the life course ( Marmot, Allen, & Goldblatt, 2010).

Only acute medical admissions will be eligible because the primary endpoint of the study is a reduction in the acute medical readmission rate. Waikato Hospital is the only site for recruitment for feasibility and cost reasons.

The selection criteria mean that the eligibility criteria for entry into the study (an acute admission) use a more restrictive definition than that of the primary endpoint (an acute readmission). The reasons for this are pragmatic. It is not feasible to recruit patients to this study from the Emergency Department or from other hospitals in Waikato DHB. Even with these criteria it is possible that some patients who are admitted to a paediatric ward and are discharged before the research staff can approach them will be missed. This proportion is likely to be low and will be taken into consideration when interpreting the findings. The characteristics of patients who it is not possible to approach will be recorded for this purpose.

### Recruitment Procedure

This has been partly described above in the section on [Patient Information and Informed Consent](#_Patient_Information_and). Recruitment will be the responsibility of the Harti research assistant(s) who will be present, when possible, on the wards from seven days per week. This will enable 95-100% of eligible admitted children to be invited to participate. Consent will not be sought if participants are so ill that they are deemed (by their medical team) likely to die within 6 months of admission. This will be advised by the charge nurse who will provide a daily list of patients not to approach.

## Randomisation Procedure

Randomisation will proceed according to a strict protocol. Owing to the relatively large size of the study, a simple (i.e. non-stratified) randomisation strategy will be employed. For those parents who consent to having their child take part in the trial, randomisation will be performed by using an online randomisation tool to determine allocation to intervention or control group. Randomisation will take place after the whānau have consented to having the child take part in the trial.

## Intervention

The intervention consists of assessment and follow-up using the HHTt ([Appendix 2](#_Appendix_2._)) and in accordance with the process shown in Figure 2. Intervention group patients and their whānau are invited to go over the HHTt with the Harti research assistant and provided with an information and activity booklet (whānau booklet). The purpose of whānau booklet is to:

* Inform families about Harti Hauora and related processes
* Promote health messages aligned to Harti Hauora focus areas and provide relevant health information
* Entertain kids during their hospital stay

The research assistant will follow established HHT protocols to follow up on any identified areas of need. For example, if a child is not enrolled with a service, the research assistant will offer to assist with enrolment; if the patient or another child present or at home has a sore throat, then Rheumatic Fever prevention protocols will be followed. Research assistants will have smart cell phones and an iPad to enable referrals and enrolment to take place at the bedside or in the interview room. The Harti research assistant will be trained in delivering high quality smoking cessation interventions for whānau and safe sleep devices including Pepi Pods will be made available. If the whānau are not sure of the child’s enrolment status (anecdotally a common occurrence), the Harti research assistant will match the patient’s National Health Index (NHI) number with selected data bases and double check for access or check enrolment with the service directly, .e.g. oral health services.

## Control Group

This group will receive usual care only without the HHTt.



Figure 2. Schematic of Trial Design

## Blinding and Other Measures to Avoid Bias

### Contamination

There is a risk of contamination or a spill over effect - meaning the control group could get a small amount of the intervention. This could happen for example if the nurses caring for control patients included some of the HHT screening questions in their assessments – more so than they normally would. The Hawthorne effect could also contaminate the project, meaning that just having this project happening may lead to better assessment and documentation in the control patients. To mitigate the effect of contamination we have removed all HHT resources from the ward (September 1st, 2017) and have ended the use of the HHTt 7 months before the study starts. This will give enough time for staff to become accustomed to not doing a HHT assessment and to forget the individual questions. HHT questions are not included in the design of new patient assessment forms. We will explain that a study is taking place but not go into detail as to which consented whānau are in the intervention or control group. Instead, we will emphasise the patient satisfaction component of the study. During the study period, the HHT research assistant will keep any HHT forms out of sight so as not to contaminate the ward environment. We recognise that it will be impossible to remove all forms of contamination.

### Concealment

The only person on the ward who will know explicitly what status the child has is the Harti research assistant. The child and whānau may be able to guess from the intervention but will not be told explicitly which group they are in. Results of the HHT assessment will be kept off the ward. As all patients will be consented, complete Form A (ascertainment) and given the whānau satisfaction questionnaire by the Harti research assistant, other ward staff will see the research assistant sitting with every admitted child and whānau. They may be able to tell who gets an intervention because the Harti research assistant will spend longer with those who get the intervention than s/he does with those who are randomised to the control group and just get consented. However, this is not expected to influence outcomes unduly as ward staff change regularly throughout a child’s admission period and ward staff will not have the HHTt to guide the assessment of needs and have not had the training or tool to access the services to meet those needs.

### Blinding

Participants will be aware that they are taking part in this trial but will not be told explicitly which group they are in. The following roles will be blinded to treatment allocation; the person matching NHIs with service data bases to assess enrolment and service use; the person matching NHIs with hospital readmission data.

### Non-informative Censoring

In survival analysis, which is the basis for quantitative assessment of the primary endpoint (acute readmission); it is important to avoid non-informative censoring where possible as this can bias the results. Non-informative censoring occurs when the probability of a patient being censored is not independent of the outcome or endpoints. Censoring occurs at the point in time when data is no longer being collected on a patient who has not yet experienced the event being studied (in this case acute readmission is the primary endpoint of our survival analysis). Typically, censoring for patients who have not experienced the endpoint at the time the study ends, but it can also occur when the ages out of the eligibility range, or when the patient is lost to follow-up.

## Data and Follow-up

A variety of data sources will be used in this trial. Data that will be collected as part of this study for both the intervention and control groups includes self-identified ethnicity data using the Ministry of Health protocols (collected at consent). Readmission dates within the twelve-month follow-up period for each subject will be drawn from the hospital Inpatient Management System database and involves matching consented patients data against discharges. We have a quick and easy system in place for this already.

### Baseline data collection

A record will be kept of all patients screened for eligibility to participate in the trial. Reasons for non-eligibility and/or refusal to participate will also be recorded (whilst acknowledging that the patient has no obligation to provide a reason for non-enrolment in the trial). At the time of obtaining patient consent (i.e. after the patient has been deemed to be eligible to participate in the trial) a baseline patient study enrolment form will be completed, known as Form A. Form A will record: demographic information, transport to hospital, household structure, housing, and NZiDep (Salmond, Crampton, Kin and Waldegrave, 2006). It will be entered online using online survey software.

### Patient experience

A questionnaire on the patient and whānau satisfaction with their hospital experiences will be administered just prior to discharge, or within 2 weeks post discharge, from the index admission. The quantitative data will also be captured online. We will be utilising Mārama, a recently developed standard survey tool[[3]](#footnote-3). We will be using the standard 7 Mārama questions and an additional 2 questions (see [Appendix 3](#_Appendix_3._)).

### Health and non-health needs

Data on documentation of assessment of health and non-health needs will be collected using the HHT screening questions. This will involve a review of clinical notes for the control group and recording the HHT assessment for the intervention group. The clinical notes should have many of the issues documented – because they have been deemed to be easily identifiable addressable health issues that could impact on the wellbeing of the child and its whānau. Lack of documentation in the clinical notes – versus detailed documentation from the HHT assessment will demonstrate the point of difference for HHT and the need for such a tool. As previously noted, this was done a small scale and use of the HHTt resulted in 90% of the HHT questions and answers being documented. In comparison, only 17% of the questions and answers were documented in notes for children who didn’t get a Harti review (Figure 1.)

Data on provision of whānau ora type services in hospital, referrals and enrolments and use of preventative health and non-health services will be recorded where data are available for the HHT screening questions for each patient in both the control and HHT groups. We will develop protocols for doing this (See Table 1).

### Access to and utilisation of Preventive Health Services

The data required for Secondary Endpoint 2 will come partly from external sources. **GP enrolment** and **WCTO status** at the time of admission will be drawn from the NChip database (Pinnacle Midlands Health Network). **Oral health enrolment** data will be extracted from the Titanium database (WDHB). **Immunisation status** will be obtained by interrogating the National Immunisations Register.

### Smoking Cessation Referral

To identify the households checked for smoking cessation service referral, the child’s clinical record will be reviewed at discharge and the households addresses that had smokers present will be transferred to an electronic database. The smoking referral service will be asked to confirm whether these addresses were referred to their service, and if so, the date on which that occurred.

### Whare Ora Referrals

At the end of the study, the Whare Ora service will be provided with a list of the NHI numbers of all study participants (without identifying whether they were in the HHT or UC groups) and asked to match against their records to identify those for whom a referral had been received.

### Length of Stay and Frequency of Admission

This data will be obtained from the Waikato DHB data warehouse.

##### Table 1. Information collected for RCT: documentation, referrals, and utilisation of services and the time point this information is collected.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Question** | **Documentation UC and HHT** | **Record of referrals made UC and HHT** | **Utilisation of service (secondary endpoints)** | **Time data gathered** |
| GP | ✓ | ✓ | ✓ | 1 & 12m |
| WCTO |  | ✓ | ✓ | 1 & 12m |
| Oral health | ✓ | ✓ | ✓ | 1 & 12m |
| Power to protect | 0-2 years |  |  | AD |
| B4SC |  | ✓ |  | 1 & 12m |
| ECE |  | ✓ |  | AD |
| Immunisation | ✓ | ✓ | ✓ | 1 & 12m |
| Smoking | ✓ | ✓ | ✓ | 1 & 12m |
| Breast Fed | 0-2 years | ✓ |  | AD |
| Housing | ✓ | ✓ | ✓ |  1 & 12 |
| Safe sleep | 0-6 months | ✓ |  | AD |
| Car Seat | ✓ |  |  | AD |
| Fam Violence | ✓ | ✓ |  | AD |
| Sore Throat | 4 years | ✓ |  | AD |
| BMI | 3-4 years | ✓ |  | AD |
| Frequent flyer | ✓ | ✓ |  | AD |
| Vision Hearing |  | ✓ |  | AD |
| Development |  | ✓ |  | AD |
| Skin | ✓ | ✓ |  | AD |
| Support services |  | ✓ |  | AD |
| Drug alcohol |  | ✓ |  | AD |
| Gambling |  | ✓ |  | AD |

# Ethics and Safety

## Ethics application

A full application to the Health and Disability Ethics Committee (HDEC) will be made. No patient will be recruited to the study until HDEC approval is received.

## Data Safety Monitoring

The Health and Disability Ethics Committee has determined that a Data Safety Monitoring (DSM) Committee is not required as this is not deemed to be a clinical trial.

## Data Management

Information provided by participants will be only accessible to members of the research team. Participant study files and all other information will remain strictly confidential, unless there is an immediate risk of serious harm to them or others. No potentially identifying information will be used in any reports on this study. Records will be stored for at least 5 years in a secure place at the Waikato District Health Board after the completion of the study. All electronic records will be password protected and stored on a restricted access shared drive at Waikato District Health Board.

## Consultation

The Waikato DHB has a governance relationship with the local iwi through its Iwi Māori Council. The Iwi Māori Council has been in existence since 2000 and has provided the Waikato DHB with an opportunity to consult with iwi Māori on Māori health within the Waikato health district. The research team has met with the Iwi Māori Council who were keen to see an ongoing relationship. The research leaders (Nina, Polly, Bridgette) have committed to give the Council 6 monthly updates.

An Advisory Group consisting of experts in their areas was formed at the commencement of the study, see members listed above (p. 5). The purpose of this group is to meet twice yearly and provide advice and make recommendations to ensure key aims and objectives of the study are met. The Advisory Group will oversee, review and advise on the operations and research development of the Harti Hauora Tamariki research project. The group will help ensure the research aligns with Kaupapa Māori research practice and is culturally responsive, support the appropriate and effective dissemination of findings, and advise on the translation of outcomes into practice.

# Qualitative Research Component

## Overview of Design

The qualitative component of this study consists of two in-depth semi-structured interviews with 20 priority whānau (10 from the intervention group and 10 from the control group). Priority whānau has been defined as those who are the whānau of a Māori child admitted with a disease of poverty (a disease with a social gradient) and who reside in a NZDep level 10 area. These interviews will utilise Kaupapa Māori research practice and will seek to understand whānau experiences of hospital from an individual level and as part of the wider whānau group. Of particular interest are whānau perspectives on how engagement occurs between whānau, Harti staff, and other hospital members.

The primary focus for the 10 whānau who received an HHTt while the child was in hospital will be on the ways in which the HHT process enabled whānau to access services, with a particular focus on the subsequent utilisation (or not) of these services.

For the 10 whānau who did not receive a HHTt assessment during their hospital stay, the primary focus of the interviews will be their experiences of hospital care and how their needs, broad health and non-health were assessed and addressed.

Taken together, these conversations will act as a first step towards answering the research question: “What works for tamariki Māori and their whānau?” and will provide increased understanding of the needs of whānau who have experienced a child’s hospitalisation and what difference the HHTt has (or hasn’t) made to the provision of a holistic, whānau ora approach to health. These conversations will also provide in-depth information regarding how and whether whānau accessed and utilised additional health and non-health services subsequent to the HHTt.

## Rationale for research approach

Taking a qualitative approach helps to answer the question of “What works for tamariki Māori and their whānau?” The value of this approach lies in its ability to pursue answers for the kinds of research questions that are not easily answerable by experimental methods (Green & Britten, 1998, pp. 1230-1232). Consequently, we approach the use of qualitative interviews as a process that will enable us to more fully understand the experiences of whānau. Whānau perspectives on how engagement occurred between whānau and hospital staff are crucial to understanding how we can improve access to services by priority whānau, and thus improve access to holistic health and services for tamariki Māori. Through utilising a methodology that centres on whānau, we are able to more fully investigate patients’ experiences of care and produce wider understanding of the needs of whānau who have experienced a child’s hospitalisation and what difference (if any) the HHTt has made to this.

Utilising kanohi ki to kanohi (face-to-face) interviews with priority whānau aligns with a Kaupapa Māori research practice (see the Recruitment and Selection section for more). It also contributes to the increased recognition of the importance of non-health care needs in healthcare, prioritises the experiences of Māori whānau within the healthcare system, and is recognised as more effective than traditional clinical approaches when working with Indigenous groups. Having multiple engagements with whānau gives members time to reflect on their experiences and to more fully consider aspects of healthcare previously left unsaid. It also develops trust within the research relationship, which in turn provides for greater depth and honesty in conversations held.

Interviews will include the use of visual methods (mapping and photo-elicitation). Mapping involves talking with whānau as they draw aspects of the hospital visit, such as entering the hospital, the ward, parking and transport, accessing food, and how these spaces inter-relate from their perspective as whānau. Engaging in activities such as mapping often reveals aspects of care otherwise not considered, and provides insight into whānau experience(s) that may have remained unnoticed and unremarked upon.

The photo-elicitation interviews will involve participant(s) taking photographs of their ‘child’s world of health’ and then an interview where the (printed) photographs are discussed. When participants produce and then talk about the images they have taken, they are seeking to make sense of their everyday experiences, and look to make sense with, rather than of, photographs. This orientates participants to see their world from a different perspective, with a focus on things worth showing. The images become communicative and generative; communicative because they provoke and convey meaning and generative because through the discussion and analysis of the photographs new understandings and deeper insights are created. The process of picturing allows links between personal experiences, local contexts and social practices to be invoked and revealed. The use of photo-elicitation deliberately moves the interview format away from the question and answer of verbal surveys towards conversation about issues represented in participant photographs and how these relate to the general research aims. The medications project (Nikora, Hodgetts, Carlson, & Rua, 2011) provides one such example of how this type of research has been undertaken and the results have contributed to a more in-depth understanding of the way in which medications are approached within the domestic space of the home.

Utilising methods such as mapping and photo-elicitation creates an enjoyable and equitable research paradigm, not only locating the researcher more fully into the lifeworld’s of participants, but also situating participants as co-creators of knowledge. Qualitative interviews produce additional information to verbal surveys and readmission data. Visual aids such as photographs and drawings are useful in triggering participant thoughts, memories, reactions, and explanations. This in turn assists in uncovering taken-for-granted (and thus unspoken) aspects of healthcare practice. In doing so they work to capture the experiences of Māori within the hospital setting, this helps to build base line evidence to facilitate improved health delivery and outcomes relevant to the HHT for improved Māori health outcomes.

Suggested questions in the interview guide are grouped around the core areas of interest in this research project. If the interview process were to proceed in a linear fashion, then each interview would build on the topic of the one before. As trust was built and rapport established, then questions that are more in-depth and more personal will occur. However, it is recognised that qualitative interviews often do not proceed in a linear fashion, but rather follow a more circuitous route, with diversions and asides and interesting digressions. As such, specific interview questions are presented as a general guide and as a prompt for remaining on-topic or for suggestions when a lull in the conversation or a distraction occurs. Some participants may prefer to answer questions in the order suggested, and others may wish to discuss health needs first: the key is to be responsive. Subsequently, the areas of interest will be outlined at the beginning of each interview, with the participants to determine which area(s) they wish to discuss. The role of the interviewer is to guide discussion and be responsive to the participants, whilst keeping the conversation(s) related to the topics of interest to minimise unnecessary additional demands on time for both parties.

### Manaakitanga / reciprocity as part of research design

In accordance with the values implicit to manaakitanga, we will offer participating whānau a $100 supermarket voucher per interview as a way of reimbursing their time and in recognition of their expertise as patients and whānau members. It is unethical to expect priority whānau to provide their time and expertise for free, particularly when the research is funded and research team members will be paid. Within a Kaupapa Māori research methodology it is also culturally appropriate to bring a gift of food at the beginning of each research interview. The exact form this will take will be left to the researcher’s discretion, and will depend on the time of the interview (i.e. if the interview is in the morning, the researcher will bring a culturally appropriate morning tea to share).

### Analysis

Interviews will be digitally voice-recorded and transcribed. The transcriptions, along with researcher field notes, drawings and photographs will form the basis of the research data. These will be analysed interpretatively with regards to the research question: “What works for tamariki Māori and their whānau?” Findings will be presented as anonymised composite case studies that reflect the key themes for each group.

## Informed Consent, Selection and Recruitment

All Harti participants will be given a short qualitative study flyer prior to discharge at the time of completing the satisfaction with care questionnaire. Research assistants will identify priority whānau and approach them for consent to be referred to the qualitative researcher. Every effort will be made by the qualitative researcher to meet whānau while they are still on the ward in order to introduce the qualitative aspect of the study. For whānau who are unable to be met, an introduction to the qualitative aspect of the study will be made over the phone.

The researcher will telephone potential whānau members 2-4 weeks after discharge in order to further outline the interview process and to determine if whānau are still interested in participating. If whānau express interest, the researcher will confirm a mutually agreeable time and place to further discuss the interview process. At this meeting the researcher will provide a full Participant Information Sheet (See [Appendix 4](#_Appendix_5._)), discuss participation and answer any questions participating whānau may have. If whānau agree to take part, the consent form (See [Appendix 4](#_Appendix_4._Patient)) will be signed by those present and the researcher will commence the first interview. Whānau will be able to withdraw from the interview process at any time prior to beginning analysis. In terms of consent for the use of images (see Interview process for details), participating whānau will initial photos to indicate consent for use of images, and the researcher will discuss informed consent for the use of images with whānau. No identifiable images of people or third parties will be used in any way in any public documents or presentations.

The sampling approach for qualitative involvement will be purposeful. We aim to recruit whānau with different life experiences and to incorporate a range of ages and whānau member roles (such as partner, sibling and child), as well as a mix of genders. The diversity of the sample and potential impacts of clustered sampling will be further considered as interviews and recruitment of whānau progresses. Unless saturation is achieved earlier, interviews will occur with 20 whānau (10 from each group).

# Funding

The HHT trial is principally funded by the Health Research Council of New Zealand under Contract number: 17/441

# Reporting and Dissemination

If results from this proposed research show that the Harti Hauora Tamaraki tool results in improved outcomes for tamariki Māori, we will work with DHBs and other key stakeholders to disseminate the HHTt in the Midland Region. While not taking responsibility for national dissemination under this project, the team has the required relationships to make a very good start on achieving the goal of national dissemination.

We will work with our networks and seek guidance from leaders, and academic and coal face experts in the Māori health, health, policy/Ministry of Health, iwi health, and political spheres to develop an effective dissemination strategy. Throughout the research process we will update key stakeholders through our extensive established networks; these include regional child health action groups, and paediatric and Māori networks. Traditional academic dissemination techniques will also be used including publication in peer-reviewed journals, and presentation at national and international paediatric, and Māori health conferences. We will keep local Māori stakeholders abreast of our process and have built the development of a comprehensive stakeholder engagement and dissemination plan into our timeline and budget.

# Study acknowledgement

By signing below, I confirm that I have received, read andunderstood the protocol, dated 4-Nov-19, for the Harti Hauora Tamariki study.

I agree to follow the protocol and attachments and provide the necessary assurance that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements and to the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice.

If other personnel at my practice are involved in the trial I will provide and discuss the protocol with them to ensure that they are fully informed about the treatment and the study.

I understand that the protocol may be revised at any time and I undertake to ensure the most current version is adhered to at all times.

I understand that the study may be terminated or enrolment suspended at any time if it becomes necessary to protect the best interests of the study participants.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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# Appendices

## Appendix 1. Patient Information Sheet and Consent Form (PISCF) for RCT

|  |  |  |
| --- | --- | --- |
| Study ID Number: | Participant Initials: | Date of Birth: |

|  |  |
| --- | --- |
| **Participant Information Sheet** |  |
| Study title: | *Harti Hauora Tamariki* |
| Locality: | Waikato District Health Board | Ethics committee ref.: |  |
| Lead investigator: | Dr Nina Scott | Contact phone number: | +64 839 8899 ext 97558 |

An invitation

You are invited to take part in this research because you are a parent/caregiver of a child currently in Waikato Hospital. This study is looking at wellbeing for children.

It is your choice to take part or not. If you don’t want to take part, you don’t have to give a reason and you and your child will receive the same care. If you do want to take part now, but change your mind later, you can pull out of this research at any time.

This Participant Information Sheet will help you decide if you’d like to take part.

It tells you:

* why we are doing the research (or the study)
* what taking part would involve
* what the benefits and risks to you might be
* what will happen after the study ends

You do not have to decide today whether you want to take part or not. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of the Participant Information Sheet and Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages. We can also answer any questions you may have.

What is the purpose of the study?

The aim of this study is to find out about patient and whānau satisfaction with care. We will also look at access to health and other services for hospitalised children and their whānau. We are interested in services and care that can be provided on top of the care you are receiving for your child’s current illness. We hope this might lower the chances of children needing to go back to hospital in the future. This study will help us look at the best ways to keep whānau well and healthy.

If you agree to take part in this study you will be randomly allocated to take part in either the ‘intervention group’ or ‘no intervention’ group. Like the flip of a coin - you will have equal chance of being in either group.

Both groups will be asked a series of questions. The only difference between the two groups is the type and number of questions that you will be asked.

What will my participation in the study involve?

A research assistant will explain the study to you and ask for your consent to take part.

**Questions**

The research assistant will ask you a set of questions about your whānau wellbeing. You will also be asked about your satisfaction with hospital care right before or after your child is discharged home. You may be asked questions about your access to and use of a range of health and wellbeing services.

It should take between 20-40 minutes to ask all the questions, but the total time will depend on some of the answers, and on what group you are in. An iPad will be used to collect the answers that you give. Where possible, these questions will be asked somewhere private.

You do not have to answer any questions that you find too sensitive, or that make you uncomfortable, and you can stop answering questions at any time. You can answer the questions in English or te reo Māori.

**Information from records**

With your consent, health information about your child’s hospital visit will be collected from your child’s medical records. All information will remain confidential, or private, and will not be looked at by anyone else. Any information that is not about this study will not be looked at. With your consent we will also collect information from outside of your child’s hospital medical records. This includes information about whether your child is enrolled with a GP and GP records, whether they are enrolled in oral (or dental) health services, and whether your child has had their Well Child/Tamariki Ora Health Checks or their immunisations. We will **not** be collecting any personal information from your child’s GP.

What are the possible benefits and risks of this study?

Taking part in this study may take some time to answer all the questions and you do not have to answer any questions if they make you feel too uncomfortable. We will try to make sure that the questions are being asked at a time, and in a place, that works for you and you can stop at any time.

You will still receive the same care from the hospital, your doctor and other health services. Your child’s and your own usual medical care will not be affected in any way by participating in the study, or by declining to participate or withdrawing from the study at any time.

You may not directly benefit from the study. However, new findings from this study will help the people who fund, provide and deliver health services find out how to better support whānau with a child in hospital. This study may be of benefit to the greater population.

The information that you share with us will be treated with respect, privacy, protection and care.

Who pays for the study?

This study is funded by a research grant provided by the Health Research Council (HRC) of New Zealand.

What if something goes wrong?

If you were injured in this study, which is very unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

Confidentiality

The information you provide will be only accessible to members of the research team. The study files and all other information that you provide will remain strictly confidential, unless there is an immediate risk of serious harm to yourselves or others. No material that could personally identify you will be used in any reports on this study. When the study ends, your records will be stored for at least 5 years in a secure place at the Waikato District Health Board. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

The study findings will be published, but there will be no identifying information included, so there is no way that anybody could identify you from what is reported.

What are my rights?

If you have any questions or concerns regarding your rights as a participant in this study, you may wish to contact an independent Health and Disability Advocate. This is a free service provided under the Health and Disability Commissioner Act:

Free phone: 0800 555 050

Free fax: 0800 2787 7678 (0800 2 SUPPORT)

Email: advocacy@hdc.org.nz

Or For Māori health support, please contact:

Te Puna Oranga (Waikato DHB Māori Health Unit), Hockin Building, Level 1, Pembroke St, P.O. Box 934, Hamilton. Ph: (07) 834 3628 Fax: (07) 834 3619.

You can also contact the health and disability ethics committee (HDEC) that approved this study:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

What happens after the study or if I change my mind?

If you take choose to take part in this study, you can choose not to answer any of the questions, and you can also change your mind and stop at any time. If you want to completely pull out of the study, you can do so at any time by contacting me via my contact details below. You are also very welcome to ask any other question about the study by contacting us at the email address below.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

*Dr Nina Scott, Chronic Conditions Advisor, (Lead Investigator)*

*Te Puna Oranga, Hockin L1*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

*Email: nina.scott@waikatodhb.health.nz*

*Phone: 839 8899 ext 97548*

*Dr Amy Jones, Project Manager*

*Te Puna Oranga, Hockin L1*

*Pembroke Street*

*Waikato District Health Board*

*Hamilton, 3204*

Email: amy.jones2@waikatodhb.health.nz

*Phone: 839 8899 ext 97548*

***Please keep this brochure for your information.***

***Thank you for reading about this study***

|  |  |
| --- | --- |
| Consent Form |  |

**Please tick to indicate you consent to the following**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given enough time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting information about my child’s health from their hospital medical records from Midland Region District Health Boards. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting health data about my child’s and my health (including dental care enrolment, GP enrolment, immunisation, smoking cessation (‘Once and for all’ – Pinnacle), gambling addiction services and Well Child/Tamariki Ora checks) from health databases. | Yes 🞏 | No 🞏 |
| I consent to research staff accessing GP records for my child, including information relating to referrals and visits. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | Yes 🞏 | No 🞏 |
| I understand that my involvement in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Child’s name: |
| Participant’s name *(caregiver/parent)*: |
| Signature: | Date: |

**Declaration by member of research team**:

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Research Assistant’s name: |
| Signature: | Date: |

## Appendix 2. Harti Haurora Tamariki tool

|  |  |  |
| --- | --- | --- |
| **Assessment** | **Actions** | **Protocol/resources** |
|  **General Practice** |  |
| Are you and your child/infant enrolled with a GP or practice? | □ Yes □ No or □ Unsure**If no enrolment, why not:** | □ GP/Practice details checked in Clinical records (check NCHIP up to date)**If yes:** Approximate date of child’s last GP visit)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **The whānau choose to** □ Be referred for enrolment (NCHIP for children, enrolment form for adults) □ Not be referred□ Cost □ Transport issues□ Issues regarding connection with GP □ Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | * Provide a list of GP practices in Hamilton/Waikato to locate one close by
* Provide GP fact sheet
* Check website for costs and whether taking enrolment
* HHT GP referral letter
* CaY-C pamphlets provided
 |
|  **Well child/Tamariki Ora (0-3 years)** |  |
| Is your child/infant enrolled with a Well child/Tamariki Ora provider (WCTO)? | □ Yes□ No or □ Unsure | □ No action required (check NCHIP up to date)**The whānau choose to** □ Be referred for enrolment in NCHIP or direct with provider □ Not be referred | * Provide WDHB WCTO pathway/provider info sheet
* CaY-C pamphlets provided
 |
|  **B4 School Check (4-5 years)** |  |
| Has your child/infant had a B4 School check? | □ Yes□ No or □ Unsure | □ No action required (check NCHIP up to date)**The whānau choose to** □ Be referred to GP for a B4S check □ Not be referred | * Provide B4SC pamphlets
* CaY-C pamphlets provided
* HHT GP referral letter
 |
|  **Early childhood education (3-4 years)** |  |  |  |
| Is your child enrolled with an ECE centre? | □ Yes□ No or □ Unsure | □ No action required**The whānau choose to** □ Be referred for ‘Engaging priority families’ □ Not be referred□ Not eligible for EPF – help find local ECE | * Provide ECE ‘Be involved get enrolled’ pamphlet
* Check criteria for EPF contractors
* Contact Early childhood participation 858 7140 to refer for EPF contractors
* Provide list of low cost providers
 |
|  **Oral Health (9months+)** |  |
| Has your child/infant had a community oral health check in the past 12months?And what about other children in your whānau? | □ Yes□ No or □ Unsure | □ Offer to do lift the lip score □ Decline lift the lip assessment**The whānau choose to** □ check or be referred for enrolment/apt ring 07 859 9160 (0-12 years)□ Be provided with a list of dentists (13-17 years) □ Not be referred□ Offer fluoride painting for child □ whānau decline fluoride paint□ **Offer to do lift the lip score** □ Decline lift the lip assessment | * Ring 07 859 9160 (oral health)
* Provide preschool 5 tips fridge magnet
* Provide oral health brochures
* Māori oral health referral form WDHB
 |
| What is the child’s Lift the Lip Score? | □ Nil teeth□ No decay (1)□ Decay present (2-4) | □ No action required**The whānau choose to** □ Be referred for immediate oral health apt OR be referred to Māori oral health □ Not be referred  |  |
|  **Immunisations** |  |  |  |
| **Check the NIR and ask parent:** Is your child/infant up-to-date with their immunisations? | □ Yes□ No  | □ No action required (check NCHIP up to date)**The whānau choose to** □ Immunise in hospital□ Be referred to their GP/Practice for immunisation □ Not Immunise | * Refer to whānau booklet info and immunisation schedule
* HHT GP referral letter
* give pamphlets on HPV vax (11-12ys) and whooping cough recommended for everyone in household (no funding for this if not on schedule)
 |
| Is anyone in your whānau/family pregnant right now? *(between 28-38 weeks)* | □ No□ Yes  | □ No action required**The whānau choose to** □ Be referred to their GP/Practice or Pharmacy for immunisation □ Not Immunise | * Pregnancy immz brochures
* Resources: MOH and immunize.org
 |
| Would you or anyone in your whānau want the flu vaccination? (Apr-Dec, 6m+) | □ No□ Yes  | □ No action required**The whānau choose to** □ Be referred to their GP/Practice (under 13) or Pharmacy (13+) for immunisation □ Eligible for subsidy and referred to Pharmacy on Meade (13+) □ Not Immunise | * Provide flu vax pamphlet
* Check eligibility for free flu vax MOH
* Check eligibility for families of child DHB subsidised vax at POM ($10 for 13y+)
* Provide HHT flu vax form for Pharmacy on Meade
 |
| **Housing and safety** |  |  |  |
| Do you and your child/infant live in a home that is warm, dry, not overcrowded and in a good state of repair? | □ Yes□ No | □ No action required □ Refer to Whāre ora (if eligible) Crowding index *(from Form A)*:\_\_\_\_\_\_\_\_\_\_ □ Not be referred/not eligible | * Whare ora brochure
* Refer to Whare ora web page for tips on housing
 |
| Do you know if your home has insulation in the ceiling or under the floor? | □ Yes both□ None or one | □ No action requiredIs your home owned by you?If no, □ Offer to write letter to landlord on their behalf □ Decline letter offer □ check ECCA insulation grant eligibilityIf yes, □ check ECCA insulation grant eligibility | * Harti letter for landlord
 |
| Can I go through a home safety checklist with you? *12 questions* | □ No□ Yes | □ No action required□ Go through safety checklist | * Safety brochures (kids safe etc)
* Hot water cylinder information
* Refer to NZ fire service information
 |
|

|  |  |  |  |
| --- | --- | --- | --- |
| **Smoking** |  |  |  |

 |  |  |  |
| Do you smoke cigarettes? | □ No□ Yes | □ No action required□ Brief advice to quit provided NRT given □ Yes □ Declined □ UsedReferral made □ Yes □ Declined □ Quit pack given | * Refer to whānau booklet info
* give Once and for All brochure
* NRT- samples shown by RAs, nurses to give out ward supplies
* WDHB referral form or enrol online
* Quit pack: smoking resources/brochures
 |
| Does anyone else in your child’s household smoke cigarettes? | □ No□ Yes | □ No action requiredOffer to speak to whānau member □ Yes □ Declined Referral made online or phone □ Yes □ Declined □ Quit pack given |
| **Drug and alcohol use** |  |  |  |  |
| Are you concerned about your own or anyone else in the household’s alcohol use? | □  No□  Yes myself□  Yes someone else | □  No action required**Complete Audit C for parent/caregiver** □   Brief advice delivered, refer to whānau booklet |  |
| Complete Audit CComplete full Audit | □ <5 no concernsScore of 5+ □  total 5-7□  total 8-19  □ total 20+ | □  No action required***complete full Audit below***□  No action required□ Brief advice delivered, refer to whānau booklet□ be referred to other community service (provide info or phone)  □ be referred to Family Start *(child under 1yr)*       □ refer to WDHB social worker □  choose not to be referred□  Refer to GP    □ be referred to other community service (provide info or phone)  □  choose not to be referred           | * Provide list of Waikato alcohol/drug support services (NGOs)
* Family Start brochure referral criteria and form
* HHT GP referral letter
* Family services directory https://www.familyservices.govt.nz/directory/
 |
| Are you concerned about your own or anyone else in the household’s other drug use? | □  No□  Yes | □  No action required**The whānau choose to:**□  Refer to GP      □  be referred to Family Start *(child under 1yr)*□ be referred to other community service (provide info or phone □  refer to WDHB social worker □ choose not to be referred | * Provide list of Waikato alcohol/drug support services
* Family Start brochure referral criteria and form
* Family services directory https://www.familyservices.govt.nz/directory/
 |
| **FVSQ** |  |  |  |
| Routine enquiry completed (4 questions) | □ No□ Yes | Comment *(reason for non-completion)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Disclosure□ No □ Yes Referral- WDHB social worker □ No □ Yes Safety plan completed □ No □ Yes □ be referred to Family Start *(child under 1yr)**Refer to IPV Health & Risk Assessment form to inform safety planning*  | * Women’s refuge info
* NGO- safety cards, stickers for key contacts
* IPV Health & Risk Assessment form WDHB
* Referral to social worker form WDHB
* Family Start brochure referral criteria and form
 |
| **Gambling** |  |  |  |
| Do you think you are affected by your own or someone else’s gambling? | □ No, never□ Yes, in the past OR□ Yes, happening now | □ No action required ***MOVE TO NEXT SECTION****Ask next gambling questions* |  |
| How would you describe the effect of your own or that person’s gambling on you now? | □ It doesn’t affect me anymore□ I worry about it sometimes□ It is affecting my health | □ It is hard to talk with anyone about it□ I am concerned about my or my family’s safety□ I’m still paying for it financially |  |
| How can we help you? | □ I would like information□ I would like to talk about it in confidence with someone□ I would like some support or help□ Nothing at this stage | □ Refer to whānau booklet*Refer to gambling support service*□ Problem gambling foundation□ Salvation army | * Problem gambling foundation brochure
* Oasis Salvation army information for gambling support
 |
| **SUPPORT SERVICES****CSC, WINZ or MOH entitlements, NTA, prescription subsidies** |  |  |
| Do you have a current Community Services card? | □ Yes □ No | □ No action required□ check CSC eligibility □ eligible for CSC, application form completed | * CSC information
* CDC eligibility website
* CSC application forms
 |
| Can we check your eligibility for a range of social support subsidies you and your whānau may be eligible for? | □ No □ Yes | □ No action required**The whānau choose to:**□ eligible for NTA □ submit enrolment for NTA□ check WINZ subsidies □ entitled to benefit (not previously aware of)□ Refer to Te Whare Kokonga - Melville Community Centre, Salvation army or a whānau ora provider (see list) □ be referred to Family Start *(child under 1yr)* □ refer to WDHB social worker □ eligible for prescription subsidy □ accommodation at Te whare taurima (100km+ away) – phone custodian | * Provide NTA brochure and forms
* Provide prescription subsidy info
* Provide health shuttle brochures
* Provide Health consumer service brochure
* Provide hospital parking info/flyer
* Provide list of whānau ora providers (Waikato)
* Te Whare taurima information/brochure
* Family Start brochure referral criteria and form
* Spark JUMP package info
* Salvation army info: budgeting advice and food parcels
 |
|

|  |  |  |  |
| --- | --- | --- | --- |
| **Breastfeeding** |  |  |  |

 |  |  |  |
| Is there breastfeeding in your home?How is breastfeeding going for you/the mother?(pain, supply, weight gains..) | □ No□ Yes□ Good□ Some issues | □ No action required***Next question***□ No action required □ Refer to lactation consultant for admitted child/infant□ Refer to community LC, resources and app | * ‘Breastfeeding for your baby’ MOH brochure (Te Reo also)
* Mama aroha APP
* Midlands Breastfeeding app BreastFedNz
 |
| **Car Restraints** |  |  |  |
| Are there car seats available for your children/tamariki? <7 years or <148cm | □ Yes □ No or □ Unsure | □ No action required□ Discuss and provide information  | * Refer to whānau booklet
* Refer to ‘In loving arms’ if under 1 years
* Refer to health shuttle services or K’aute for use of car restrains/travel for health apts.
* Provide ‘Car restraints save lives’ NZTA pamphlet
 |
| **Safe sleep (SUDI) 6m and under** |  |  |  |
| Do you have a space to sleep your baby? | □ Yes □ No | □ No action required□ Provide safe sleep advice – or play DVD□ Pepi pod provided □ Pepi pod not needed/declined | * Check if have/wanting pepi pod
* Show safe sleep DVD
* Safe sleep brochure
 |
| **Power to protect Shaken baby (0-2 years)** |  |  |  |
| Have you watched the “Power to protect” video before? | □ Yes□ No or □ Unsure | □ No action required□ Play the Power to protect DVD to the family □ Family declined DVD | * Power to protect brochure
* Link to Power to protect video
 |
| **Sore throats**  |  |  |  |
| Does your child currently have a sore throat? *(4 years only)* | □ No□ Yes | □ No action required *(offer sore throat messages to everyone)*□ Promote Sore Throats Matter message□ Refer to nurse for Swab throat on ward if 4 years old | * Rheumatic fever pocket size brochure
 |
| Do others/anyone in the household have a sore throat? | □ No or □ Unsure□ Yes | □ Promote Sore Throats Matter message□ Promote Sore Throats Matter message□ 4+ Recommend community throat swabbing service (check eligibility) and refer to Pharmacy on Meade | * Rheumatic fever pocket size brochure
* HHT Throat swab referral form for POM
* Throat swabbing service brochures
 |
| **BMI (2-4 years)** |  |  |  |  |
| **Complete from clinical records FIRST** *What is the child’s BMI?* | KG |  | CM |  | (4 year olds) BMI |  |  |
| *Is the child within a healthy weight range?*Do you have concerns about the weight/size of any other children in your whānau/family? | □ Yes□ No  | □ No action required□ Discuss with whānau and promote Be Smarter message**The child is** □ Underweight □ Overweight □ Obese or Overweight + Comorbidity **The whānau choose to:**□ Alert medical team □ Refer to GP □ Whaanau Kori Tamariki ora (Sport Waikato) - 4yrs+ overweight/obese*For concerns about other children in whānau 5+ provide information*□ Sport Waikato □ Bodywise □ Whānau choose not to be referred | * Growth chart for 2-3 yos
* BMI chart/calculator for 4yos
* Be smarter messages
* List of ECE providers that are part of Under 5 Energise programme
* HHT GP referral letter
* Sport Waikato Green prescription info
* Bodywise brochure
 |
| **Development (0-5 years)** |  |  |  |  |
| Are there any concerns in regards to your child’s/infant’s development? | □ No□ unsure Or Yes | □ No action required**The whānau choose to:**□ Go through milestones checklist □ CDC criteria not met□ criteria met, refer to CDC □ Whānau choose not to be referred | * Milestones checklist
* Refer to milestones tracker app
* Development resources
* CDC brochure/flyer
* CDC referral form WDHB
 |
| **Skin** |  |  |  |  |
| Do you have any concerns in regards to your child’s/infant’s skin or other children in the whānau/family? | □ No□ Yes | □ No action required**The whānau choose to:**□ inform medical team/ refer to GP for other children□ Provide eczema brochure and information □ Common skin infections resources | * ‘Stop skin infections’ brochure/flyer
* Eczema and other skin resources
* HHT GP referral letter
* Head lice information
 |
| **Vision and hearing** |  |  |  |  |
| Do you have any concerns about your child’s/infant’s hearing or other children in the whānau hearing? | □ No □ Yes | □ No action required**The whānau choose to:**□ 0-3 years - refer to medical team OR onto GP□ 4-17 years – make an appointment with the vision and hearing screening clinic□ Not engage with a service  | * Glue ear and earache brochures
* Waikids ‘Blow your nose’ flyer
* HHT GP referral letter
 |
| Do you have any concerns about your child’s/infant’s vision or other children in the whānau vision? | □ No □ Yes | □ No action required**The whānau choose to:**□ 0-3 years - refer to medical team or make an appointment with an private optometrist□ 4-17 years – make an appointment with the vision and hearing screening clinic□ Not engage with a service | * Advise free eye exam for up to 16ys at Spec savers, glasses free with CSC
* Spectacles subsidy brochure
* List of suitable optometrists for children
 |
| **Frequent flyers**  |  |  |  |  |
| **Check past admissions in iPM**5 or more admissions in previous 6 months? | □ No □ Yes | □ No action required□ alert medical team  |  |
| **TIMING** |  |  |  |
| **Time taken to complete Harti Hauora tool assessment?** | \_\_\_\_\_\_\_\_\_\_\_\_ mins |  |  |

## Appendix 3. Patient Satisfaction with Hospital Care (Mārama survey)

**Satisfaction With Care questionnaire**

*To be completed just prior to or after discharge from hospital*

Thinking about your most recent stay here at Waikato Hospital and the people who support(ed) you and your whānau, how much do you agree or disagree with the following statements…

**Q1 Relationship/Partnerships**

* I feel respected

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q2 Communication/Information**

* I am involved in decision making

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q3 Continuity of Care/Coordination**

* The people I see communicate with each other when I need them to

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Don’t know |
| 1 | 2 | 3 | 4 | 5 |  |

**Q4 Family Involvement**

* My family / whānau are given information and encouraged to be involved

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree | I didn’t want them to be involved |
| 1 | 2 | 3 | 4 | 5 |  |

**Q5 Recovery and Support**

* I have the support I need for the future

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q6 Recovery and Support**

* Our plan is reviewed regularly

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q7 Friends and Family question**

* I would recommend this service to friends and family if they needed similar care or treatment.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q8 Free Form Text Question**

Is there anything you want to say about your recent experience with the service or anything you think we can improve on?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Q9 Additional question**

* Staff cared about the well-being of our family/whānau

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

**Q10 Additional question**

* As well as our child's physical health needs -   other needs our child had were also met

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| 1 | 2 | 3 | 4 | 5 |

* The following needs of my child were considered (tick all that apply)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Social | Cultural | Psychological | Physical | Mental |
|  |  |  |  |  |

## Waik_Word_RGB_V-NewAppendix 4. Patient Information Sheet and Consent Form (PISCF) for Qualitative component

**Participant Information Sheet**

|  |  |
| --- | --- |
| Study title: | Rangahau Hauora Māori: Qualitative |
| Locality:  | Waikato | Ethics committee ref.: TBA |
| Lead investigator: | Dr Bridgette Masters-Awatere | Contact phone number: 07 838 4080 |

You are invited to take part in a research project on improving access to holistic health and services for tamariki Māori. This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have.

You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this. If you do agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can withdraw from the study. This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of this research project?

This project is part of a wider study that aims to assess how Waikato Hospital currently addresses the holistic health and non-health needs for hospitalized children and their whānau. The purpose of this research is to improve access to holistic health and social services for tamariki Māori and their whānau. We also want to improve the recognition of, and need for, Māori-led culture change within hospital environments. It is expected that this study will contribute to the translation of findings into Māori health gains, and result in tangible health improvements for tamariki Māori and their whānau.

We are interested in your experiences at Waikato Hospital. In particular, what you thought of their services, how your needs (health and non-health) were assessed and addressed, and what effect (if any) the services offered to you had on the health of your whānau. We would like to have a conversation with you about this.

Ethical approval for this research has been given by the **Waikato DHB** **Health and Disability Ethics Committee (HDEC)**. This project is being carried out by the Waikato DHB and the University of Waikato. The lead investigator for this part of the study is Dr Bridgette Masters-Awatere from the University of Waikato. The Primary Investigator for the entire research project is Dr Nina Scott from the Waikato DHB (see page 3 for contact details).

What will my participation involve?

We want to talk with Māori whānau with children who have been admitted to Waikato Hospital during 2018. These conversations, or research interviews, will involve answering some questions about the care you received, and will provide us with valuable information regarding your care and the services you received.

In detail, once you leave the hospital a researcher will in touch. If you are willing to participate in this research project, the researcher will arrange a time and place to meet with you and your whānau. There will be 2 interviews for each whānau group. It is expected that each interview will take about one hour of your time. For the second interview, we will ask you to photograph images that reflect your “world of health” and/or your experiences with health-related services. During the second interview we will look at these images together and talk about them. This process will be explained in more detail during the interviews. After each interview the researcher will offer you a koha of a $100 supermarket voucher in recognition of your contribution to the research project.

Who pays for the research?

This project is funded by the Health Research Council of New Zealand. There will be no cost to you or your whānau if you decide to participate.

What if I feel uncomfortable and wish to stop the interview(s)?

If at any time you feel uncomfortable, or do not wish to answer a question, the researcher will be attentive to your needs. You can also ask for the interview to stop at any time, and the researcher will end the interview. If you would like to restart or reschedule the interview, the researcher will do so.

What if something goes wrong?

If you were injured during an interview, which is **unlikely**, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

What are my rights?

You have the right to access any information about you or your whānau that is collected as part of this study. We will make every provision to ensure your privacy and all information will be kept confidential.

What if I change my mind?

You have the right to decline to participate, or to withdraw from the research at any practicable time. If you wish to withdraw from the study, this will not in any way affect the care you or your whānau receive.

What will happen to my information after the study?

We would like to sound record the interviews, however, you may request for the sound recorder to be turned off at any stage during the interview(s). The sound-recorded interviews will be transcribed, but the researcher(s) will ensure that your actual names are not recorded anywhere. All records relating to this study will be kept in a secure place (either a locked cabinet or password-protected computers) and every effort will be made to ensure that your information is not identifiable. Information about the research will not be used for any other purpose and we will not disclose personal information. The results from this study will be used to help improve things for people in general, through writing academic articles, presenting to the Waikato DHB, and broader discussions around health. If you want to receive a copy of the findings of this study please let the interviewer know.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact the lead investigator for this project: **Dr** **Bridgette Masters-Awatere** from Waikato University, via Phone: (07) 838 4080 or Email: bmasters@waikato.ac.nz

You can also contact the primary investigator, **Dr Nina Scott** from the Waikato DHB, via Phone (07) 839 8899 ext. 97528 or Email: nina.scott@waikatodhb.health.nz

If you want to talk to someone who isn’t involved with the study, you can contact an **independent health and disability advocate**:

Phone: 0800 555 050
Email: advocacy@hdc.org.nz

For **Māori health support** please contact the Kaitiaki team on 021 806 171 or ask at any Waikato hospital ward reception/information centre.

You can also contact the **Health and Disability Ethics Committee** (HDEC) that approved this study:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

**Consent Form**

**Please tick to indicate you consent to the following:**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | Yes 🞏 | No 🞏 |
| I consent to being interviewed by the research staff, and to having these interviews sound-recorded and transcribed. | Yes 🞏 | No 🞏 |
| If I decide to withdraw from the study, I agree that the interviews done to the point when I withdraw may continue to be used. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material which could identify me personally will be used in any reports. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it. I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher’s name: |
| Signature: | Date: |

1. Note that since recruitment will only be performed at Waikato hospital for the reasons stated below, the definition of the Acute Hospital Admission for the purposes of this study restricts this to inpatients of Waikato Hospital Acute Paediatric wards, while the definition of an acute readmission allow patients to be admitted to any of Waikato DHB’s acute paediatric services. [↑](#footnote-ref-1)
2. Non-compliance (used in an entirely non-pejorative sense) is defined as: not being enrolled with a GP, not being up to date with immunizations, not being up-to-date with WCTO (including before school check) or not being up-to-date with oral health checks. [↑](#footnote-ref-2)
3. Mārama developed by CBG in a large one year trial funded by the Health and Disability Commissioner. See <http://hdcrtf.co.nz/> for more [↑](#footnote-ref-3)