



ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

CDT-AFRICA

PRACTICE AND PERCEIVED EFFECTIVENESS OF *RUTA CHALPENSIS* FOR INFANTILE COLIC BY PARENTS OR CAREGIVERS OF INFANTS IN ADDIS ABABA, ETHIOPIA

A THESIS REPORT SUBMITTED TO CENTER FOR INNOVATIVE DRUG DEVELOPMENT AND THERAPEUTIC TRIALS FOR AFRICA, COLLEGE OF HEALTH SCIENCES ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF REQUIREMENT FOR MASTERS OF SCIENCE DEGREE IN CLINICAL TRIAL

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Letter of Certificate

This is to confirm that Dureti Moti's final project work, "Practice and perceived effectiveness of *Ruta chalpensis* for infantile colic by parents or caregivers of infants in Addis Ababa, Ethiopia" has been completed and presented to in partial fulfillment of Master of Science in Clinical Trial degree requirement in conformity with university requirement and fulfills acceptable criteria in terms of originality and quality.

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Letter of Declaration

I, Dureti Moti Gobena, certify that this thesis is my original work under the supervision of Professor Abebaw Fikadu and Professor Eyasu Mekonnen. All sources of information utilized in the thesis have been properly credited. I further affirm that the thesis has not been submitted to any other higher learning institution in part or in whole to acquire a master degree.

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ACRONYMS

ADHD	Attention Deficit Hyperactivity Disorder
ADR	Adjusted Odds Ratio
CAM	Complementary and Alternative Medicine
CSA	Central Statistical Agency
EFY	Ethiopian Fiscal Year
FGIDs	Functional Gastro Intestinal Disorders
GI	Gastro Intestinal
HC	Health Center
IC	Infantile Colic
MOH	Ministry of Health
OR	Odds Ratio
RC	Ruta chalepensis
RCT	Randomized Controlled Trial
SPSS	Statistical Package for Social Sciences
TCM	Traditional and Complementary Medicine
WHO	World Health Organization

ABSTRACT

Background: Infantile colic, also known as excessive crying is a common condition affecting infants during the first months of life and also have a significant impact on parents or caregivers, leading to increased stress, parental distress, and disrupted family dynamics. Though there is anecdotal evidence and traditional knowledge regarding the use of *R. chalpensis* for infantile colic there is no any scientific evidence. Therefore, this study aims to investigate the practice and perceived effectiveness of *R. chalpensis* for infantile colic by parents or care givers.

Method: Facility based cross-sectional study was conducted on randomly selected 422 parents or caregivers of infants aged between 1 and 6 months who came for immunization to selected health centers in Addis Ababa City, Ethiopia, from February 1 to February 30, 2024. The data were collected using pre-tested semi-structured questionnaire by trained data collectors using ODK collect v 2023.2.4. The collected data were exported to Statistical Package for Social Science version 26 for analysis. Descriptive statistics was used to calculate prevalence of practice of *R. chalpensis*. Graphs, charts, Statistical tables and texts were used to present the data.

Result: Overall, 133(34.9%) of the study participants reported that their infants had infantile colic. From them 116(87%) of the participants reported that they administered RC as a therapeutic intervention for treating colic symptoms of their infants. Notably, 76(65%) perceived the remedy to be effective in relieving their infants' colic symptoms.

Conclusion: While *R.Chalpensis* is perceived as effective and safe by many users, the lack of scientific validation highlights a need for caution. Further scientific research, including clinical trials, is recommended to validate the safety and efficacy.

Key words: *Infantile colic, R. chalpensis, herbal medicine, complementary and alternative medicine.*

CHAPTER ONE

1. INTRODUCTION

1.1 Background

Infantile colic (IC) is a common condition in early infancy, characterized by excessive and inconsolable crying without an apparent cause. From a physiological perspective, infantile colic can be defined as a functional gastrointestinal illness that exhibits recurring gastrointestinal symptoms in the absence of any significant structural or biochemical abnormalities. The updated ROME IV guidelines outline the definitions of the condition relevant to both clinical research and routine clinical practice(1). Infantile colic (IC) is a common condition in early infancy, characterized by excessive and inconsolable crying without an apparent cause. Globally, its prevalence varies widely, with estimates ranging from 5% to 40% of infants, reflecting differences in diagnostic criteria and population characteristics(2). A 2016 literature review suggests that approximately 20% of all infants may experience colic. Furthermore, IC is a leading cause of concern among new parents and is responsible for 10% to 20% of pediatric consultations during the first few weeks of life(3). Usually beginning in the second or third week of life, the illness peaks around six weeks, and then subsides by 12 weeks. Colic is characterized by unrelenting sobbing, irritability, and screaming without a clear explanation; during these episodes of fussiness, which tend to happen more frequently in the evenings, the affected infant will typically have red faces, pull their legs up, and clench their fist(2). Since 1954, the IC has been defined as "crying for at least three hours per day, for at least three days per week, for a period of three weeks or longer in otherwise healthy infants"; this is also known as the Wessel "rule of threes "(4). The three-week duration criterion was recently replaced by a seven-day duration criterion in the Rome classification of functional gastrointestinal disorders (Rome IV), which further refines the Wessel criteria(4,5).

The infantile colic is currently a topic of clinical investigation in terms of both causation and management. Numerous etiological hypotheses have been put forth, but none are

compelling enough to fully explain the illness. However, several factors have been suggested as potential contributors, including changes in fecal microbiota, intolerance to lactose or the protein in cow's milk, gastrointestinal immaturity or inflammation, increased serotonin release, improper feeding method, maternal smoking, and nicotine replacement therapy. Colic is a diagnosis of exclusion, suggesting that all other possible rationales have been ruled out by a thorough history and physical examination(6).

Regarding the treatment, a variety of therapeutic approaches for colic's are being used, including behavioral and nutritional counseling, lactase and probiotic supplementation, and analgesics(7). For evidence-based recommendations, the clinical community is looking for the IC treatments that have been proven effective in clinical trials. However, systematic review of clinical trials that have been published using pharmaceutical treatments, probiotics, nutritional modification (dietary changes), and massage have concluded that these have limited effectiveness in reducing crying episodes and severity of IC symptoms(8–11). The interest in herbal remedies has grown because they have an intriguing chemical makeup and are widely used in folk medicine. One of the potential sources for the development of novel agents and medications is plant-based natural products.(12).

Ruta plants are perennial shrubs of the Rutaceae family that have historically been employed in folk medicine, mostly for the treatment of various ailments. The *Ruta* genus contains ten species, the two most frequently mentioned are *R. chalepensis* and *R. graveolens*(13).The *Ruta* species may be a source of organic compounds having biological properties. In order to increase the value of these plants, *Ruta* extracts, essential oils, and isolated chemicals have demonstrated a wide range of potential applications in the treatment of various diseases as well as the management of pests(12).

In Ethiopia, *R. chalpensis*, known as *Tenadem* in Amharic, is grown as an ornamental and medicinal herb in gardens where it is used as an anti-inflammatory, antiviral, and antibacterial agent, as well as to prevent the formation of free radicals, enhance milk

flavor, and treatment of eye pain(14). The aromatic medicinal plant genus Rue (*R. chalpensis*) has been used in the Ethiopian folk medicine as a natural therapy for a number of ailments(15). *R. chalpensis* is commonly used for the treatment of stomach pain, common cold, nausea and headache by putting the leaves in to tea or coffee or by sniffing the leaves directly(16). The main objective of this research was to assess the practice and perceived effectiveness of *R. chalpensis* for infantile colic by parents or caregivers.

1.2 Statement of the problem

Infantile colic (IC), is frequently seen in the first three months of life, which affects between 2% and 73% of babies globally, depending on the diagnostic criteria used(5,17). According to a meta-analysis, children who have a history of excessive crying are more likely to have general behavioral issues, internalizing behavioral issues (such as anxiety, depression, or withdrawal), externalizing behavioral issues (such as violent or destructive behavior) or attention deficit hyperactivity disorder (ADHD) (18).

Some evidence suggests that infants with colic have a higher risk of developing recurring abdominal pain, functional gastrointestinal disorders (FGIDs) and mood disorders as they become adolescents or adult than healthy infants in the control group who do not experience colic(19). It has been suggested that infants with infantile colic may be more likely to get migraines (20).

According to a prospective 10-year study, there is a link between IC and recurrent abdominal pain and the study revealed that there is an association between colic and allergic conditions like atopic eczema, food allergies, and respiratory and ocular allergies. Subjects who have infantile colic are more likely to experience certain GI allergy, and psychological disorders in childhood.(19).

Consistent IC can cause parents' exhaustion and distress, and it can also harm their bond with their child and their engagement as a parent(21). Study done in Turkey emphasized

that depression, anxiety and stress levels are high in mothers who have babies suffering from infantile colic(22).

Mothers with colic-affected babies had multidimensional psychological suffering. For instance, they reported higher levels of physical dysfunction, fears, disordered thinking, depression, anxiety, fatigue, hostility and impulsive decisions. When it comes to parenting, they also experienced larger sentiments of personal inferiority and inadequacy(23).

According to a study conducted in Switzerland, there is a strong correlation between maternal health and mood disorders in the immediate postpartum period and infant crying issues as observed by midwives. The most significant component was mother's depression, which had an adjusted odds ratio of 4.02 for crying issues in the infant compared to the instance where she wasn't depressed(24). Infants exposed to maternal depression exhibit more dysregulated behavior, such as irregular or disorganized sleep and challenging temperament, which might in turn make the depression in the mother worse(25).

It is believed that a variety of factors, including those related to the maternal, paternal, infant, and surroundings, contribute to excessive crying and IC(26). Stress and postpartum depression were maternal considerations, nevertheless, an infant's temperament, developmental milestones reached, sensory processing ability, and underlying organic causes are considered to be infant factors. Food intolerances and/or food protein allergies are considered to have organic causes(27).

The treatment of IC is aimed at reducing the intensity of crying or eliminating factors that appear to exacerbate the crying. As there is no gold standard treatment for colic, many treatment options are used(28). A Cochrane review found low- to moderate-quality evidence that herbal remedies shorten crying episodes, with varying degrees of benefit reported across studies(8).

Current conventional treatments for infantile colic, including pharmacological agents, dietary modifications, and behavioral interventions, have demonstrated inconsistent

efficacy and, in some cases, carry potential risks of adverse effects(29). Consequently, parents and caregivers often seek alternative approaches, including the use of traditional medicinal plants, to alleviate their infants' distress(30).

In Ethiopia, traditional medicine plays a prominent role in primary health care, particularly in managing pediatric conditions such as infantile colic(31). Among these traditional remedies, *R. chalpensis* has been widely cited for its potential benefits in treating colic symptoms. However, there exists a significant gap in the scientific literature regarding the safety, efficacy, and pharmacological properties of *R. chalpensis* specifically for infantile colic. The absence of robust, evidence-based studies on this herbal remedy limits the ability of health professionals to provide informed recommendations, potentially leaving caregivers reliant on anecdotal reports and traditional beliefs.

This lack of universally effective conventional treatments, coupled with insufficient empirical research on traditional herbal remedies such as *R. chalpensis*, underscores an urgent need for systematic investigation. Understanding the prevalence of *R. chalpensis* use, caregivers' perceptions of its effectiveness, and its methods of preparation and administration is crucial to informing future clinical research. This study seeks to address this knowledge gap by exploring the use of *R. chalpensis* in the management of infantile colic among caregivers in the study setting.

1.3 Significance of the Study

Plants with medicinal properties play an increasingly important role in food and pharmaceutical industries for their functions on disease prevention and treatment. Conducting a study on the practice and perceived effectiveness of traditional remedies for infantile colic adds to the body of evidence to herbal medicine. The findings will contribute to the scientific understanding of this specific remedy and potentially guide for future research and clinical practice in the field of herbal medicine. The study aims to deepen the understanding of the utilization of *R. chalpensis* for managing colic pain and provide evidence-based data. Furthermore, the study will help us assess the prevalence of herbal medicine usage in infants.

CHAPTER TWO

2. LITERATURE REVIEW

2.1 Prevalence of infantile colic

According to a 2016 literature review around 20% of all infants are thought to experience infantile colic. A study conducted in Scotland indicated that the majority of homeopathic prescriptions for children were made for those under one year of age, with a rate of 8 prescriptions per 1,000 registered children and the most common conditions for which homeopathic medicines were prescribed were colic which accounts for 85% (32).

A study in India stated that approximately 97% pediatricians in the survey reported colic and regurgitation as the most common GI issues in the younger age group of 0-6 months(33).

A Study done in the middle east and east African region revealed that Above 63%, of pediatricians surveyed, believed that the colic prevalence rate was >40%, which is greater than the 20% rate reported in worldwide surveys(34).

2.2 Current conventional (orthodox) pharmacological treatments for IC

Current conventional pharmacological treatments for IC are limited, and most are used cautiously due to variable efficacy and safety concerns. Simethicone is one of the most commonly used medications for infantile colic. It acts as an anti-foaming agent that reduces the surface tension of gas bubbles in the gastrointestinal tract, allowing them to coalesce and be expelled more easily. This mechanism is intended to relieve discomfort caused by gas accumulation. However, clinical studies have shown inconsistent results, with many trials reporting no significant difference compared to placebo(21). Dicyclomine (Dicycloverine) is an anticholinergic and antispasmodic agent that works by blocking muscarinic receptors in the gastrointestinal smooth muscle. This reduces intestinal spasms and theoretically decreases pain associated with colic. Although some studies showed effectiveness, its use in infants is now

contraindicated due to serious adverse effects such as apnea, seizures, and coma(35). Proton Pump Inhibitors (PPIs) and H2-Receptor Antagonists are sometimes prescribed when gastroesophageal reflux is suspected. PPIs inhibit the hydrogen-potassium ATPase enzyme in gastric parietal cells, thereby reducing gastric acid secretion. H2-receptor antagonists block histamine receptors on parietal cells, also decreasing acid production. However, evidence indicates that acid suppression does not significantly improve colic symptoms in otherwise healthy infants, and routine use is not recommended(36). Probiotics like *Lactobacillus reuteri* DSM 17938 are increasingly used in conventional management, particularly in breastfed infants. These act by modulating the gut microbiota, reducing intestinal inflammation, improving gut motility, and enhancing mucosal barrier function. Some randomized controlled trials have shown a reduction in crying time in breastfed infants, although results are inconsistent in formula-fed infants(37). Overall, conventional pharmacological management of infantile colic remains limited, with most guidelines emphasizing reassurance and non-pharmacological strategies.

2.3 Uses of *R. chalapensis* in traditional medicine

Medicinal plants are utilized extensively in traditional medicine and have a fascinating chemical makeup that has enhanced their therapeutic value. One possible source for the discovery of novel agents and/or medications is plant-based natural products(12).

In many countries, *R. chalapensis* is cultivated for its pharmacological and biological activities and it is frequently used for treatment of gastric, diuretic, inflammation, headache and rheumatic illnesses(38).

Extensive research done on the family of Rutaceae shows the potential application of these natural products in the treatment of such diverse conditions as Alzheimer's disease, depression and cancer, as well as in treating infections, due to their anti-bacterial, anti-fungal, anti-leishmanial and antiparasmodial properties(39).

Study done on ethnobotanical knowledge in setecidades, Azores village in Portugal reported that the leaves of *R. chalpensis* is used to treat pains of kidney, bladder, stomach and spines(40).

A decoction of the plant's aerial portions is used in Saudi Arabia to treat mental illnesses, rheumatism, and as an analgesic and antipyretic. In Indian medicine, the herb is prescribed to cure rheumatism, drop-sy, neuralgia, and many bleeding diseases related to menstruation. The plant's roots are prepared and used as an antivenom in China. This suggests that *R. chalpensis* may have anti-inflammatory properties(41).

R. chalpensis has been used in traditional Palestinian medicine to treat a variety of conditions, including ear infections, inflammations of the eyes, bacterial and fungal infections of the skin, backaches, arthritis, rheumatism, and renal colic. In addition, it has been used as a sedative, bronchodilator, antitussive, antispasmodic, anti-inflammatory, anti-lice, and sedative as well as to treat snake bites(42).

2.4Uses of *R. chalpensis* in Ethiopia

Traditional medicine remains the main source for a large majority of people in Ethiopia. About 80% of the human population depend on traditional medicines for treating health problems. A variety of traditional medicinal plants have been widely used by different indigenous people in Ethiopia for many human and livestock ailments.(43)

An ethnobotanical study of medicinal plants done in different parts of Amhara region in Ethiopia stated that *R. chalpensis* is one of the preferred medicinal plants used for treating stomachache(44–46).The mode of preparation of the remedy is by boiling the leaf and stem of *R. Chalepensis* with water and drinking and fumigating(45).

Ethnobotanical study of medicinal plants done in Ganata Afeshum district in eastern zone of Tigray, Ethiopia stated that *R. chalpensis* is one of plant species which have the highest use value in the study area and were used to treat the highest number of diseases, indicating that it is more effective to treat ailments(47).

An ethnobotanical study of medicinal plants in Amaro special woreda in Ethiopia reported that *R. chalpensis* is used to treat stomachache, malaria, herpes simplex and

evil eye. Mode of preparation and usage were somehow different for each disease. For example, fresh leaves or seeds are chewed for treating stomachache and herpes simplex, for malaria the leaf powder is mixed with water and drunk in the morning before breakfast for three days and for evil eye fresh leaves are mixed with coffee and drunk(48).

Researchers and pharmaceutical companies are increasingly using current scientific methods in conjunction with traditional knowledge to identify novel medications. Herbal medicines can aid in the formation of a new era of the healthcare system to treat human ailments in the future. Therefore, the merging of traditional knowledge and scientific study holds enormous potential for identifying novel drug sources and developing medical science(49).

In Ethiopia, therapeutic products from traditional medicinal plants are not yet developed, and the country's indigenous knowledge of using medicinal plants is vanishing as a result of urbanization, industrialization, the rapid loss of natural habitats, and changes in lifestyle(50).

2.5 Practice of traditional medicine for infantile colic

In the care of IC, alternative therapies have taken on a more significant role in the absence of safe and effective pharmaceutical interventions(29). Herbs such as fennel (*Foeniculum vulgare*), chamomile (*Matricariae recutita*) and lemon balm (*Melissa officinalis*) may help calming the infant and reducing abdominal distension(51,52).

According to a Cochrane systematic review of clinical trials herbal agents such as *Matricaria recutita*, *Foeniculum vulgare*, and *Melissa officinalis* extracts, fennel seed emulsion, *Fumaria* extract, and herbal tea preparation were linked to shorter crying episodes compared to placebo or no treatment, as well as improved symptoms compared to placebo(8). Complementary medicines are often promoted in the treatment of IC however, there are limited reports available on their use, safety and effectiveness in the treatment of this condition(53) . Studies conducted in clinical pediatric settings revealed that 20–30% of general pediatric patients had utilized one or more

complementary and alternative medicine (CAM) treatments. These treatments were used to treat illnesses, lessen symptoms, prevent illnesses, promote wellbeing, or achieve inner peace and harmony(54).

In a systematic review of all complementary and alternative medications and nutritional supplements for the treatment of IC Fennel extract, mixed herbal tea, and sugar solutions showed promising benefits(53).

According to study done in Turkey the most common CAM method used by mothers for their babies was massage (59.0%). The most second frequent methods were determined as fennel tea (48.4%) and rhythmic rocking (48.4%). The least applied methods were amulet (3.0%), acupuncture (3.0%) and poppy oil (3.0%). A minority (4.5%) of mothers swaddled their babies(55).

According to a study done in Jordan of the complementary and alternative medicines used for bloating and colic in infants, the most frequently used one was aniseed (used by 70.2%), cumin (36.7%), chamomile (34.8%), sage (27.3%), mint (26.2%) and fennel (26.0%)(56).

A study done in rural South Africa stated that a total of 97% infants received non-prescribed medications in the first 3 months of life: most of the medications are given rectally and orally. The most common enema contained traditional Zulu medicine made from herbs, given more than once weekly, usually for perceived constipation; the most common oral medication was gripe water, given once daily, mainly for 'colic'(57)

In a study done in South Africa, the use of both complementary medicine and conventional medicine to treat their infant's colic was indicated by 73.0% of participants, while complementary medicine alone was only used by 27.0% of participants. The most commonly used complementary medicines stated in the study were individual homeopathic remedies which accounts 58.6% of the participants, 46.7% of the participants used probiotics, 44.1% of the participants used either Colic Calm or herbal medicines, 41.4% of the participants used gripe water and 34.9% of the participants used herbal teas (58).

A study conducted in Nigeria found that mothers frequently treat their children's colic at home. The 67.7% of mothers who treated their infants' colic without seeking medical advice backed with this conclusion. The study revealed that the two home-based therapies most frequently used were self-medication and the use of herbal remedies. About 51.8% of women who used home-based therapies used herbal remedies in their colicky babies(59).

Study done on Ethnobotanical information of medicinal plants used by traditional healers in Ethiopia in Gullele botanical garden for treating human diseases revealed that *R. chalpensis* is used for Frequent, prolonged, and intense crying or fussiness in a healthy infant (Colicky babies), diarrhea, earache, heart pain, hemorrhoids, influenza symptoms and intestinal disorders(60).

2.6 Perceived effectiveness of traditional medicine for infantile colic

Complementary medicine was chosen as a modality for treatment for it is perceived safe and less harmful with fewer or no side effects. Study done in Jordan stated that 79.0% of mothers believed that their infants had benefitted from complementary and alternative medicines(56).

Results from the study conducted on the perceived effectiveness of complementary medicine by mothers of infants with colic in Gauteng, indicated that participants perceived complementary medicine as an effective form of treatment for infantile colic. However, there is uncertainty whether it works well in conjunction with conventional medicine(58).

With limited scientific evidence available on the use, safety and effectiveness of complementary medicines in the treatment of IC, it is important to establish which complementary medicines are popular and perceived to be effective for IC, allowing for further clinical, investigatory and safety research to be conducted on them(53).

In Ethiopia when infants cry excessively without any known cause most of the time people suggest to use herbal medicines like *R. chalpensis* assuming the cause for the crying is infantile colic. However, there are no documented studies on the practice,

perceived effectiveness, safety and efficacy of this herbal medicine. Therefore, the aim of this study is to determine the practice and perceived effectiveness of *R. chalpensis* for infantile colic *by* parents or caregivers.

CHAPTER THREE

3. OBJECTIVES

3.1 General objectives

- ❖ The aim of the study is to determine practice and perceived effectiveness of *R. chalpensis* for infantile colic.

3.2 Specific objectives

- To determine the practice of *R. chalpensis* usage use among parents or caregivers for managing infantile colic.
- To determine the perceived effectiveness of *R. chalpensis* for infantile colic
- To investigate the common methods of preparation and administration of *R. chalpensis* in treating infantile colic.

CHAPTER FOUR

4. SUBJECTS AND METHODS

4.1 Study area

This study was conducted in Addis Ababa, the capital city of Ethiopia. The city contains 11 sub cities. According to the 2012 (EFY) Health and Health Related Indicators published by the Ministry of Health (MoH), Addis Ababa has 13 Government hospitals, and 98 Health Centers. The city has an estimated total population of 3,686,068 consisting of 1,389,817 males and 1,527,478 females (CSA 2017).

4.2 Study design and period

Facility based cross-sectional study were done from February 1 to February 30, 2024.

4.3 Populations

4.3. 1 Source Population

The source population of the study were parents or caregivers of infants aged between 1 and 6 months that come to visit Health Centers for their infant's immunization

4.3.2 Study Population

The study population were parents or caregivers of infants aged between 1 and 6 months that came to selected health centers for their infant's immunization.

4.4 Eligibility criteria

4.4.1. Inclusion Criteria

- Parents or caregivers of infants who come for immunization of their infants to health center
- Parents or caregivers willing to participate on the study
- Age of infants between 1 and 6 months

4.4.2. Exclusion criteria

Parents or caregivers with critically ill infants.

Parents or caregivers who are not residents of Addis Ababa, Ethiopia for more than 6 months of period.

4.5. Sample size determination

The sample size was calculated by Epi Info version 7.1(CDC, 1980, Georgia, USA) using a single population proportion formula considering the following assumptions:

95% confidence interval (CI), 5% marginal error, and 50% estimated proportion is taken because as there is no prior data or estimate of prevalence of parents or caregivers use of *R. chalybeatus* for infantile colic with a 10% non-response rate the minimum required sample size was 422 study participants.

4.6. Sampling technique and procedures

The study was conducted in three Addis Ababa sub cities. The sub cities were selected by lottery method. From the selected sub cities one health center per sub city was selected by simple random sampling method. The first site was Arada health center from Arada sub city located around Addis Ababa city administration. Previous three-month average report of the HC showed that around 460 infants under 1 year were vaccinated.

The second health center was Alem bank health center from kolfe-keraniyo sub city located on the south west periphery of Addis Ababa city administration. Previous three months average report of the HC showed that around 1230 infants under 1 year were vaccinated.

The third health center was Philpos health center from Addis ketema sub city. Previous three-month average report of the HC showed that around 660 infants under 1 year were vaccinated.

Then proportional allocation was done based on previous three-month average vaccination report of health centers before data collection. A systematic random sampling method was used to recruit participants from health centers.

The sampling interval was calculated using $(K=N/n)$ $2350/422 = 5.56 \sim 6$

Where K is sampling interval, N= total number of infants vaccinated in previous month and n is the required sample size. So, after random selection of the first participant, every 6th participant was selected. Figure 1 shows sampling procedure

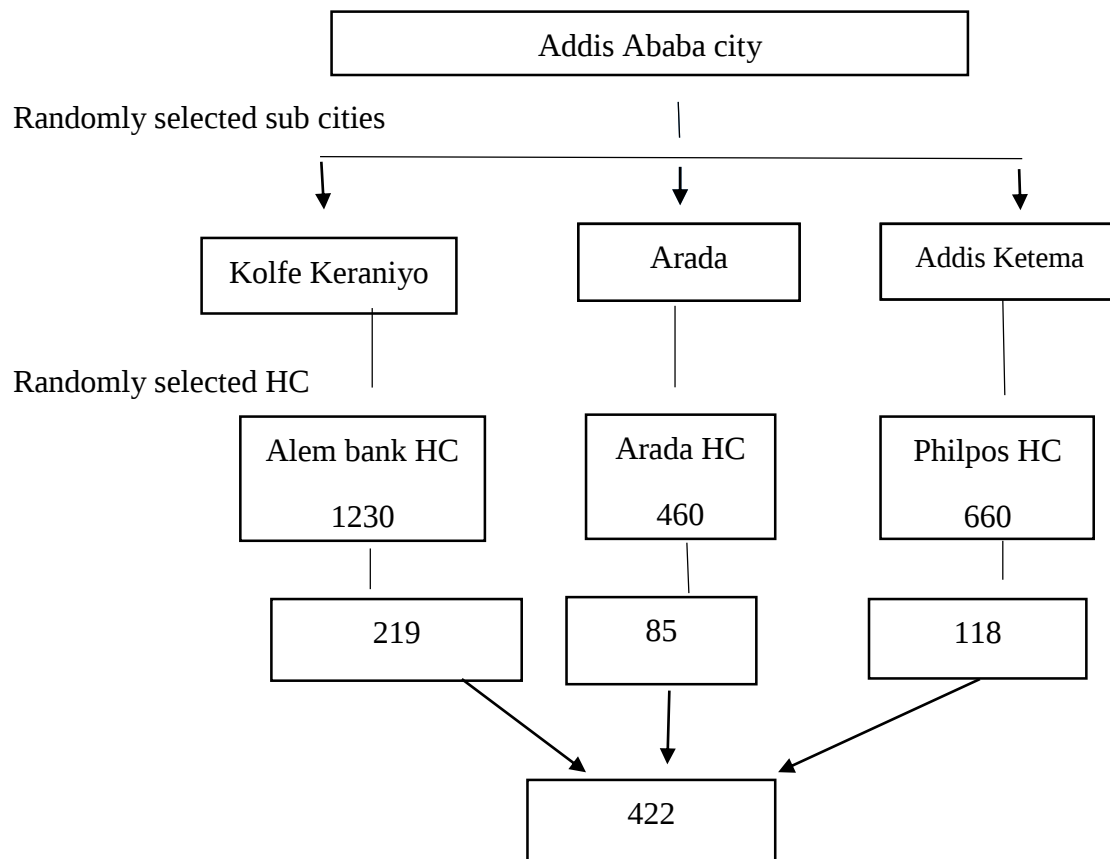


Figure 1: schematic presentation showing sampling procedure and proportional allocation of study participant

4.7 Data collection procedures

Three data collectors with a BSc in nursing and prior data collection experience were employed. The primary investigator provided training to data collectors on the fundamental guidelines that must be followed during data collection, how each item in the questionnaires must be understood and supervise the overall work. The data was collected using a pre-tested semi structured questionnaire using ODK collect vs 2023.2.4.

4.8 Data collection instruments

A semi structured questionnaire was administered to collect data on sociodemographic, infantile colic related questions adapted from coliQ questionnaire(61) CAM and *R. chalpensis* related questions. The tool was first prepared using English language and later translated in to the local language (Amharic).

4.9 Study Variables

4.9.1. Dependent Variables

- Practice of *R. chalpensis*
- Perceived effectiveness

4.9.2. Independent Variable

- Sociodemographic factors age, sex, education, occupation, marital status, number of children, family income (economic status) and residence of caregiver
- Age of the infant
- Sex of the infant
- Belief and attitude
- Previous experience and awareness of *R. chalpensis*

4.10 Operational definitions

- **Traditional medicine:** It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness(58).
- **Herbal medicine:** include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations(62).
- **Complementary and alternative medicine:** the terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries(62).
- **Registered children:** children who are officially enrolled or listed within a specific healthcare system or general practice clinic.
- **Practice of *R. chalpensis*:** use of *R. chalpensis* for treating infantile colic.

- **Perceived effectiveness:** study participants who scored $\geq$ mean score in Likert scale for perceived effectiveness question are considered as they perceived *R. chalpensis* as effective.

4.11 Data quality Assurance

Training was given to data collectors on the objective and relevance of the study, how the data had to be collected and how the ODK collect app is utilized. The data collection questioner was reviewed for being complete and appropriate before commencement of data collection. Completeness and consistency of the data were checked at every end of the data collection to check if there are unnecessary or missing variables before accepting the data and start to use the data. To minimize missing variables, the ODK collect app were used by making variables fields required and using appropriate skipping patterns. Excel template for the ODK was prepared with relevant restrictions and necessary commands and was tested before actual data collection.

4.11.1 Pretest

In order to determine the clarity and understandability of the data collection instrument, pretest was conducted on 21 women (5% of sample size) of respondents at Lideta health center.

4.12 Data Processing and Analysis

After data collection by ODK collect v 2023.2.4 was done, each completed forms were checked for completeness and was exported to SPSS version 26 statistical package software to analyze the data. Descriptive statistics was used to calculate the prevalence of practice of *R. chalpensis*.

4.13 Ethical Consideration

Ethical approval was obtained from the Scientific and Ethical Review Committee of CDT-Africa. Permission to conduct the study in the health centers was obtained from Addis Ababa health Bureau.

The objective of the study was explained to the study participants, privacy and confidentiality were ensured; Study participants were involved in the study based on their willingness.

Signed informed consents were obtained from all participants before data collection. Participant's confidentiality was protected and privacy was respected.

4.14 Data presentation and Dissemination of the Results

The result was expressed as percentage and presented using tables, charts and graphs. The findings of the study will disseminated in the form of publication and presentations in conferences.

CHAPTER FIVE

5. RESULT

5.1 Sociodemographic characteristics

From a total of 422 study participants 381 gave exit interviews with response rate of 90.3%. The age distribution of study participants showed that 259(68%) of them were in the age range of 25-34 years, and 80(21%) were in the age range of 18-24. The mean age of study participants was $27.95 \pm (SD=4.72)$.

Majority of the study participants were females which accounted for 374(98.2%). Of the study participants 365(95.8%) were married. One hundred sixty-six (43.6%) study participants were orthodox Christians, 157(41.2%) Muslims, 46(12.1%) protestants and 12(3.1%) catholic Christians. Regarding educational status, 367(96.3) were literate, of whom 169(44.4 %) had primary education, 86(22.6%) secondary education and 36(9.4%) had tertiary education. Majority of the study participants 207(54.3%) were homemaker. Regarding sex of the babies included in the study 202(53%) were boys and 179(47) were girls (Table 1).

Table 1: Sociodemographic characteristics of parents having infants under 6 months in selected health centers, Addis Ababa, Ethiopia (n=381)

<i>Variables</i>	<i>Category</i>	<i>Number</i>	<i>Percentage</i>
<i>Age</i>	18-24	80	21
	25-34	259	68
	35-44	42	11
<i>Marital status</i>	Married	365	95.8
	Single	9	2.4
	Divorced	3	0.8
	Widowed	4	1
<i>Educational status</i>	No read and write	14	3.7
	Read and write	61	16
	Primary education	169	44.4
	Secondary education	86	22.6
	Vocational education	15	3.9
<i>Religion</i>	Tertiary education	36	9.4
	Orthodox	165	43.3
	Catholic	12	3.1
	Protestant	48	12.6
	Muslim	156	40.9
<i>Occupation</i>	Government employee	52	13.6
	Private employee	84	22
	Daily laborer	10	2.6
	Home maker	207	54.3
	Business owner	28	7.3
<i>Number of children</i>	One	134	35.2
	Two	121	31.8
	Three	56	14.7
	Four	44	11.5
	Five	26	6.8
<i>Sex of last baby</i>	Male	202	53
	Female	179	47
<i>Age of last baby</i>	One	84	22
	Two	108	28.3
	Three	121	31.8
	Four	51	13.4
	Five	17	4.5

5.2 prevalence of infantile colic

From the total 133(34.9%) of the study participants, reported that their infants had periods of crying that began and ended for no apparent reason. Most of the infants cried for more than three hours every day (Figure 2).

About 126 (33.1%) of the total, indicated that their babies were suffering from digestive discomfort or stomachaches. Parents observed that during these episodes; their babies exhibited a range of symptoms associated with gastrointestinal distress. The most commonly reported signs were hard belly (43.6%), being restless (45.1%), clenching fists (43.6%), and passing gas (32.3%). These physical signs, coupled with crying, suggest that digestive discomfort was a significant source of distress for many infants, and it can manifest in various ways.

Majority of parents 98 (38.3%) who reported their babies had crying episodes stated that they felt stressed when their babies cried and suffered from digestive discomfort. And 82(32%) of study participants who claimed their babies had crying episodes indicated difficulty in managing their baby's crying associated with digestive discomfort or stomach pain. A significant number of participants 116(53.2%) reported that cuddling was their primary technique for soothing their crying infant. Several parents 89(40.8%) also mentioned that they offered breast or bottle to calm their children when they cried. About 71(49.3%) of the participants reported consulting with healthcare practitioners about their baby's crying episodes or stomach pain (Table 2).

Table 2: prevalence of infantile colic in infants based on the response of parents, Addis Ababa, Ethiopia (n=381)

Colic Features	Response category	Number	Percentage
<i>Baby experience crying episodes that start and stop for no apparent reason</i>	Yes	133	34.9
	No	248	65.1
<i>Estimate how long your baby cries(n=133)</i>	Less than 1 hour per day	17	12.8
	Between 1 and 2 hrs./day	57	42.9
	Between 2 and 3 hrs./day	50	37.6
	More than 3 hrs./day	9	6.7
<i>Does these episodes last for 3 hours or more each day at least three times a week during a whole week(n=133)</i>	Yes	30	22.6
	No	103	77.4
<i>Baby suffering from digestive discomfort or stomach aches</i>	Yes	126	94.7
	No	7	5.3
<i>Baby feeling when he or she cries and suffers from digestive discomfort/stomach pain(n=133)</i>	Baby has a swollen belly	30	22.6
	Baby has hard belly	58	43.6
	Baby has excessive gas	43	32.3
	Baby's leg is folded up on his/her belly	2	1.5
	Baby's face is red/strained	22	16.5
	Baby has clenched fists	58	43.6
	Baby is restless	60	45.1
	Find the situation difficult	82	32
	Feel stressed	98	38.3
	Feel depressed	12	4.7
<i>Feeling when your baby cries and suffers from digestive discomfort /stomach pain(n=133)</i>	Feel helpless	3	1.2
	Cry	3	1.2
	remain calm and control	58	22.6
	Give a bath	4	1.8
	Give a massage	9	4.1
	Cuddle with	116	53.2
	Give breast/bottle	89	40.8
<i>What do you do to calm baby at that moment(n=133)</i>			

5.3 Complementary and alternative medicine usage

Thirty-eight percent of the study participants indicated using traditional medicine to alleviate their infant's ailments, whereas from them 92.4% claimed to use herbal medicines. Specifically, *R. chalpensis*, flax seed, and *Ocimum lamifolium* were mentioned herbal medicines by the study participants for treating their infants' colic symptoms (Table 3).

Table 3: Complementary and alternative medicine use for infants based on the response of parents having infants under 6 months in selected health centers, Addis Ababa, Ethiopia(n=381)

<i>Characteristics</i>	<i>Response Category</i>	<i>Number</i>	<i>Percentage</i>
<i>ever used TM for your infant</i>	Yes	145	38.1
	No	236	61.9
<i>If yes which of the following TM(n=145) any MP or herbal medicine that you have used in treating IC(n=134)</i>	Herbal medicine	134	92.4
	Religious /prayer therapy	11	7.6
	<i>R. chalpensis</i>	116	86.6
	Flaxseed	12	8.4
	<i>Ocimum lamifolium</i>	6	4.5

5.4 Practice of *R. chalpensis*

From the total majority of the study participants 324(85%) reported having heard about *R. chalpensis* as a remedy for infantile colic. About 235(58.2% of the participants stated that they learned about *R. chalpensis* from their neighbors, while 169(41.8%) credited their parents as the source of this information. Around 198(52%) of the study participants reported that they had observed someone using *R. chalpensis* to alleviate infantile colic pain. These study participants stated that it was specifically the leaves of *R. chalpensis* that were being used.

From study participants who claimed their babies have infantile colic based on their symptoms 116(87.2%) of them reported that they used *R. chalpensis* as a therapeutic intervention for managing infantile colic in their infants. Notably, a substantial proportion of these participants indicated that they administered the remedy consistently whenever their infant exhibited signs of discomfort.

Almost all study participants of those who used *R. chalpensis* 115(99.1%) prepared the remedy using the fresh leaves. They used to add the fresh leaves to hot water and then administered the mixture orally to their infants.

About 88(76%) of the study participants who administered *R. chalpensis* to their infants noticed that their babies became quieter and more relaxed. These parents did not report observing any adverse effects following the use of the herbal remedy. Table 4 shows Practice of *R. chalpensis* for infantile colic.

Table 4: Practice of *R. chalpensis* for infantile colic based on parents having infants under 6 months in selected health centers, Addis Ababa, Ethiopia(n=381)

Characteristics	Response Category	Number	Percentage
<i>heard about R. chalpensis as a remedy for infantile colic</i>	Yes	324	85
	No	57	15
<i>learn about R. chalpensis</i>	My parents told me about its use	169	41.8
	From neighbor	235	58.2
<i>Anyone recommended you</i>	Yes	220	57.7
	No	161	42.3
<i>If yes, who(n=220)</i>	Family	154	46.7
	Neighbor	176	53.3
<i>see anyone using it</i>	Yes	198	52
	No	183	48
<i>ever used R. chalpensis for IC(n=133)</i>	Yes	116	87.2
	No	17	12.8
<i>If yes, frequency(n=116)</i>	Once	19	16.4
	Twice	23	19.8
	Thrice	28	24.1
	Every time when the infant cry for no apparent reason	46	39.7
<i>Part of RC used(n=116)</i>	Leaves	115	99.1
	Fruit	1	0.9
<i>Preparation method(n=116)</i>	adding RC in hot water	104	89.6
	Adding RC in hot milk	9	7.8
	Squeezing	3	2.6
<i>change you noticed after RC(n=116)</i>	Infant become quitter	88	75.9
	Continued crying	28	24.1
<i>notice any problems after the consumption of RC(n=116)</i>	No	116	100

5.5 Perceived effectiveness of *R. chalpensis*

From those who used *R. chalpensis*, (101) 87% observed a positive effect on their infants' colic symptoms. Among the study participants who reported that they used *R. chalpensis* to manage infantile colic, 76(65%) perceived the remedy to be effective in relieving their infants' colic symptoms. (Table 5).

Table 5: Perceived effectiveness of *R. chalpensis* for infantile colic based on parents who had infants under 6 months in selected health centers, Addis Ababa, Ethiopia (n=116)

<i>Characteristics</i>	<i>Category</i>	<i>Number</i>	<i>Percentage</i>
<i>observed any positive effects after RC</i>	Yes	101	87.1
	No	11	9.5
	Not sure	4	3.4
<i>How would you rate for efficacy of R. chalpensis for your infant</i>	Very poor	3	2.6
	Poor	3	2.6
	Fair	13	11.2
	Good	58	50
	Very good	39	33.6
<i>How would you rate the satisfaction of R. chalpensis for your infant</i>	Completely dissatisfied	2	1.7
	Somewhat dissatisfied	1	0.9
	Neither satisfied nor dissatisfied	3	2.6
	Somewhat satisfied	58	50
	Completely satisfied	52	44.8
<i>How likely are you to continue using R. chalpensis</i>	Very unlikely	2	1.7
	Unlikely	3	2.6
	Neutral	34	29.3
	Likely	42	36.2
	Very likely	35	30.2
<i>How likely would you recommend using R. chalpensis</i>	Very unlikely	2	1.7
	Unlikely	3	2.6
	Neutral	24	20.7
	Likely	75	64.7
	Very likely	12	10.3
<i>Perceived effectiveness</i>	Perceived effective	76	65.4
	Perceived not effective	40	34.5

CHAPTER SIX

6. DISCUSSION

The findings of this study highlight the significant role of *R. chalpensis* in managing infant colic symptoms, reinforcing the importance of traditional medicine in pediatric care. Around 85% reported having heard about *R. chalpensis* as a remedy for infantile colic. A substantial number of participants reported receiving recommendations from neighbors and family to use *R. chalpensis* for colic, reflecting the strong influence of community knowledge on health-related decisions. This aligns with previous study conducted by Savino *et al.*, which emphasizes how cultural practices and social networks play a critical role in shaping parental choices regarding infant care. The reliance on familial and community advice highlights the importance of cultural context in healthcare(63).

In this study, 87% of study participants who claimed their babies had infantile colic based on their symptoms utilized *R. chalpensis* for their infants, with 87.1 % observing positive effects on colic symptoms. This finding is consistent with research on other herbal remedies, such as fennel and chamomile, which have been widely used and shown to alleviate colic symptoms effectively(52). Like *R. chalpensis*, these herbs are believed to possess anti-spasmodic and soothing properties, which may contribute to their popularity among caregivers. The method of preparation in this study—using fresh leaves steeped in hot water—mirrors practices observed in various cultures where herbal teas are commonly administered to infants as natural remedies(51,52).

Notably, 76% of participants reported that their infants became quieter after receiving *R. chalpensis*, with no adverse effects documented. This reflects findings from studies on other herbal treatments, where parents also reported reductions in crying without significant side effects(64). However, the absence of reported adverse effects should be approached with caution, as many herbal remedies lack comprehensive clinical trials to establish their safety, particularly for infants(51).

About 49.3% of participants consulted healthcare providers regarding their infants' colic. This contrasts with findings in more developed settings, where parents are more inclined to seek medical advice and utilize conventional treatments, such as simethicone or dietary adjustments(9).

While the results of this study support the potential efficacy of *R. chalpensis* as a remedy for colic, they underscore the need for further scientific investigation to validate its safety and effectiveness. Similar calls for more rigorous trials have been made for other herbal treatments for infant colic(51,52,63). This research contributes to the growing body of evidence that highlights the critical role of herbal medicine in managing infant colic across different cultures.

CHAPTER SEVEN

7. STRENGTH AND LIMITATION

7.1 Strength

A significant strength of this thesis lies in its originality and pioneering nature. To the best of the researcher's knowledge, this is the first study of its kind to investigate the use of *R. chalpensis* as a potential remedy for infantile colic within the studied population. By exploring both the prevalence of its use and users' perceptions of its effectiveness, the research provides valuable preliminary evidence that *R. chalpensis* may hold therapeutic promise for managing infantile colic. This contribution is particularly noteworthy given the widespread reliance on traditional medicine in many communities and the limited formal evaluation of such practices. The findings offer an important foundation for future research and could serve as a basis for integrating traditional remedies into broader health discussions and potential clinical investigations.

7.2 Limitations

However, this study has its own limitations. The major constraint was the limited availability of published scientific literature specifically addressing the use of *R. chalpensis* for infantile colic. This scarcity of prior research posed challenges in contextualizing and comparing the findings within a broader evidence base. As a result, the discussion relied partly on general studies of herbal medicine use in pediatric populations and ethnobotanical reports, which may limit the depth of comparison and critical analysis. Further studies, including experimental or clinical trials, are warranted to build a more comprehensive understanding of the efficacy and safety of *R. chalpensis* for infantile colic.

CHAPTER EIGHT

8. Conclusion and recommendation

8.1 Conclusion

This study shows the important role of traditional herbal remedies, particularly *R. chalpensis*, in managing infantile colic symptoms among the study population. The majority of caregivers rely on recommendations from family and neighbors, reflecting the significant influence of community knowledge in healthcare decisions. From 133 study participants who stated their babies had infantile colic 116(87%) used *R. chalpensis* and from study participants who used *R. chalpensis* 87% reporting positive effects after giving to their infants, it is clear that this herbal remedy is widely trusted and integrated into infant care routines.

While *R. chalpensis* is perceived as effective and safe by many users, the lack of scientific validation highlights a need for caution. The absence of adverse effects reported in this study does not guarantee the herb's safety, especially considering the lack of clinical trials on its efficacy and safety for infants. As with other herbal treatments, *R. chalpensis* may pose risks if improperly used or administered in incorrect dosages.

8.2 Recommendation

- It is recommended that further rigorous scientific investigations, including clinical trials, be conducted to establish the safety, efficacy, and appropriate use of *R. chalpensis* in the management of infantile colic.
- Efforts should be made to systematically document and preserve ethnobotanical knowledge related to *R. chalpensis* and similar traditional practices, to support future research and cultural heritage conservation.

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ANNEX

Annex I: participant Information sheet English version

Addis Ababa University

College of health sciences

Center for innovative drug development and therapeutic trials for Africa

(CDT-Africa)

My name isI am here on the behalf of Dureti Moti who is MSc student in Addis Ababa university, CDT Africa. She is working her thesis on “The practice of using rue (*R. chalpensis*) for infantile colic in Addis Ababa, Ethiopia. She obtained permission from Addis Ababa University Scientific and Ethics Review Committee (SERC) of CDT-Africa.

Title Practice and perceived effectiveness of *R. chalpensis* as a traditional treatment for infantile colic among parents or caregivers of infants in Addis Ababa, Ethiopia

Principal investigator: Dureti Moti

Name of the institution: Addis Ababa University, College of Health Sciences, CDT Africa

Purpose: This study aims to evaluate the practice of using rue (*R. chalpensis*) in the treatment of infantile colic. You are being invited to take part in this research because we feel that your experience as a parent or caregiver can contribute much to our understanding of practice of *R. chalpensis* for infantile colic.

This study will be useful in determining whether *R. chalpensis* is practiced to treat infantile colic and whether parents or care giver of infants perceived it to be successful. It will help to provide information for researchers.

Procedure: If you are willing to participate you are going to be asked about your experience regarding you and your infants using a semi structured questionnaire which

includes sociodemographic related questions, infantile colic related questions, your practice of complementary and alternative medicine and questions related to practice of *R. chalpensis*. To complete the semi structured questionnaire it will take 20-30 minutes.

Participation: your participation in this study is entirely voluntary and. There won't be any consequences for you if you decide against taking part.

Risk : I would like to assure you that there is absolutely no problem in participating in this study unless you are not comfortable using 30 minutes of your time for this study. We hope that you will be willing to participate for the sake of the successful outcome of the study.

Benefit: There are no direct incentives or financial benefits for participating in this study, your participation is crucial for achieving our research objectives. As a result, you won't receive any payment or other incentives for taking part in the study.

Confidentiality: No one will be able to access your responses or personal information since all of your responses and findings are kept confidential using a coding system. You don't have to provide the data collectors with your name. The information given to us is kept confidential and there will be no information that can be used to identify you. The results of the study will not be related to individual but to the general population.

Of opposition and termination: As the full consent of the participant is necessary to participate in the research, the individual has the right to participate or not to participate, even if they participate, they have the right to stop at any time and not to answer any questions they do not want to answer.

To confirm your willingness to participate in this study, please sign the agreement form.

Address of principal investigator phone no: Dureti Moti +251922280885

Email: duretimoti85@gmail.com

Annex II: participant Informed consent form English version

I have read the participant information form or it has been read to me: I have clearly understood the purpose of the study, procedure, risks and benefits, confidentiality, right to participate and contact addresses. I have been given the opportunity to ask questions that are not clear to me. Therefore, I have informed my willingness to participate in this study.

Signature _____ date _____

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ AND Thumb print of participant

Signature of witness _____

Date _____



Name of the Data Collector _____

Interview Start Time, Hour _____ Minute _____

Interview Completed Time, Hour _____ Minute _____

Questioner code. _____

Data Collector Agreement I confirm that I have completed the questionnaires in accordance with the training and instructions given to me and that the information provided is correct.

Signature _____ Date ____/____/____ E.C

Supervisor's Name _____

Signature _____ Date ____/____/____ E.C

Annex III: Semi structured English version questionnaire

Sociodemographic characteristics of parents and infant			
No	Questions	Responses	Remark &/ Skip pattern
101	Sex	1.Male 2.Female	
102	Age in years	_____	
103	What is your current marital status?	1.Married 2.Single 3.Divorced 4.Widowed	
104	Residence	1. Urban 2. Rural	
105	What is the highest educational level you completed?	1. No read and write 2. Read and write 3. Primary education 4. Secondary education 5. Vocational education 6. Tertiary education	
106	What is your religion?	1.Orthodox 2.Catholic 3.Protestant 4.Muslim 5.Others_____(specify)	
107	What is your current occupation?	1. Government employ 2. Private employee 3. Daily-laborer 4. House wife 5. Merchant 6. Others_____(specify)	

108	How many children do you have?		
109	Sex of your baby	1. Male 2. Female	
110	Age of your baby	_____	
Infantile colic related questions			
201	Does your baby experience crying episodes that start and stop for no apparent reason?	1. Yes 2. No	
202	Can you estimate how long your baby cries for?	1. Less than 1 hour per day 2. Between 1 and 2 hours per day 3. Between 2 and 3 hours per day 4. More than 3 hours per day	
203	Of the following descriptions, which one best describes your child's crying	1. Screaming 2. Howling 3. Prolonged crying 4. Normal crying	
204	Does these episodes last for 3 hours or more each day at least three times a week during a whole week?	1. Yes 2. No	
205	Is your baby suffering from digestive discomfort or stomach aches?	1. Yes 2. No	
206	How your baby feels when he or she cries and suffers from digestive discomfort/stomach pain?	1. Baby has a swollen belly 2. Baby has hard baby 3. Baby has gas 4. Baby's leg are folded up on his/her belly 5. Baby's face is red 6. Baby's face strained	

		7. Baby has clenched fists 8. Baby is restless	
207	How you feel when your baby cries and suffers from digestive discomfort /stomach pain?	1. Find the situation difficult 2. Feel stressed 3. Feel hopeless 4. Feel guilty 5. Feel useless 6. Feel depressed 7. Feel helpless 8. I cry 9. I remain calm and in control	
208	Is there anything you face because of your baby's crying and digestive discomfort/stomach pain	1. Sleep poorly 2. I don't sleep enough 3. I am tired 4. I am in pain (my arms, my back...) 5. I don't have enough time for my self 6. I don't have enough time to take care of things around the house 7. I don't have enough time for my family and friend's 8. I don't have time to go out and see people	
209	When your baby cries what do you do to calm him /her at that moment	1. Give him or her a bath 2. Give him or her a massage 3. Cuddle with him /her 4. Hold him/her skin to skin 5. Give him /her breast/bottle 6. Other (specify)_____	
210	What have you tried to do to about it?	1. I have spoken to health care provider	

		2. I have given him/her medicine 3. I have given him/her traditional medicine 4. I do something else	
Complementary and alternative medicine related questions			
301	Have you ever used traditional medicine for your infant?	1. Yes 2. No	
302	If yes which of the following traditional medicine, did you use for your infant?	1. Herbal medicine 2. Massage 3. Religious /prayer therapy	
303	Could you tell me any medicinal plant or herbal medicine that you have used in treating your infant's colic pain?		
Practice of <i>R. chalpensis</i> related questions			
401	Have you heard about <i>R. chalpensis</i> as a remedy for infantile colic?	1. Yes 2. No	
402	How did you learn about <i>R. chalpensis</i> ?	1. My parents told me about its use 2. From neighbor 3. From herbalist 4. Other (specify)_____	
403	Have you ever used <i>R. chalpensis</i> for your infant's colic symptoms?	1. Yes 2. No	If no skip the next questions
404	If yes, how frequently have you used <i>R. chalpensis</i> for your infant's colic symptoms?	1. Once 2. Twice 3. Trice 4. Every time when the infant feels sick 5. Other (specify)_____	

405	Did anyone recommended you to use it?	1. Yes 2. No	If no skip next question
406	If yes who recommended you?	1. Family 2. Neighbor 3. Herbalists 4. Other (specify)_____	
407	Did you see anyone using it for infantile colic pain?	1. Yes 2. No	
408	What part of <i>R. chalpensis</i> did you used for treating your infant's colic pain?	1. Leaves 2. Flower 3. Fruit 4. Seed 5. Root 6. Stem	
409	What is the mode of use	1. Fresh 2. Dried 3. Both fresh and dried	
410	What preparation methods do you use (write down details of preparation procedures)	1. By adding <i>R. chalpensis</i> in hot water 2. By adding <i>R. chalpensis</i> in hot milk 3. By Squeezing 4. Other (specify)_____	
411	Is there any medicinal plant or other additive mixed with it?	1. Yes 2. No	If no skip the next Q
412	If yes, please mention it with the importance of its incorporation		

413	What is the route of administration?	1. Oral 2. Topical 3. Nasal 4. Inhalation 5. Other (specify)_____	
414	What is the solvent you used for the preparation?	1. Water 2. Milk 3. Oil 4. Tea 5. Other, specify	
415	What is the change you noticed on the infant after providing <i>R. chalpensis</i> ?	1. Infant become quitter 2. Continued crying 3. Got worse 4. Other (specify)_____	
416	Did you notice any problems after the consumption of <i>R. chalpensis</i> on your infant?	1. No 2. Yes	
417	If yes what kind of problems did you notice?	1. Started or increased vomiting with hours taking it 2. Had diarrhea with the hours of taking it 3. Was coughing after the use 4. Other (specify)_____	
Perceived effectiveness of <i>R. chalpensis</i> related questions			
501	Have you observed any positive effects on your infant's colic symptoms after using <i>R. chalpensis</i> for your infant?	1. Yes 2. No 3. Not sure	
502	How would you rate the efficacy of <i>R. chalpensis</i> for your infant?	1. Very poor 2. Poor 4. Fair	

		5. Good 6. Very good	
503	How satisfied are you with the overall effectiveness of <i>R. chalpensis</i> for managing your infant's colic symptoms?	1. Completely dissatisfied 2. Somewhat dissatisfied 3. Neither satisfied nor dissatisfied 4. Somewhat satisfied 5. Completely satisfied	
504	How likely are you to continue using <i>R. chalpensis</i> for managing your infant's colic symptoms?	1. Very unlikely 2. Unlikely 3. Neutral 4. Likely 5. Very likely	
505	How likely would you recommend using <i>R. chalpensis</i> for managing infant's colic symptoms?	1. Very unlikely 2. Unlikely 3. Neutral 4. Likely 5. Very likely	

Annex V: Information sheet Amharic version

እንደምንደረ/ዋሉ

ስሜ.....ይባላል።

እዚህ የመጣሁት በአዲስ አበባ ዩኒቨርሲቲ ጤናና ህክምና ሳይንስ ኮሌጅ የክሊኒካል ትሪያል የማስተረስ

ድግሪ ተመራ ቁጥጥሪ የሆኑትን ዱሬቲ ሞቲን ወክዬነው።

የመመርቂያ ጥናት ጤና አዳም ለጨቅላ ህፃናት የሆድ ቁርጥት ላይ ያለውን ተግባር ለማይቅጥ ጥናት ላይናት።

የጥናቱ ርዕስ፡-

በ

አዲስ አበባ ጤና አዳም ለጨቅላ ህፃናት የሆድ ቁርጥት ላይ ያለው ተግባርና አጠቃቅም

የጥናቱ ባለቤት፡ ዱሬቲ ሞቲ

የተቋሙ ስም፡ አዲስ አበባ ዩኒቨርሲቲ፣ የጤና ሳይንስ ኮሌጅ፣ ሲዲቲ አፍሪካ

የጥናቱ ዓላማ፡- ጤና አዳም ለጨቅላ ህፃናት የሆድ ቁርጥት ላይ ያለውን ተግባርና አጠቃቅም መመዝገብ

ተሳትፎ፡ በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ ነው።

ለመሳተፍ ከወሰኑ ለእርስዎም ንግድ አይነት ጉዳት አይኖር ዉም።

ተሳታፊዎች፡- ከ 1 ወር -6 ወር እድሜ ያላቸው ህፃናትን ለክትባት ጤና ጣቢያ ያመጡ ወላጆች ወይም አሳዳጊዎች

ቅደም ተከተል እና የሚፈጀው ጊዜ

ጤና አዳም ለጨቅላ ህፃናት የሆድ ቁርጥት ላይ ያለውን ተግባርና አጠቃቅም ለመገምገም

በሚደረገው ጥናት ላይ እንዲሳተፉ ከተጋበዙ በኋላ ፈቃደኛ ከሆኑ የ ስምምነት ቅፅ

ይፋርማሉ። በመቀጠል መጠይቁን እያካሄድን የተዘጋጁትን መጠይቆች ምላሽ ይሰጣሉ።

መጠየቁን ለማጠናቀቅ 30 ደቂቃ ያስፈልጋል ስለዚህ ይህን ስዓት እንድጠቀም እንዲፈቅዱልኝ ስል በትህትና እጠቃለሁ።

የሚፈጠር ችግር / አለመመችት የጊዜው 30 ደቂቃ ለዚህ ጥናት መጠቀም ካለተመችዎ በቀር እዚህ ጥናት ላይ መሳተፉዎ ምንም አይነት ችግር እንደማያመጣ በእርግጠኝነት አስረግጬ መናገር እፈልጋለሁ። ለጥናቱ የተሳካ ውጤት ሲሉ ለመሳተፍ ፈቃደኛ እንደሚሆኑ ተስፋ እናረጋለን።

ማበረታቻ/ ክፍያ ዕዚህ ጥናት ላይ በመሳተፈዎ በቀጥታ የሚያገኙት ማበረታቻ ወይም ክፈያ ባይኖርም ።የጥናቱ አላማን ለማሳካት ግንባርዚህ ጥናት ውስጥ ያለዎት ተሳትፎ አስፈላጊ ነው። ስለዚህ ጥናቱ ላይ ስለተሳተፉ የሚያገኙት ክፍያ ወይም ማበረታቻ አይኖርም።

ሚስጥራዊነት የሚሰጠን መረጃ ምስጥራዊነት የተጠበቀ ከመሆኑም በላይ እርሶዎን ነጥሎ የሚጠቀም ምንም አይነት መረጃ አይኖርም የጥናቱ ውጤቶች ከጠቅላላው ህዝብ ጋር እንጂ ከግለሰብ ጋር ለብቻው የተያያዘ ነገር አይኖራቸውም መጠይቆች ስም እንዳያስፈልጋቸው ተደርገው የተዘጋጁ ከመሆናቸው በላይ ተሳታፊ ግለሰብን ከጥናቱ ጋር ሊያገናኙ የሚችሉ የቃልም ይሁን የተፃፈ ማጠቀሻዎች አይኖሩም

የመቃወም ውይም የማቋረጥ መብት ጥናቱ ላይ ለመሳተፍ የተሳታፍው ሙሉ ፍቃድ አስፈላጊ እንደመሆኑ ግለሰቡ የመሳተፍም ሆነ ያለመሳተፍ ሙሉ መብት አላቸው ከተሳተፉም ብቻላም ቢሆን በፈለጉት ሰአት የማቋረጥ እና መመለስ የማይፈልጉትን ጥያቄ ያለመመለስ ሙሉ መብት አላቸው

የዋናውተመርማሪስልክቁጥር፡- ዱሬቲሞቲ +251922280885

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Annex VI: Consent form Amharic version

የተሳታፍ የፍቃድ ቅጽ

የተሳታፍ መረጃ ቅጹን አንብቤያለሁ ወይም ተነበልኛል፡ ስለጥናቱ ዓላማ፣ ቅድመ ተከተል ፣ ጉዳትና ጥቅሞች ፣ምስጥራዊነት ፣ይየተሳትፎ መብት እና የግንኙነት አድራሻዎች በግልጽ ተረድቻለሁ ፣ ግልጽ ያልሆኑልኝን ነገሮች እንደጠይቅም እድሉ ተሰቶኛል ፡ ፡ በፈለኩት ሠዓት ጥናቱን ማቋረጥ እና መመለስ ማልፈልጋቸውን ጥያቄዎችም አለመመለስ ዕንደምችል አሳውቀውኛል ፡ ፡ ስለሆነም በዚህ ጥናት ላይ ለመሳተፍ ያለኝን ፍቃደኝነት አሳውቄአለሁ፡፡ግለሰቡ ለቃለ መጠይቁ ፈቃደኛ ካልሆኑ አመስግነን ወደ ቃጣይ ተሳታፊ ይታለፋል፡፡

የተሳታፊፊርማ_____ ቀን _____

ያለተማሩከሆነ

የስምምነት ቅጹን በትክክል ማንበብ ለሚችለው ተሳታፊ ተመልክቻለሁ፣ እናም ግለሰቡ ጥያቄዎችን የመጠየቅ እድል አግኝቷል፡፡ ግለሰቡ በነፃነት ፈቃድ መስጠቱን አረጋግጣለሁ፡፡

የምሥክር ስም _____ የተሳታፊ አውራ ጣት አትም

የምሥክር ፊርማ _____



ቀን _____

የመረጃው ሠብሳቢው/ዎ ስም _____

ቃለመጠየቁ የጀመረበት ጊዜ፣ ሠዓት _____ ደቂቃ _____

ቃለመጠየቁ የተጠናቀቀበት ጊዜ፣ ሠዓት _____ ደቂቃ _____

መጠይቅ ቁጥር _____

የመረጃ ሠብሳቢ ስምምነት መጠይቆችን የሞላሁት በተሰጠኝ ስልጠና እና መመሪያዎች

መሠረት መሆኑ እና ያሉት መረጃዎች ትክክለኛ መሆናቸውን አረጋግጣለሁ።

ፊርማ _____ ቀን ____/____/____ E.C

የተቆጣጠረው ስም _____

ፊርማ _____ ቀን ____/____/____ E.C

Annex VII: Semi structured questionnaire Amharic version

1. የወላጅ እና የጨቅላሕ ግናት አጠቃላይ ሁኔታ			
ተ.ቁ	ጥያቄዎች	ምላሽ	
101	ፃታ	1. ወንድ 2. ሴት	
102	ዕድሜዎ ሰንት ነው?	_____	
103	አሁን ያሉበት የጋብቻ ሁኔታ ?	1. ያገባ/ች 2. ያላገባ/ች 3. የተለያየ/ች 4. የሞተበት/ባት	
104	የመኖሪያ አደራሽ	1. ከተማ 2. ገጠር	
105	ያጠናቀቁት ከፍተኛ የትምህርት ደረጃ ?	1. ማንበብ እና መጻፍ አልችልም 2. ማንበብ እና መጻፍ እችላለሁ 3. የመጀመሪያ ደረጃ ትምህርት 4. ሁለተኛ ደረጃ ትምህርት 5. የሙያ ትምህርት 6. የሶስተኛ ደረጃ ትምህርት	
106	የየትኛው ሃይማኖት ተከታይ ነዎት	1. ኦርቶዶክስ 2. ካቶሊክ 3. ፕሮቴስታንት 4. ሙስሊም	

		5.ሌላካለ (ይግለጹ)	
107	አሁን ያሉበት የሥራ አይነት?	1. የመንግስት ሰራተኛ 2. የግል ሰራተኛ 3. የቀንሠ ሰራተኛ 4. የቤት እምቤት 5. ነጋዴ 6. ሌላካለ (ይግለጹ)	
108	ስንት ልጆች አሉዎት?		
109	የልጅ ወጪዎች	1. ወንድ 2. ሴት	
110	የልጅ ዕድሜ	_____	
2. ከጨቅላህጻናት የሆድ ቁርጥት ጋር የተያያዙ ጥያቄዎች			
201	ልጅዎ ያለምንም ክንያት የሚጀምር እና የሚቆም የማልቀስ ሁኔታ አጋጥሞት ያውቃል?	1. አዎ 2. የለም	
202	ልጅዎ ለምን ያህል ጊዜ እንደሚያለቅስ መገመት ይችላሉ?	1. በቀን ከ 1 ሰዓት ያነሰ 2. በቀን ከ 1 እስከ 2 ሰዓታት መካከል 3. በቀን ከ 2 እስከ 3 ሰዓታት መካከል 4. በቀን ከ 3 ሰዓታት በላይ	
203	ከሚከተሉት መግለጫዎች ውስጥ የትኛውን ውይይት ያለቅሰውን በደንብ የሚገልጽው	1. መጫህ 2. ማልቀስ	

		3. ለረጅምጊዜማልቀስ 4. መደበኛማልቀስ	
204	ልጅታሲያልቅስ /ሰታልቅስበየቀኑለ 3 ሰዓታትወይምከዚያበላይቢያንስበሰምንትሦስትጊዜይቆያል/ትቆያልች?	1. አዎ 2.የለም	
205	ልጅዎበምግብመፍጨትችግርወይምበሆድህመምእየተሰቃየነውበለውያሰባሉ?	1. አዎ 2. የለም	
206	ልጅዎሲያለቅስእናበምግብመፍጨትችግር/በሆድቁርጥትህመምሲሰቃይምንአይነትምልክቶችንያሳያል?	1. ሆድያበጣል 2. ሆድከሌላጊዜይጠንክራል 3. ፈስያበዛል 4. የሕፃኑእግርበሆዱላይተጣብቋል 5. የፊትመቅላት 6. የድካምሰሜትበፊትላይይታያል 7. እጃችውንጨብጥኦድርግውይቆያሉ 8. ዕርፍትያጣሉ	
207	ልጅዎሲያለቅስእናየምግብመፈጨትችግር/በሆድቁርጥትህመምሲሰቃይምንይሰማዎታል?	1. ሁኔታውአስቸጋሪነውየሚሆንብኝ 2. ውጥረትይሰማኛል 3. የተስፋመቁረጥስሜትይሰማኛል 4. የጥፋተኛስሜትይሰማኛል 5. ምንምጥቅምእንደሌለውሰውይሰማኛል 6. የመንፈስጭንቀትይሰማኛል 7. አቅመቢስነትይሰማኛል 8. አለቅሳለሁ 9. ተረጋግቼለመቆጣጠርእሞክራለው	

208	በልጅዎልቅሶእናየምግብመፈጫትችግር/በሆድቁርጥትህመምምክንያትየሚያጋጥምዎትነገርአለ	1. እንቅልፍበደንብአልተኛም 2. በቂእንቅልፍአላግኝም 3. ደክሞኛል 4. በህመምላይነኝ (እጅጅ፣ጀርባዬ...) 5. ለራሴበቂጊዜየለኝም 6. በቤቴዙሪያያሉትንነገሮችለመንከባከብበቂጊዜየለኝም 7. ለቤተሰቤእናለጓደኞቼበቂጊዜየለኝም 8. ወጥቼሰዎችንለማየትጊዜየለኝም	
209	ልጅዎሲያልቅስ/ስታለቅስበዛቅጽበትለማረጋጋትምንያደርጋሉ?	1. ገላውንማጡብ 2. ማሸት 3. ማቅፍ 4. ጡት/ጡጦመሰጥት 5. ሌላካለ (ይግለጹ) _____	
210	በልጅትህምመጉዳይላይምንለማድረግሞክረዋል?	1. የጤናባለሙያለማንጋገርሞክርያለው 2. መድሃኒትሰጥቼዋለሁ 3. የባህልህክምናሞክርያለው 4. ሌላነገርአደርገያለው	
3. ማሟያእናአማራጭሕክምናተዛማጅጥያቂዎች			
301	ለጨቅላህጻንባህላዊመድሃኒትተጠቅመውያውቃሉ?	1. አዎ 2. የለም	
302	ከሚከተሉትባህላዊመድሃኒቶችውስጥየትኛውንለጨቅላዎተጠቅመዋል?	1. ከዕፅዋትየተቀመጡመድኃኒቶች 2. ማሸት	

		3. ሃይማኖታዊ / የጾሎች ሕዝምና	
303	የጨቅላህጻናት ዎንዮሆድህመም ለማከምየት ጠቀሙበትን ማንኛውንም መድሃኒት ወይም የእፅዋት መድሃኒት ሊነግሩኝ ይችላሉ?		
4. ከጤና አዳምጪ መድኃኒቶች ጋር የተያያዙ ጥያቄዎች			
401	ጤና አዳምን ለጨቅላህጻናት የሆድ ቁርጠት እንደመድኃኒት እንደሚጠቀሙ ሰምተው ያውቃሉ?	1. አዎ 2. የለም	
402	ጤና አዳም ለጨቅላህጻናት የሆድ ቁርጠት እንደሚውል እንዴት አወቁ?	1. ወላጆቼ ስለ አጠቃቀሙ ነግረውኛል። 2. ከጎረቤት 3. ከእፅዋት ባለሙያ 4. ሌላ ካለ (ይግለጹ)	
403	ለጨቅላህጻን የሆድ ቁርጠት ህመም ምልክቶች ጤና አዳም ተጠቅመው ያውቃሉ?	1. አዎ 2. የለም	ካልሆነ የሚቀጥለውን ጥያቄ ዝለል
404	ከላይ ለተጠቀሙ ጥያቄ መልሶች አዎ ከሆነ፣ ለጨቅላህጻን ዎንዮሆድ ቁርጠት ህመም ምልክቶች ምን ያህል ጊዜ ጤና አዳም ተጠቅመዋል?	1. አንዴ 2. ሁለት ጊዜ 3. ሶስት ጊዜ 4. ህጻኑ በሚታመም በትጊዜ ሁሉ 5. ሌላ ካለ (ይግለጹ)	
405	ጤና አዳምን ለጨቅላህጻን የሆድ ቁርጠት ህመም ምልክቶች እንድትጠቀሙ የመከረከ/ህ ሰው ነበረ?	1. አዎ 2. የለም	ካልሆነ የሚቀጥለውን ጥያቄ ዝለል

406	ጤና አዳምን ለጨቅላህ ጸንዖሆ ድቁርጠትህ መምልከቶችን ድትጠቀም የመከረከ/ህ ማንነበረ?	1. ወላጆች 2. ጎረቤት 3. ከእፅዋት ባለሙያ 4. ሌላካለ (ይግለጹ)	
407	ጤና አዳምን ለጨቅላህ ጸንዖሆ ድቁርጠትህ መምልከቶችን ለማከም ሲጠቀሙ አይተሽ/ህ ታውቂያለሽ/ህ	1. አዎ 2. የለም	
408	የትኛውን የጤና አዳም ክፍል ለጨቅላህ ጸንዖሆ ድቁርጠትህ መምልከቶችን ለማከም ተጠቅሙ	1. ቅጠሎች 2. አበባ 3. ፍሬ 4. ዘር 5. ሥር 6. ግንድ	
409	አጠቃቀሙ እንዴት ነው	1. እንደተቀንጠሰ በእርጥቡ 2. ከደረቀ በኋላ 3. በሁለቱም መንገድ	
410	ምንዓይነት የዝግጅት ዘዴዎችን ይጠቀማሉ (የዝግጅት ሂደቶችን ዝርዝር ይገለጹለን)	1. በትኩስ ውሃው ሰጥ ጤና አዳምን በመጨመር 2. በትኩስ ወተት ውሃው ሰጥ ጤና አዳምን በመጨመር 3. በመጨመቅ 4. ሌላካለ (ይግለጹ)	
411	ከጤና አዳም ጋር የሚቀላቀል የባህል መድኃኒት ወይም ሌላ ተጨማሪ ነገር አለ?	1. አዎ 2. የለም	ካልሆነ የሚቀጥለውን ጥያቄ ዝለል

412	አዎከሆነ፣ እባክዎንከመካተቱአስፈላጊነትጋርይጥቀሱት።		
413	ለ ህጻኑየአሰጣጥመንገዱእንዴትነው?	1. በአፍ 2. በሚቀባ 3. በአፈንጨ 4. በማሸትተ 5. ሌላካለ (ይግለጹ)	
414	ጤናአዳምለማዝግጅትየተጠቀሙበትፈሳሽምንነበረ?	1. ውሃ 2. ወተት 3. ዘይት 4. ሻይ 5. ሌላካለ (ይግለጹ)	
415	ለጨቅላህጻንጤናአዳምከተጠቀሙበኋላበጨቅላህጻንየሆድህመምምልክቶችላይያዩትለውጥአለ?	1. ማለቀሱንአቆመ 2. ማለቀሱንቀጠለ 3. እንዲያውምባሰበት 4. ሌላካለ (ይግለጹ)	
416	ለጨቅላህጻንፈጆየጤናአዳምንከስጡትበኅላያዩትችግርነበረ?	1. አዎ 2. የለም	ካልሆነየሚቀጥለውንጥያቄዝለል
417	አዎከሆነመልሶትምንአይነትችግሮችአስተውለዋል?	1. ማስታወክ 2. ተቅማጥነበረው 3. ሌላካለ (ይግለጹ)	
5. ስለጤናአዳምየተገነዘቡትውጤታማነትጋርየተያያዙጥያቂዎች			
501	ለጨቅላህጻንጤናአዳምከተጠቀሙበኋላበጨቅላህጻንየሆድህመምምልክቶችላይአዎንታዊተጽእኖአስተውለዋል?	1. አዎ 2. የለም 3. እርግጠኛአይደለሁም	ካልሆነየሚቀጥለውንጥያቄዝለል

502	ለጨቅላዎጤናአዳምከተጠቀሙበኋላያለው ንውሴታማነትእንዴትይገመግማሉ?	1. በጣምዝቅተኛ 2. ዝቅተኛ 3. መጠነኛ 4. ጥሩ 5. በጣምጥሩ	
503	የጨቅላዎንየሆድቁርጠትህመምምልክቶችለ መቆጣጠርበጤናአዳምአጠቃላይውሴታማ ነትምንያህልረክተዋል?	1. ሙሉበሙሉአልረካውም 2. በመጠኑአልረካውም 3. አልረካውም 4. በመጠኑረክቻለሁ 5. ሙሉበሙሉረክቻለው	
504	የጨቅላዎንየሆድቁርጠትህመምምልክቶችለ መቆጣጠርበጤናአዳምንየመቀጠልእድሎምን ያህልነው?	1. በጣምዝቅተኛ 2. ዝቅተኛ 3. መጠነኛ 4. ከፍተኛ 5. በጣምከፍተኛ	
505	የጨቅላዎንየሆድቁርጠትህመምምልክቶችለ መቆጣጠርበጤናአዳምእንዲጠቀሙሌሎችሰዎችንምንያህልይመክራሉ?	1. በጣምአልመክርም 2. አልመክርም 3. ገለልተኛ 4. እመክራለው 5. በጣምእመክራለው	